付録 2.7.4- 35　最終投与後 90 日までに発現した Grade 3 以上の重篤な有害事象（いずれかの投与群で発現割合 0%超）
001 試験＋002 試験＋006 試験＋010 試験
MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	682		1,232		1,567		2,799	
with one or more adverse events	213	(31.2)	384	(31.2)	474	(30.2)	858	(30.7)
with no adverse events	469	(68.8)	848	(68.8)	1,093	(69.8)	1,941	(69.3)
Blood and lymphatic system disorders	**8**	**(1.2)**	**12**	**(1.0)**	**27**	**(1.7)**	**39**	**(1.4)**
Anaemia	4	(0.6)	5	(0.4)	19	(1.2)	24	(0.9)
Autoimmune haemolytic anaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Disseminated intravascular coagulation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Febrile neutropenia	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphadenopathy	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Microcytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neutropenia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Normochromic normocytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pancytopenia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thrombocytopenia	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Cardiac disorders	**20**	**(2.9)**	**42**	**(3.4)**	**29**	**(1.9)**	**71**	**(2.5)**
Acute coronary syndrome	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Acute myocardial infarction	1	(0.1)	4	(0.3)	3	(0.2)	7	(0.3)
Atrial fibrillation	1	(0.1)	2	(0.2)	7	(0.4)	9	(0.3)
Atrial flutter	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Atrial thrombosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Atrioventricular block complete	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Bradycardia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cardiac arrest	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac failure	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Cardiac failure congestive	0	(0.0)	2	(0.2)	6	(0.4)	8	(0.3)
Cardiac tamponade	1	(0.1)	6	(0.5)	0	(0.0)	6	(0.2)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**20**	**(2.9)**	**42**	**(3.4)**	**29**	**(1.9)**	**71**	**(2.5)**
Cardiac ventricular disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cardio-respiratory arrest	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Cardiomyopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cardiopulmonary failure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Coronary artery disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myocardial infarction	2	(0.3)	3	(0.2)	2	(0.1)	5	(0.2)
Palpitations	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pericardial effusion	6	(0.9)	9	(0.7)	4	(0.3)	13	(0.5)
Pericarditis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Right ventricular failure	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Supraventricular tachycardia	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Congenital, familial and genetic disorders	**3**	**(0.4)**	**3**	**(0.2)**	**0**	**(0.0)**	**3**	**(0.1)**
Pyloric stenosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tracheo-oesophageal fistula	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Ear and labyrinth disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.0)**
Vertigo positional	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Endocrine disorders	**4**	**(0.6)**	**8**	**(0.6)**	**16**	**(1.0)**	**24**	**(0.9)**
Adrenal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Adrenal insufficiency	1	(0.1)	2	(0.2)	5	(0.3)	7	(0.3)
Adrenocortical insufficiency acute	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperthyroidism	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Hypophysitis	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Hypopituitarism	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Hypothyroidism	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Secondary adrenocortical insufficiency	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eye disorders	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(0.2)**	**3**	**(0.1)**
Eye movement disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(0.2)**	**3**	**(0.1)**
Glaucoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal disorders	**20**	**(2.9)**	**40**	**(3.2)**	**109**	**(7.0)**	**149**	**(5.3)**
Abdominal distension	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Abdominal mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Abdominal pain	2	(0.3)	3	(0.2)	9	(0.6)	12	(0.4)
Abdominal pain lower	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Anal fistula	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ascites	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Colitis	3	(0.4)	7	(0.6)	18	(1.1)	25	(0.9)
Constipation	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Diarrhoea	0	(0.0)	1	(0.1)	18	(1.1)	19	(0.7)
Diverticulitis intestinal haemorrhagic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dysphagia	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Enterocolitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Faecaloma	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Gastric disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastric haemorrhage	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Gastric perforation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Gastric ulcer haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastritis	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal haemorrhage	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Gastrointestinal pain	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal perforation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Haematemesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haematochezia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ileus	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Inguinal hernia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Intestinal obstruction	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Intestinal perforation	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Intussusception	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**20**	**(2.9)**	**40**	**(3.2)**	**109**	**(7.0)**	**149**	**(5.3)**
Large intestinal obstruction	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Large intestinal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Large intestine perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Malabsorption	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nausea	2	(0.3)	6	(0.5)	7	(0.4)	13	(0.5)
Obstruction gastric	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oesophageal obstruction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Oesophagitis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Pancreatitis	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Rectal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Small intestinal obstruction	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Small intestinal perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stomatitis necrotising	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vomiting	1	(0.1)	4	(0.3)	11	(0.7)	15	(0.5)
General disorders and administration site conditions	**20**	**(2.9)**	**44**	**(3.6)**	**55**	**(3.5)**	**99**	**(3.5)**
Adverse drug reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Asthenia	1	(0.1)	3	(0.2)	7	(0.4)	10	(0.4)
Chest pain	2	(0.3)	5	(0.4)	3	(0.2)	8	(0.3)
Cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Death	6	(0.9)	8	(0.6)	9	(0.6)	17	(0.6)
Device dislocation	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Drug withdrawal syndrome	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Fatigue	2	(0.3)	6	(0.5)	2	(0.1)	8	(0.3)
General physical health deterioration	4	(0.6)	6	(0.5)	13	(0.8)	19	(0.7)
Generalised oedema	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Impaired healing	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**20**	**(2.9)**	**44**	**(3.6)**	**55**	**(3.5)**	**99**	**(3.5)**
Influenza like illness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Malaise	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Multi-organ failure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Non-cardiac chest pain	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Oedema	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Oedema peripheral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pain	3	(0.4)	7	(0.6)	4	(0.3)	11	(0.4)
Pyrexia	2	(0.3)	5	(0.4)	4	(0.3)	9	(0.3)
Hepatobiliary disorders	**4**	**(0.6)**	**5**	**(0.4)**	**22**	**(1.4)**	**27**	**(1.0)**
Autoimmune hepatitis	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Bile duct obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bile duct stone	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Biliary dilatation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cholecystitis	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Drug-induced liver injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hepatic failure	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Hepatic function abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatitis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Hepatocellular injury	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Jaundice cholestatic	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Liver disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune system disorders	**1**	**(0.1)**	**1**	**(0.1)**	**4**	**(0.3)**	**5**	**(0.2)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Drug hypersensitivity	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Hypersensitivity	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infections and infestations	**58**	**(8.5)**	**93**	**(7.5)**	**93**	**(5.9)**	**186**	**(6.6)**
Appendicitis perforated	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bacillus bacteraemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Bacterial sepsis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Bronchitis	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Catheter site infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**58**	**(8.5)**	**93**	**(7.5)**	**93**	**(5.9)**	**186**	**(6.6)**
Cellulitis	0	(0.0)	0	(0.0)	14	(0.9)	14	(0.5)
Cellulitis streptococcal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Clostridium difficile colitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Clostridium difficile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Device related sepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Diverticulitis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Endocarditis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Enterocolitis infectious	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erysipelas	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Escherichia bacteraemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastroenteritis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Gastroenteritis viral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Herpes simplex encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Herpes zoster	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infected cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infectious pleural effusion	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Infective exacerbation of chronic obstructive airways disease	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Influenza	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Listeriosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Liver abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lobar pneumonia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Localised infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lower respiratory tract infection	1	(0.1)	4	(0.3)	0	(0.0)	4	(0.1)
Lung infection	2	(0.3)	4	(0.3)	2	(0.1)	6	(0.2)
Lyme disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Mastitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meningitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)

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(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**58**	**(8.5)**	**93**	**(7.5)**	**93**	**(5.9)**	**186**	**(6.6)**
Meningitis listeria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Oesophageal candidiasis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Osteomyelitis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Pelvic abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pleural infection	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumocystis jirovecii pneumonia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia	35	(5.1)	49	(4.0)	22	(1.4)	71	(2.5)
Pneumonia bacterial	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia pneumococcal	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pulmonary sepsis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pyelonephritis acute	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pyopneumothorax	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory tract infection	5	(0.7)	6	(0.5)	1	(0.1)	7	(0.3)
Respiratory tract infection viral	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Sepsis	0	(0.0)	2	(0.2)	11	(0.7)	13	(0.5)
Septic shock	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Sinusitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin infection	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Soft tissue infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Staphylococcal infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Upper respiratory tract infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urinary tract infection	1	(0.1)	1	(0.1)	9	(0.6)	10	(0.4)
Urosepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Viral infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Wound infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Wound sepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Injury, poisoning and procedural complications	**9**	**(1.3)**	**11**	**(0.9)**	**21**	**(1.3)**	**32**	**(1.1)**
Contusion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Facial bones fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fall	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**9**	**(1.3)**	**11**	**(0.9)**	**21**	**(1.3)**	**32**	**(1.1)**
Femoral neck fracture	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Femur fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fracture displacement	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hip fracture	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Humerus fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Incisional hernia, obstructive	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Joint injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lower limb fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pneumonitis chemical	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Radiation necrosis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Radiation pneumonitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Rib fracture	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Spinal compression fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Spinal fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Traumatic intracranial haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper limb fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Wound decomposition	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Wound haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Investigations	**4**	**(0.6)**	**7**	**(0.6)**	**12**	**(0.8)**	**19**	**(0.7)**
Alanine aminotransferase increased	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Aspartate aminotransferase increased	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Aspiration bronchial	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Bilirubin conjugated increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood alkaline phosphatase increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood bilirubin increased	1	(0.1)	3	(0.2)	1	(0.1)	4	(0.1)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**4**	**(0.6)**	**7**	**(0.6)**	**12**	**(0.8)**	**19**	**(0.7)**
Blood creatine phosphokinase increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood prolactin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Electrocardiogram change	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gamma-glutamyltransferase increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Intraocular pressure decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Liver function test abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neutrophil count decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolism and nutrition disorders	**16**	**(2.3)**	**28**	**(2.3)**	**55**	**(3.5)**	**83**	**(3.0)**
Cachexia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Decreased appetite	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Dehydration	2	(0.3)	5	(0.4)	15	(1.0)	20	(0.7)
Diabetes mellitus	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Diabetic ketoacidosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Diabetic metabolic decompensation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Electrolyte imbalance	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Failure to thrive	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Gout	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypercalcaemia	5	(0.7)	9	(0.7)	2	(0.1)	11	(0.4)
Hyperglycaemia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Hyperkalaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypertriglyceridaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hyperuricaemia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hypoalbuminaemia	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Hypoglycaemia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hypokalaemia	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Hyponatraemia	2	(0.3)	4	(0.3)	14	(0.9)	18	(0.6)
Hypophosphataemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Insulin resistant diabetes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**16**	**(2.3)**	**28**	**(2.3)**	**55**	**(3.5)**	**83**	**(3.0)**
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Type 1 diabetes mellitus	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Musculoskeletal and connective tissue disorders	**14**	**(2.1)**	**24**	**(1.9)**	**28**	**(1.8)**	**52**	**(1.9)**
Arthralgia	1	(0.1)	3	(0.2)	2	(0.1)	5	(0.2)
Arthritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Back pain	4	(0.6)	6	(0.5)	7	(0.4)	13	(0.5)
Bone pain	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Costochondritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Flank pain	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Groin pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intervertebral disc protrusion	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Muscle haemorrhage	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Muscular weakness	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Musculoskeletal chest pain	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Musculoskeletal pain	2	(0.3)	3	(0.2)	4	(0.3)	7	(0.3)
Myalgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neck pain	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Osteolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Osteoporotic fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pain in extremity	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Pathological fracture	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Spinal column stenosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Spondylolisthesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**6**	**(0.9)**	**15**	**(1.2)**	**41**	**(2.6)**	**56**	**(2.0)**
Adenocarcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Adenocarcinoma gastric	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Basal cell carcinoma	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**6**	**(0.9)**	**15**	**(1.2)**	**41**	**(2.6)**	**56**	**(2.0)**
Basosquamous carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Breast cancer	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Cancer pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Colon cancer metastatic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastric cancer	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrointestinal carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intracranial tumour haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Invasive ductal breast carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Leiomyosarcoma	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Lung neoplasm malignant	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Lymphangiosis carcinomatosa	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Malignant melanoma	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Malignant neoplasm progression	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Malignant pleural effusion	1	(0.1)	3	(0.2)	0	(0.0)	3	(0.1)
Metastases to central nervous system	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Metastases to large intestine	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metastases to meninges	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metastatic malignant melanoma	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Metastatic pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Papillary thyroid cancer	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pericardial effusion malignant	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Prostate cancer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Squamous cell carcinoma	0	(0.0)	0	(0.0)	7	(0.4)	7	(0.3)
Tumour haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**6**	**(0.9)**	**15**	**(1.2)**	**41**	**(2.6)**	**56**	**(2.0)**
Tumour pain	1	(0.1)	4	(0.3)	4	(0.3)	8	(0.3)
Nervous system disorders	**13**	**(1.9)**	**20**	**(1.6)**	**46**	**(2.9)**	**66**	**(2.4)**
Amnesia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ataxia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Brain oedema	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Cerebral haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cerebrovascular accident	2	(0.3)	3	(0.2)	4	(0.3)	7	(0.3)
Depressed level of consciousness	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Dizziness	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Encephalopathy	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Epilepsy	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhage intracranial	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhagic stroke	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Headache	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hemiplegia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hydrocephalus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ischaemic stroke	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Lethargy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lumbar radiculopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myelitis transverse	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neuralgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neurological decompensation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Paraesthesia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Partial seizures	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Presyncope	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sciatica	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Seizure	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)

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PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**13**	**(1.9)**	**20**	**(1.6)**	**46**	**(2.9)**	**66**	**(2.4)**
Spinal cord compression	2	(0.3)	2	(0.2)	7	(0.4)	9	(0.3)
Syncope	1	(0.1)	4	(0.3)	4	(0.3)	8	(0.3)
Toxic leukoencephalopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Vasogenic cerebral oedema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Psychiatric disorders	**6**	**(0.9)**	**7**	**(0.6)**	**10**	**(0.6)**	**17**	**(0.6)**
Anxiety	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Completed suicide	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Confusional state	3	(0.4)	3	(0.2)	5	(0.3)	8	(0.3)
Delirium	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Depression	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Disorientation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Mental status changes	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Renal and urinary disorders	**6**	**(0.9)**	**14**	**(1.1)**	**19**	**(1.2)**	**33**	**(1.2)**
Acute kidney injury	4	(0.6)	6	(0.5)	9	(0.6)	15	(0.5)
Calculus ureteric	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Dysuria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Obstructive uropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Postrenal failure	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Renal failure	0	(0.0)	2	(0.2)	8	(0.5)	10	(0.4)
Tubulointerstitial nephritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Urge incontinence	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Urinary retention	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Urinary tract obstruction	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Reproductive system and breast disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.1)**	**2**	**(0.1)**
Metrorrhagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pelvic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Respiratory, thoracic and mediastinal disorders	**56**	**(8.2)**	**120**	**(9.7)**	**69**	**(4.4)**	**189**	**(6.8)**

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**56**	**(8.2)**	**120**	**(9.7)**	**69**	**(4.4)**	**189**	**(6.8)**
Acute respiratory failure	1	(0.1)	5	(0.4)	1	(0.1)	6	(0.2)
Atelectasis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Bronchial obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chronic obstructive pulmonary disease	7	(1.0)	11	(0.9)	2	(0.1)	13	(0.5)
Cough	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diffuse alveolar damage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Dyspnoea	5	(0.7)	16	(1.3)	17	(1.1)	33	(1.2)
Dyspnoea exertional	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Epistaxis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemoptysis	4	(0.6)	4	(0.3)	4	(0.3)	8	(0.3)
Haemothorax	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hiccups	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypoxia	2	(0.3)	5	(0.4)	2	(0.1)	7	(0.3)
Interstitial lung disease	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Laryngeal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lung consolidation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Obstructive airways disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Painful respiration	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pleural effusion	7	(1.0)	20	(1.6)	11	(0.7)	31	(1.1)
Pleuritic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pneumonia aspiration	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Pneumonitis	14	(2.1)	24	(1.9)	10	(0.6)	34	(1.2)
Pneumothorax	0	(0.0)	3	(0.2)	2	(0.1)	5	(0.2)
Pneumothorax spontaneous	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pulmonary embolism	13	(1.9)	23	(1.9)	12	(0.8)	35	(1.3)
Pulmonary haemorrhage	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Pulmonary hypertension	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Pulmonary oedema	2	(0.3)	4	(0.3)	0	(0.0)	4	(0.1)
Pulmonary thrombosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pulmonary vascular disorder	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory distress	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**56**	**(8.2)**	**120**	**(9.7)**	**69**	**(4.4)**	**189**	**(6.8)**
Respiratory failure	3	(0.4)	12	(1.0)	2	(0.1)	14	(0.5)
Wheezing	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin and subcutaneous tissue disorders	**2**	**(0.3)**	**6**	**(0.5)**	**10**	**(0.6)**	**16**	**(0.6)**
Dermatitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Drug eruption	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Erythema multiforme	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lichenoid keratosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Rash generalised	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash maculo-papular	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Skin mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stevens-Johnson syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Surgical and medical procedures	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.1)**	**2**	**(0.1)**
Mitral valve replacement	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin neoplasm excision	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vascular disorders	**8**	**(1.2)**	**17**	**(1.4)**	**18**	**(1.1)**	**35**	**(1.3)**
Aortic stenosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arterial thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Deep vein thrombosis	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Embolism	1	(0.1)	5	(0.4)	1	(0.1)	6	(0.2)
Femoral artery occlusion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhagic infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypotension	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Lymphoedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Orthostatic hypotension	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Peripheral ischaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Phlebitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**8**	**(1.2)**	**17**	**(1.4)**	**18**	**(1.1)**	**35**	**(1.3)**
Poor venous access	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Shock haemorrhagic	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Superior vena cava syndrome	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Thrombosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Vasculitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Vena cava thrombosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Venous thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted]).

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 36　　最終投与後 90 日までに発現した Grade 3 以上の重篤な副作用（いずれかの投与群で発現割合 0%超）

001 試験＋002 試験＋006 試験＋010 試験

MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Grade 3-5 Serious Drug-Related Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	682		1,232		1,567		2,799	
with one or more adverse events	55	(8.1)	90	(7.3)	130	(8.3)	220	(7.9)
with no adverse events	627	(91.9)	1,142	(92.7)	1,437	(91.7)	2,579	(92.1)
Blood and lymphatic system disorders	**1**	**(0.1)**	**3**	**(0.2)**	**6**	**(0.4)**	**9**	**(0.3)**
Anaemia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Autoimmune haemolytic anaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Microcytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neutropenia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pancytopenia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thrombocytopenia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cardiac disorders	**3**	**(0.4)**	**7**	**(0.6)**	**2**	**(0.1)**	**9**	**(0.3)**
Acute myocardial infarction	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Atrioventricular block complete	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cardiac tamponade	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Cardio-respiratory arrest	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Myocardial infarction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pericardial effusion	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Pericarditis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Endocrine disorders	**4**	**(0.6)**	**7**	**(0.6)**	**14**	**(0.9)**	**21**	**(0.8)**
Adrenal insufficiency	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Hyperthyroidism	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Hypophysitis	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Hypopituitarism	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Hypothyroidism	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Secondary adrenocortical insufficiency	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Drug-Related Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.0)**
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal disorders	**4**	**(0.6)**	**10**	**(0.8)**	**38**	**(2.4)**	**48**	**(1.7)**
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Colitis	3	(0.4)	6	(0.5)	15	(1.0)	21	(0.8)
Diarrhoea	0	(0.0)	1	(0.1)	13	(0.8)	14	(0.5)
Dysphagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Enterocolitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Ileus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intestinal obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nausea	0	(0.0)	2	(0.2)	2	(0.1)	4	(0.1)
Oesophagitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Rectal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Small intestinal perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vomiting	0	(0.0)	2	(0.2)	2	(0.1)	4	(0.1)
General disorders and administration site conditions	**3**	**(0.4)**	**4**	**(0.3)**	**8**	**(0.5)**	**12**	**(0.4)**
Asthenia	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Chest pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fatigue	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
General physical health deterioration	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Generalised oedema	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Pyrexia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatobiliary disorders	**1**	**(0.1)**	**1**	**(0.1)**	**12**	**(0.8)**	**13**	**(0.5)**
Autoimmune hepatitis	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Drug-induced liver injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hepatic function abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatitis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Liver disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Drug-Related Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Immune system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(0.2)**	**3**	**(0.1)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infections and infestations	**6**	**(0.9)**	**8**	**(0.6)**	**8**	**(0.5)**	**16**	**(0.6)**
Bacterial sepsis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diverticulitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erysipelas	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Listeriosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Liver abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meningitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Meningitis listeria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia	6	(0.9)	6	(0.5)	2	(0.1)	8	(0.3)
Injury, poisoning and procedural complications	**2**	**(0.3)**	**2**	**(0.2)**	**0**	**(0.0)**	**2**	**(0.1)**
Pneumonitis chemical	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Investigations	**1**	**(0.1)**	**3**	**(0.2)**	**7**	**(0.4)**	**10**	**(0.4)**
Alanine aminotransferase increased	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Aspartate aminotransferase increased	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Blood bilirubin increased	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood creatine phosphokinase increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood prolactin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intraocular pressure decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Drug-Related Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**1**	**(0.1)**	**3**	**(0.2)**	**7**	**(0.4)**	**10**	**(0.4)**
Liver function test abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolism and nutrition disorders	**8**	**(1.2)**	**9**	**(0.7)**	**12**	**(0.8)**	**21**	**(0.8)**
Decreased appetite	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dehydration	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Diabetes mellitus	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Diabetic ketoacidosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Failure to thrive	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperglycaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypertriglyceridaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hypoalbuminaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypokalaemia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hyponatraemia	2	(0.3)	3	(0.2)	3	(0.2)	6	(0.2)
Hypophosphataemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Insulin resistant diabetes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Type 1 diabetes mellitus	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Musculoskeletal and connective tissue disorders	**2**	**(0.3)**	**2**	**(0.2)**	**3**	**(0.2)**	**5**	**(0.2)**
Arthralgia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Arthritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Myalgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(0.1)**	**1**	**(0.1)**	**0**	**(0.0)**	**1**	**(0.0)**
Malignant neoplasm progression	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Nervous system disorders	**3**	**(0.4)**	**3**	**(0.2)**	**8**	**(0.5)**	**11**	**(0.4)**
Amnesia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Drug-Related Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**3**	**(0.4)**	**3**	**(0.2)**	**8**	**(0.5)**	**11**	**(0.4)**
Brain oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cerebrovascular accident	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Encephalopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Epilepsy	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myelitis transverse	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Presyncope	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Toxic leukoencephalopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Psychiatric disorders	**2**	**(0.3)**	**2**	**(0.2)**	**2**	**(0.1)**	**4**	**(0.1)**
Confusional state	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Disorientation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Renal and urinary disorders	**1**	**(0.1)**	**2**	**(0.2)**	**4**	**(0.3)**	**6**	**(0.2)**
Acute kidney injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Dysuria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Renal failure	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Tubulointerstitial nephritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory, thoracic and mediastinal disorders	**14**	**(2.1)**	**27**	**(2.2)**	**17**	**(1.1)**	**44**	**(1.6)**
Chronic obstructive pulmonary disease	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cough	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dyspnoea	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Interstitial lung disease	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Laryngeal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pleural effusion	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Pleuritic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Grade 3-5 Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**14**	**(2.1)**	**27**	**(2.2)**	**17**	**(1.1)**	**44**	**(1.6)**
Pneumonitis	12	(1.8)	22	(1.8)	10	(0.6)	32	(1.1)
Respiratory failure	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin and subcutaneous tissue disorders	**2**	**(0.3)**	**4**	**(0.3)**	**5**	**(0.3)**	**9**	**(0.3)**
Drug eruption	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lichenoid keratosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Rash maculo-papular	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Stevens-Johnson syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vascular disorders	**1**	**(0.1)**	**2**	**(0.2)**	**2**	**(0.1)**	**4**	**(0.1)**
Arterial thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Peripheral ischaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Vasculitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted]).

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 37　　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 C 及び F）（安全性解析対象集団）
Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Subjects in population	61			287			202		
with one or more serious adverse events	27	(44.3)	48	108	(37.6)	197	82	(40.6)	146
with no serious adverse events	34	(55.7)		179	(62.4)		120	(59.4)	
Blood and lymphatic system disorders									
Anaemia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Autoimmune haemolytic anaemia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Lymphadenopathy	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Neutropenia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Thrombocytopenia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	2
Cardiac disorders									
Acute coronary syndrome	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Acute myocardial infarction	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
Angina unstable	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Atrial fibrillation	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Atrial flutter	0	(0.0)	0	0	(0.0)	0	2	(1.0)	2
Cardiac failure congestive	0	(0.0)	0	2	(0.7)	3	0	(0.0)	0
Cardiac tamponade	1	(1.6)	1	2	(0.7)	2	1	(0.5)	1
Cardio-respiratory arrest	1	(1.6)	1	0	(0.0)	0	1	(0.5)	1
Myocardial infarction	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Pericardial effusion	1	(1.6)	1	3	(1.0)	4	1	(0.5)	1
Right ventricular failure	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Supraventricular tachycardia	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Endocrine disorders									
Adrenal haemorrhage	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Endocrine disorders									
Adrenal insufficiency	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Hyperthyroidism	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Hypophysitis	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Hypothyroidism	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Gastrointestinal disorders									
Abdominal pain	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
Ascites	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Colitis	2	(3.3)	2	0	(0.0)	0	1	(0.5)	1
Diarrhoea	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Erosive duodenitis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Gastric perforation	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Gastritis erosive	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Gastrointestinal pain	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Gastrointestinal perforation	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Intestinal perforation	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Nausea	0	(0.0)	0	5	(1.7)	5	1	(0.5)	2
Rectal haemorrhage	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Small intestinal obstruction	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Vomiting	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
General disorders and administration site conditions									
Asthenia	1	(1.6)	1	0	(0.0)	0	2	(1.0)	3
Chest pain	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
Chills	1	(1.6)	1	1	(0.3)	1	0	(0.0)	0
Death	0	(0.0)	0	0	(0.0)	0	2	(1.0)	2
Drug withdrawal syndrome	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
General disorders and administration site conditions									
Fatigue	0	(0.0)	0	2	(0.7)	2	2	(1.0)	2
General physical health deterioration	0	(0.0)	0	0	(0.0)	0	2	(1.0)	2
Generalised oedema	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Non-cardiac chest pain	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Oedema	0	(0.0)	0	0	(0.0)	0	2	(1.0)	2
Pain	1	(1.6)	1	2	(0.7)	2	1	(0.5)	1
Pyrexia	3	(4.9)	3	6	(2.1)	6	2	(1.0)	3
Hepatobiliary disorders									
Cholecystitis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Hepatic failure	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Infections and infestations									
Arthritis bacterial	0	(0.0)	0	1	(0.3)	2	0	(0.0)	0
Bacillus bacteraemia	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Bacterial sepsis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Bronchitis	1	(1.6)	1	2	(0.7)	2	0	(0.0)	0
Diverticulitis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Herpes zoster	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Infectious pleural effusion	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Infective exacerbation of chronic obstructive airways disease	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Lobar pneumonia	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Lower respiratory tract infection	2	(3.3)	2	1	(0.3)	1	2	(1.0)	2
Lung infection	1	(1.6)	1	3	(1.0)	3	0	(0.0)	0
Lymphangitis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Meningitis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Infections and infestations									
Oesophageal candidiasis	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Pleural infection	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Pneumonia	4	(6.6)	4	6	(2.1)	7	8	(4.0)	10
Pneumonia cryptococcal	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Pneumonia viral	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Pulmonary sepsis	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Respiratory tract infection	0	(0.0)	0	1	(0.3)	2	1	(0.5)	1
Sepsis	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Sinusitis	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Staphylococcal bacteraemia	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Thrombophlebitis septic	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Urinary tract infection	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Viral infection	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Injury, poisoning and procedural complications									
Femoral neck fracture	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Hip fracture	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Thoracic vertebral fracture	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Investigations									
Blood bilirubin increased	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Blood creatine phosphokinase increased	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Metabolism and nutrition disorders									
Cachexia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Decreased appetite	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Metabolism and nutrition disorders									
Dehydration	2	(3.3)	2	3	(1.0)	3	0	(0.0)	0
Failure to thrive	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Fluid overload	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Hypercalcaemia	0	(0.0)	0	3	(1.0)	3	1	(0.5)	1
Hyperkalaemia	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Hypoglycaemia	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Hypomagnesaemia	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Hyponatraemia	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
Hypovolaemia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Musculoskeletal and connective tissue disorders									
Arthralgia	2	(3.3)	2	2	(0.7)	2	0	(0.0)	0
Back pain	0	(0.0)	0	2	(0.7)	3	1	(0.5)	1
Bone pain	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Intervertebral disc protrusion	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Muscular weakness	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Musculoskeletal chest pain	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Musculoskeletal pain	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Neck pain	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Pathological fracture	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Basal cell carcinoma	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Breast cancer	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Leiomyosarcoma	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Lymphangiosis carcinomatosa	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Malignant pleural effusion	0	(0.0)	0	1	(0.3)	1	2	(1.0)	2
Metastases to central nervous system	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Pericardial effusion malignant	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Squamous cell carcinoma	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Tumour pain	1	(1.6)	1	2	(0.7)	2	0	(0.0)	0
Nervous system disorders									
Ataxia	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Cerebrovascular accident	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
Convulsion	0	(0.0)	0	0	(0.0)	0	2	(1.0)	2
Depressed level of consciousness	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Embolic stroke	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Headache	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Lethargy	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Neuralgia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Presyncope	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Syncope	1	(1.6)	1	1	(0.3)	1	1	(0.5)	1
Vasogenic cerebral oedema	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Psychiatric disorders									
Confusional state	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Renal and urinary disorders									
Calculus ureteric	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Dysuria	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Renal failure	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Renal failure acute	1	(1.6)	1	0	(0.0)	0	2	(1.0)	2
Urge incontinence	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Urinary tract obstruction	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Respiratory, thoracic and mediastinal disorders									
Acute respiratory failure	0	(0.0)	0	2	(0.7)	2	3	(1.5)	3
Atelectasis	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Chronic obstructive pulmonary disease	0	(0.0)	0	0	(0.0)	0	6	(3.0)	6
Diffuse alveolar damage	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Dyspnoea	2	(3.3)	2	8	(2.8)	8	4	(2.0)	5
Haemoptysis	0	(0.0)	0	0	(0.0)	0	3	(1.5)	3
Hypoxia	1	(1.6)	1	0	(0.0)	0	5	(2.5)	5
Interstitial lung disease	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Obstructive airways disorder	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Pleural effusion	2	(3.3)	2	15	(5.2)	20	8	(4.0)	9
Pneumonitis	2	(3.3)	3	6	(2.1)	6	4	(2.0)	4
Pneumothorax	0	(0.0)	0	5	(1.7)	7	2	(1.0)	2
Pulmonary embolism	2	(3.3)	2	8	(2.8)	8	3	(1.5)	3
Pulmonary hypertension	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Pulmonary oedema	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Respiratory failure	0	(0.0)	0	4	(1.4)	4	3	(1.5)	3
Wheezing	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0
Skin and subcutaneous tissue disorders									

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Subjects With Serious Adverse Events, to be Reported to www.clinicaltrials.gov
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W			MK-3475 10 mg/kg Q3W			MK-3475 10 mg/kg Q2W		
	n	(%)	Number of Events	n	(%)	Number of Events	n	(%)	Number of Events
Skin and subcutaneous tissue disorders									
Dermatitis	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Erythema multiforme	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Rash	0	(0.0)	0	1	(0.3)	1	1	(0.5)	1
Surgical and medical procedures									
Mitral valve replacement	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Vascular disorders									
Deep vein thrombosis	0	(0.0)	0	2	(0.7)	2	1	(0.5)	1
Embolism	0	(0.0)	0	2	(0.7)	2	3	(1.5)	3
Hypotension	0	(0.0)	0	2	(0.7)	2	0	(0.0)	0
Peripheral ischaemia	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Shock haemorrhagic	0	(0.0)	0	0	(0.0)	0	1	(0.5)	1
Superior vena cava occlusion	1	(1.6)	1	0	(0.0)	0	0	(0.0)	0
Vasculitis	0	(0.0)	0	1	(0.3)	1	0	(0.0)	0

Every subject is counted a single time for each applicable serious adverse event.
A system organ class appears on this report only if one or more specific serious adverse events in that system organ class appear on this report.
MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.
(Database Cutoff Date: [redacted]

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付録 2.7.4- 38　　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 C 及び F）（安全性解析対象集団）

Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000605, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=105										
000605	Safety Follow-up	107	Hyperkalaemia	3 Days	Moderate	2	Y	Y		Resolved
		107	Renal failure acute	3 Days	Moderate	2	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=003038, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=1										
003038	Safety Follow-up	6	Dyspnoea	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0002, Subject ID=003010, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=										
003010	Treatment Cycle 7	133	Pneumonia	3.14 Weeks	Moderate	2	Y	N	Interrupted	Resolved
		133	Tumour pain	2 Days	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0004, Subject ID=003042, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=83										
003042	Treatment Cycle 1	8	Arthralgia	4 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 3	61	Pulmonary embolism	1 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=003039, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=45										
003039	Treatment Cycle 2	43	Colitis	1.48 Months	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=003049, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=99										
003049	Treatment Cycle 4	94	Cardiac tamponade	Continuing	Severe	4	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000602, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=400										
000602	Treatment Cycle 16	361	Hypoglycaemia	5 Days	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000611, Gender=M, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=43										
000611	Extended Safety Follow-up	75	Pleural effusion	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=003006, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=106										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=003006, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=106										
003006	Treatment Cycle 1	10	Pyrexia	2 Days	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=003054, Gender=M, Race=White, Age=81 Years, Rel Day of Study Medication Discontinuance†=41										
003054	Safety Follow-up	58	Lobar pneumonia	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=003015, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=21										
003015	Safety Follow-up	37	Pain	4 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000610, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=43										
000610	Extended Safety Follow-up	125	Cardiac tamponade	5 Days	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000604, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=190										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0023, Subject ID=000604, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=190										
000604	Treatment Cycle 1	15	Pleural effusion	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=003001, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=43										
003001	Safety Follow-up	54	Hypoxia	Continuing	Moderate	2	Y	N		Not Resolved
		54	Lymphangiosis carcinomatosa	1.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=003034, Gender=M, Race=Asian, Age=76 Years, Rel Day of Study Medication Discontinuance†=22										
003034	Safety Follow-up	30	Lethargy	Continuing	Moderate	2	Y	Y		Not Resolved
		30	Lower respiratory tract infection	Continuing	Moderate	2	Y	N		Not Resolved
		32	Cardio-respiratory arrest	1 Days		5	Y	Y	Discontinued	Fatal
Trial Number=3475-001, Site Number=0023, Subject ID=003043, Gender=M, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=										
003043	Treatment Cycle 1	2	Dehydration	4 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0023, Subject ID=003043, Gender=M, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=										
003043	Treatment Cycle 1	2	Lower respiratory tract infection	1.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0027, Subject ID=003012, Gender=M, Race=White, Age=40 Years, Rel Day of Study Medication Discontinuance†=43										
003012	Safety Follow-up	44	Pneumonia	5 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0028, Subject ID=003020, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=22										
003020	Treatment Cycle 1	8	Lung infection	3 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	37	Dyspnoea	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0031, Subject ID=003021, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=22										
003021	Treatment Cycle 1	5	Pleural effusion	1.43 Weeks	Severe	3	Y	N		Resolved
	Safety Follow-up	28	Staphylococcal bacteraemia	2 Weeks	Moderate	2	Y	N		Resolved
		41	Thrombophlebitis septic	1.57 Weeks	Moderate	2	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0057, Subject ID=003027, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=43										
003027	Safety Follow-up	50	Asthenia	3.14 Weeks	Severe	3	Y	N	Interrupted	Resolved
		50	Dehydration	3.14 Weeks	Moderate	2	Y	N	Interrupted	Resolved
		60	Chills	1.71 Weeks	Moderate	2	Y	N	Interrupted	Resolved
		60	Pyrexia	1.71 Weeks	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0070, Subject ID=003031, Gender=F, Race=Multiracial, Age=65 Years, Rel Day of Study Medication Discontinuance†=22										
003031	Safety Follow-up	43	Arthralgia	3.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0073, Subject ID=003007, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=72										
003007	Treatment Cycle 1	16	Atelectasis	1.14 Weeks	Severe	3	Y	N	Interrupted	Resolved
		16	Pericardial effusion	1.14 Weeks	Severe	3	Y	N		Resolved
	Treatment Cycle 2	41	Superior vena cava occlusion	1.57 Weeks	Mild	1	Y	N		Resolved
	Safety Follow-up	82	Pneumonia	1.14 Weeks		5	Y	N	Discontinued	Fatal

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0091, Subject ID=003014, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=108										
003014	Treatment Cycle 1	20	Syncope	1 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0091, Subject ID=003019, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=207										
003019	Treatment Cycle 7	143	Bronchitis	4 Days	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 8	176	Pneumonitis	4.29 Weeks	Moderate	2	Y	Y	Interrupted	Resolved
	Safety Follow-up	226	Pneumonitis	Continuing	Severe	4	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0092, Subject ID=003037, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=43										
003037	Safety Follow-up	51	Hepatic failure	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
		51	Pulmonary sepsis	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0111, Subject ID=003050, Gender=M, Race=Asian, Age=52 Years, Rel Day of Study Medication Discontinuance†=50										
003050	Treatment Cycle 2	41	Pulmonary embolism	Continuing	Moderate	2	Y	N		Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0121, Subject ID=003023, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=127										
003023	Extended Safety Follow-up	161	Lymph gland infection	6 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0121, Subject ID=003024, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=										
003024	Treatment Cycle 1	6	Pneumonia	1.86 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 8	154	Colitis	1.14 Weeks	Severe	3	Y	Y		Resolved
		170	Pyrexia	2.86 Weeks	Moderate	2	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=003044, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
003044	Treatment Cycle 8	186	Mitral valve replacement	5 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=003045, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
003045	Safety Follow-up	13	Pneumonitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0134, Subject ID=003045, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
003045	Extended Safety Follow-up	50	Pneumonia	4 Days	Severe	3	Y	N		Resolved
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0001, Subject ID=001027, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=										
001027	Treatment Cycle 5	97	Hyponatraemia	5 Days	Severe	3	Y	Y		Resolved
	Treatment Cycle 11	230	Nausea	3.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001519, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=1										
001519	Safety Follow-up	12	Fatigue	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001525, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=176										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001525, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=176										
001525	Treatment Cycle 1	6	Pulmonary oedema	5 Days	Severe	3	Y	N	Interrupted	Resolved
	Extended Safety Follow-up	217	Cardiac failure congestive	Continuing	Severe	3	Y	N		Not Resolved
		217	Dyspnoea	Continuing	Severe	3	Y	N	Interrupted	Not Resolved
		243	Gastrointestinal haemorrhage	2.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=000169, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1										
000169	Safety Follow-up	2	Pneumonia	3.86 Weeks	Severe	3	Y	N		Resolved
		2	Pulmonary embolism	1.08 Months	Severe	3	Y	N		Resolved
		19	Hypercalcaemia	1.43 Weeks	Severe	4	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=000971, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=114										
000971	Treatment Cycle 4	66	Acute myocardial infarction	6 Days	Severe	3	Y	Y		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0003, Subject ID=000971, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=114										
000971	Treatment Cycle 4	68	Angina unstable	4 Days	Moderate	2	Y	Y		Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=001533, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=										
001533	Treatment Cycle 5	109	Pericardial effusion	6 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000152, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=715										
000152	Treatment Cycle 25	534	Leiomyosarcoma	2 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000180, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
000180	Safety Follow-up	4	Pneumonitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000181, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=85										
000181	Safety Follow-up	106	Pneumonitis	Continuing	Moderate	2	Y	Y	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000197, Gender=F, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=										
000197	Treatment Cycle 2	41	Pulmonary embolism	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000960, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=42										
000960	Treatment Cycle 1	6	Decreased appetite	2 Weeks	Severe	3	Y	N		Resolved
		6	Pleural effusion	2 Weeks	Severe	3	Y	N		Resolved
	Treatment Cycle 2	34	Pleural effusion	4 Days	Severe	4	Y	N		Resolved
	Safety Follow-up	46	Pleural effusion	2 Days	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001005, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=21										
001005	Safety Follow-up	31	Deep vein thrombosis	1.71 Weeks	Severe	3	Y	N		Resolved
		31	Pleural effusion	1.71 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001022, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=22										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001022, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=22										
001022	Safety Follow-up	41	Failure to thrive	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001073, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=210										
001073	Treatment Cycle 2	29	Breast cancer	2.63 Months	Severe	3	Y	N	N/A	Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000189, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=1										
000189	Safety Follow-up	22	Obstructive airways disorder	1 Weeks	Severe	3	Y	N	Interrupted	Resolved
	Extended Safety Follow-up	36	Anxiety	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000814, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43										
000814	Safety Follow-up	54	Generalised oedema	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000940, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=107										
000940	Extended Safety Follow-up	191	Pneumonitis	2.86 Weeks	Moderate	2	Y	Y		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000941, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=1										
000941	Extended Safety Follow-up	68	Gastrointestinal haemorrhage	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000947, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=										
000947	Treatment Cycle 1	22	Pulmonary oedema	6 Days	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 3	53	Cardiac failure congestive	3 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 5	105	Small intestinal obstruction	4 Days	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 22	491	Cardiac failure congestive	2 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000950, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=295										
000950	Treatment Cycle 3	57	Pneumothorax	Continuing	Mild	1	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000952, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=1										
000952	Safety Follow-up	14	Tumour pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000958, Gender=M, Race=Black Or African American, Age=39 Years, Rel Day of Study Medication Discontinuance†=64										
000958	Extended Safety Follow-up	109	Listeriosis	1 Weeks	Severe	3	Y	Y		Resolved
		109	Meningitis listeria	1 Weeks	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001004, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=190										
001004	Safety Follow-up	203	Pleural effusion	3 Days	Moderate	2	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001121, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=45										
001121	Extended Safety Follow-up	125	Respiratory failure	1.31 Months		5	Y	Y	Discontinued	Fatal
Trial Number=3475-001, Site Number=0012, Subject ID=000997, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
000997	Safety Follow-up	2	Back pain	2 Days	Severe	3	Y	N	Discontinued	Resolved
		4	Back pain	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=001095, Gender=M, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=										
001095	Treatment Cycle 15	296	Basal cell carcinoma	1.58 Months	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000192, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=42										
000192	Treatment Cycle 2	22	Abdominal pain	Continuing	Severe	3	Y	N		Not Resolved
	Safety Follow-up	63	Pyrexia	Continuing	Mild	1	Y	N		Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000192, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=42										
000192	Safety Follow-up	72	Bacillus bacteraemia	1.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000193, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=44										
000193	Treatment Cycle 2	36	Headache	6 Days	Moderate	2	Y	N		Resolved
		36	Nausea	6 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000200, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=1										
000200	Safety Follow-up	11	Ataxia	4 Weeks	Severe	3	Y	N		Resolved
		11	Pyrexia	4 Weeks	Severe	3	Y	N		Resolved
		11	Urge incontinence	4 Weeks	Severe	3	Y	N		Resolved
	Extended Safety Follow-up	37	Respiratory failure	2 Days	Severe	4	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000601, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=1										
000601	Safety Follow-up	10	Pleural effusion	Continuing	Severe	4	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000801, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=20										
000801	Treatment Cycle 1	15	Pulmonary embolism	Continuing	Severe	4	Y	N		Not Resolved
	Safety Follow-up	33	Pneumonitis	4 Days	Severe	4	Y	Y	Discontinued	Resolved
		47	Pulmonary hypertension	Continuing	Severe	4	Y	N		Not Resolved
	Extended Safety Follow-up	98	Fatigue	Continuing	Severe	3	Y	N		Not Resolved
		98	Nausea	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000807, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=22										
000807	Safety Follow-up	37	Respiratory failure	1 Days	Severe	5	Y	N	Discontinued	Fatal

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000809, Gender=M, Race=White, Age=40 Years, Rel Day of Study Medication Discontinuance†=1										
000809	Safety Follow-up	8	Pneumonia	1.71 Weeks	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000816, Gender=M, Race=Asian, Age=38 Years, Rel Day of Study Medication Discontinuance†=23										
000816	Safety Follow-up	35	Dyspnoea	Continuing	Moderate	2	Y	N		Not Resolved
		36	Pleural effusion	Continuing	Severe	4	Y	N		Not Resolved
		52	Intestinal perforation	2 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000820, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=51										
000820	Safety Follow-up	55	Respiratory failure	2 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000821, Gender=M, Race=White, Age=36 Years, Rel Day of Study Medication Discontinuance†=84										
000821	Treatment Cycle 3	57	Dyspnoea	6 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000913, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=232										
000913	Treatment Cycle 2	34	Supraventricular tachycardia	2 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	233	Acute respiratory failure	2.43 Weeks	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000918, Gender=M, Race=White, Age=32 Years, Rel Day of Study Medication Discontinuance†=20										
000918	Treatment Cycle 1	8	Pyrexia	2 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	35	Pleural effusion	1 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000932, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=65										
000932	Treatment Cycle 1	7	Pulmonary embolism	6 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000943, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=1										
000943	Safety Follow-up	2	Pneumothorax	3 Days	Severe	5	Y	N	Discontinued	Fatal

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001010, Gender=F, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=1										
001010	Safety Follow-up	14	Herpes zoster	Continuing	Mild	1	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001033, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=22										
001033	Safety Follow-up	23	Pleural effusion	Continuing	Moderate	2	Y	N		Not Resolved
		35	Ascites	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001581, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=1										
001581	Safety Follow-up	12	Embolic stroke	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved
		12	Pleural effusion	2 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=000833, Gender=M, Race=Black Or African American, Age=66 Years, Rel Day of Study Medication Discontinuance†=83										
000833	Treatment Cycle 3	48	Pleural effusion	2 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0016, Subject ID=000945, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=22										
000945	Safety Follow-up	36	Dyspnoea	4 Days	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=001078, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=										
001078	Treatment Cycle 13	257	Basal cell carcinoma	2.73 Months	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000151, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=43										
000151	Safety Follow-up	53	Dyspnoea	1.71 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000184, Gender=M, Race=Black Or African American, Age=63 Years, Rel Day of Study Medication Discontinuance†=22										
000184	Extended Safety Follow-up	72	Medical observation	2 Days	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000199, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=22										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000199, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=22										
000199	Safety Follow-up	34	Fatigue	4 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000802, Gender=F, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=84										
000802	Safety Follow-up	112	Dyspnoea	1 Weeks	Severe	3	Y	N		Resolved
		112	Pericardial effusion malignant	1 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000823, Gender=F, Race=White, Age=35 Years, Rel Day of Study Medication Discontinuance†=1										
000823	Safety Follow-up	12	Back pain	5 Days	Severe	3	Y	N		Resolved
	Extended Safety Follow-up	35	Tumour pain	2 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000827, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=240										
000827	Treatment Cycle 1	14	Tumour pain	1.14 Weeks	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000827, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=240										
000827	Safety Follow-up	259	Pneumonitis	3 Days	Moderate	2	Y	Y		Resolved
	Extended Safety Follow-up	323	Pneumonitis	4 Days	Moderate	2	Y	Y		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000902, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=										
000902	Treatment Cycle 1	1	Chills	3 Days	Mild	1	Y	Y		Resolved
		1	Pyrexia	3 Days	Moderate	2	Y	Y		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000928, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=428										
000928	Safety Follow-up	453	Rash	1.43 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001505, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=211										
001505	Treatment Cycle 5	95	Pericardial effusion	5 Days	Severe	3	Y	Y		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001514, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=44										
001514	Safety Follow-up	72	Blood bilirubin increased	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001520, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=446										
001520	Safety Follow-up	460	Pleural effusion	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001524, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=253										
001524	Safety Follow-up	262	Muscular weakness	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001552, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=1										
001552	Safety Follow-up	19	Respiratory failure	2.86 Weeks	Severe	4	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001563, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=336										
001563	Treatment Cycle 3	53	Atrial fibrillation	2 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001563, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=336										
001563	Treatment Cycle 3	53	Syncope	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001586, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=30										
001586	Treatment Cycle 1	5	Pneumonia	1 Weeks	Moderate	2	Y	N		Resolved
		12	Pneumonia	5 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000203, Gender=M, Race=Asian, Age=48 Years, Rel Day of Study Medication Discontinuance†=1										
000203	Extended Safety Follow-up	48	Pneumonitis	1 Days	Moderate	2	Y	Y		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000933, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=29										
000933	Treatment Cycle 1	15	Lung infection	1.43 Weeks	Severe	3	Y	N	Interrupted	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000983, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=244										
000983	Treatment Cycle 10	211	Acute coronary syndrome	2 Days	Severe	3	Y	N	Interrupted	Resolved
		220	Chest pain	2 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001127, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=57										
001127	Treatment Cycle 1	10	Nausea	2.43 Weeks	Severe	3	Y	Y	Interrupted	Resolved
		13	Vomiting	1.71 Weeks	Severe	3	Y	Y	Interrupted	Resolved
		21	Dehydration	3 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000195, Gender=F, Race=Asian, Age=75 Years, Rel Day of Study Medication Discontinuance†=64										
000195	Treatment Cycle 3	56	Pyrexia	5 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	80	Pneumonia	3.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000603, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000603, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=										
000603	Treatment Cycle 29	617	Dehydration	4 Days	Mild	1	Y	N		Resolved
		617	Nausea	4 Days	Mild	1	Y	N		Resolved
		617	Presyncope	1 Days	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000810, Gender=F, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=169										
000810	Treatment Cycle 1	10	Hypotension	1.43 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000825, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=1										
000825	Safety Follow-up	11	Embolism	3 Days	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0023, Subject ID=000828, Gender=M, Race=Asian, Age=67 Years, Rel Day of Study Medication Discontinuance†=22										
000828	Treatment Cycle 1	21	Pericardial effusion	3 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	34	Pericardial effusion	1.71 Weeks	Moderate	2	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000953, Gender=F, Race=Asian, Age=52 Years, Rel Day of Study Medication Discontinuance†=64										
000953	Treatment Cycle 2	28	Hyperthyroidism	2 Days	Severe	3	Y	Y		Resolved
	Safety Follow-up	84	Hypothyroidism	1.43 Weeks	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000955, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=341										
000955	Treatment Cycle 5	102	Chest pain	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000993, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=										
000993	Treatment Cycle 18	483	Cerebrovascular accident	2.57 Weeks	Moderate	2	Y	N		Resolved
		483	Confusional state	2.57 Weeks	Moderate	2	Y	N	Interrupted	Resolved
		483	Metastases to central nervous system	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001163, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=85										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001163, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=85										
001163	Treatment Cycle 2	22	Fluid overload	3 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	100	Dyspnoea	Continuing	Severe	3	Y	N		Not Resolved
		102	Acute respiratory failure	1 Days	Severe	4	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001503, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=										
001503	Treatment Cycle 9	216	Hypotension	1 Days	Moderate	2	Y	N		Resolved
		216	Pneumonia	2.73 Months	Moderate	2	Y	N		Resolved
		216	Sepsis	3.14 Weeks	Moderate	2	Y	N	Interrupted	Resolved
	Treatment Cycle 22	554	Infective exacerbation of chronic obstructive airways disease	3.86 Weeks	Severe	4	Y	N	Interrupted	Resolved
		554	Respiratory failure	3.86 Weeks	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001508, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=98										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001508, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=98										
001508	Treatment Cycle 3	47	Malignant pleural effusion	4.14 Weeks	Severe	3	Y	N	Interrupted	Resolved
		47	Pericardial effusion malignant	4.14 Weeks	Severe	3	Y	N	Interrupted	Resolved
		49	Cardiac tamponade	1 Days	Severe	4	Y	N		Resolved
		51	Pulmonary embolism	Continuing	Moderate	2	Y	N	Interrupted	Not Resolved
		69	Acute myocardial infarction	2 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	99	Pleural effusion	1.29 Weeks	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001589, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=169										
001589	Treatment Cycle 2	33	Viral infection	6 Days	Moderate	2	Y	N		Resolved
	Treatment Cycle 4	113	Hypophysitis	4.14 Weeks	Severe	3	Y	Y	Interrupted	Resolved
		113	Vasculitis	1.29 Weeks	Severe	3	Y	Y		Resolved
	Safety Follow-up	185	Lower respiratory tract infection	6 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001590, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=										
001590	Treatment Cycle 1	6	Pleural effusion	2.43 Weeks	Severe	3	Y	Y		Resolved
		11	Pulmonary embolism	6 Days	Severe	4	Y	N	Interrupted	Resolved
		17	Deep vein thrombosis	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0026, Subject ID=000968, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=43										
000968	Safety Follow-up	51	Pneumonitis	1 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0026, Subject ID=001510, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=169										
001510	Safety Follow-up	179	Pneumonitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0028, Subject ID=000985, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=22										
000985	Treatment Cycle 1	14	Wheezing	1 Weeks	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0028, Subject ID=001132, Gender=F, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=1										
001132	Safety Follow-up	12	Diarrhoea	1 Weeks	Severe	3	Y	Y		Resolved
	Extended Safety Follow-up	36	Colitis	2 Weeks	Severe	3	Y	Y	Discontinued	Resolved
		68	Colitis	4 Days	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0028, Subject ID=001157, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=105										
001157	Safety Follow-up	132	Pneumothorax	3 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0028, Subject ID=001178, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=288										
001178	Treatment Cycle 8	173	Pyrexia	5 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0031, Subject ID=001103, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
001103	Treatment Cycle 2	36	Dehydration	6 Days	Severe	4	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0031, Subject ID=001103, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
001103	Treatment Cycle 2	36	Renal failure	6 Days	Severe	4	Y	N		Resolved
		36	Vomiting	6 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0032, Subject ID=001038, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=142										
001038	Treatment Cycle 3	65	Urinary tract obstruction	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0033, Subject ID=001060, Gender=M, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=1										
001060	Safety Follow-up	12	Interstitial lung disease	5 Days	Severe	5	Y	Y	Discontinued	Fatal
Trial Number=3475-001, Site Number=0036, Subject ID=001166, Gender=F, Race=White, Age=36 Years, Rel Day of Study Medication Discontinuance†=43										
001166	Treatment Cycle 1	18	Arthralgia	2.71 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0036, Subject ID=001557, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=316										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0036, Subject ID=001557, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=316										
001557	Treatment Cycle 15	309	Squamous cell carcinoma	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0040, Subject ID=000975, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=189										
000975	Treatment Cycle 7	134	Non-cardiac chest pain	1 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0055, Subject ID=001175, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=30										
001175	Treatment Cycle 1	9	Dyspnoea	2.29 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0070, Subject ID=000986, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=43										
000986	Safety Follow-up	49	Musculoskeletal chest pain	3.57 Weeks	Severe	3	Y	N		Resolved
		49	Musculoskeletal pain	3.57 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0070, Subject ID=001063, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=99										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0070, Subject ID=001063, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=99										
001063	Treatment Cycle 3	52	Infectious pleural effusion	1.86 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0073, Subject ID=001172, Gender=F, Race=Black Or African American, Age=51 Years, Rel Day of Study Medication Discontinuance†=										
001172	Treatment Cycle 1	4	Arthralgia	2.57 Weeks	Moderate	2	Y	N		Resolved
		4	Musculoskeletal chest pain	2.14 Weeks	Mild	1	Y	N		Resolved
		4	Musculoskeletal pain	2.57 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 9	183	Sinusitis	5 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0073, Subject ID=001578, Gender=F, Race=Asian, Age=76 Years, Rel Day of Study Medication Discontinuance†=										
001578	Treatment Cycle 5	106	Adrenal insufficiency	Continuing	Moderate	2	Y	Y	Interrupted	Not Resolved
		106	Hyponatraemia	3.14 Weeks	Moderate	2	Y	Y	Interrupted	Resolved
		106	Hypothyroidism	Continuing	Moderate	2	Y	Y	Interrupted	Not Resolved
		182	Cardiac failure congestive	1 Weeks	Moderate	2	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0073, Subject ID=001578, Gender=F, Race=Asian, Age=76 Years, Rel Day of Study Medication Discontinuance†=										
001578	Treatment Cycle 5	182	Pleural effusion	1 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0081, Subject ID=001040, Gender=M, Race=Asian, Age=65 Years, Rel Day of Study Medication Discontinuance†=386										
001040	Treatment Cycle 2	29	Dyspnoea	1.14 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 3	59	Pneumothorax	1 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 6	122	Pneumothorax	4 Days	Moderate	2	Y	N	Interrupted	Resolved
		127	Pneumothorax	1 Weeks	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0082, Subject ID=001082, Gender=M, Race=Asian, Age=60 Years, Rel Day of Study Medication Discontinuance†=106										
001082	Treatment Cycle 6	106	Pneumonia	1.81 Months	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0082, Subject ID=001105, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=190										
001105	Safety Follow-up	200	Calculus ureteric	1.29 Weeks	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0082, Subject ID=001110, Gender=M, Race=Asian, Age=69 Years, Rel Day of Study Medication Discontinuance†=										
001110	Treatment Cycle 3	57	Arthritis bacterial	1.05 Months	Moderate	2	Y	N		Resolved
		62	Arthritis bacterial	3.86 Weeks	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0083, Subject ID=001007, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=97										
001007	Treatment Cycle 1	6	Pneumonia viral	4.29 Weeks	Moderate	2	Y	Y	Interrupted	Resolved
		21	Blood bilirubin increased	2 Days	Severe	3	Y	Y	Interrupted	Resolved
		22	Pneumothorax	6 Days	Moderate	2	Y	Y	Interrupted	Resolved
	Treatment Cycle 2	64	Cardiac tamponade	1.14 Weeks	Severe	4	Y	Y	Interrupted	Resolved
		84	Pleural effusion	1.57 Weeks	Severe	3	Y	N		Resolved
	Safety Follow-up	101	Pleural effusion	1.29 Weeks	Severe	3	Y	N		Resolved
		109	Pleural effusion	6 Days	Severe	3	Y	N		Resolved
		117	Pleural effusion	1.86 Weeks	Severe	3	Y	N		Resolved
		120	Pulmonary embolism	1.43 Weeks	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0083, Subject ID=001007, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=97										
001007	Extended Safety Follow-up	131	Pulmonary embolism	1 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0083, Subject ID=001090, Gender=F, Race=Asian, Age=65 Years, Rel Day of Study Medication Discontinuance†=26										
001090	Treatment Cycle 1	13	Pleural effusion	2 Weeks	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001067, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=50										
001067	Treatment Cycle 1	16	Respiratory tract infection	1 Weeks	Moderate	2	Y	N		Resolved
	Safety Follow-up	59	Respiratory tract infection	3 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001133, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=1										
001133	Safety Follow-up	28	Pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0090, Subject ID=001551, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=85										
001551	Safety Follow-up	105	Hypercalcaemia	1.29 Weeks	Severe	3	Y	N	Discontinued	Resolved
	Extended Safety Follow-up	117	Septic shock	1.14 Weeks	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0091, Subject ID=001061, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=231										
001061	Treatment Cycle 1	21	Lung infection	1.14 Weeks	Moderate	2	Y	N	Interrupted	Resolved
	Treatment Cycle 10	216	Oesophageal candidiasis	1.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0091, Subject ID=001117, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=70										
001117	Treatment Cycle 1	15	Bronchitis	2 Days	Mild	1	Y	N		Resolved
	Treatment Cycle 2	33	Lung infection	2 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0091, Subject ID=001573, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=22										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0091, Subject ID=001573, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=22										
001573	Treatment Cycle 1	18	Bone pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
	Safety Follow-up	38	Bronchitis	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
		39	Pulmonary embolism	Continuing	Severe	4	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0112, Subject ID=001091, Gender=F, Race=Asian, Age=40 Years, Rel Day of Study Medication Discontinuance†=22										
001091	Safety Follow-up	23	Dysuria	Continuing	Severe	3	Y	Y	Interrupted	Not Resolved
	Extended Safety Follow-up	62	Muscular weakness	2.71 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0120, Subject ID=001087, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=296										
001087	Safety Follow-up	298	Intervertebral disc protrusion	1.57 Weeks	Severe	3	Y	N		Resolved
		323	Gastric perforation	1 Weeks	Severe	3	Y	N	Interrupted	Resolved
		323	Sepsis	1 Weeks	Severe	4	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0121, Subject ID=001125, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=										
001125	Treatment Cycle 14	341	Abdominal pain	4 Days	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001153, Gender=M, Race=Black Or African American, Age=82 Years, Rel Day of Study Medication Discontinuance†=170										
001153	Safety Follow-up	191	Hip fracture	2.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001160, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=										
001160	Treatment Cycle 8	162	Adrenal insufficiency	1.29 Weeks	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001162, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=295										
001162	Extended Safety Follow-up	339	NULL	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001185, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=91										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0134, Subject ID=001185, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=91										
001185	Treatment Cycle 2	28	Hypomagnesaemia	1.29 Weeks	Moderate	2	Y	N		Resolved
		28	Nausea	1.29 Weeks	Moderate	2	Y	Y		Resolved
		41	Cerebrovascular accident	3 Days	Moderate	2	Y	N	Interrupted	Resolved
	Safety Follow-up	103	Embolism	Continuing	Moderate	2	Y	N		Not Resolved
		110	Hypercalcaemia	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001560, Gender=M, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=83										
001560	Treatment Cycle 1	15	Pain	4 Days	Severe	3	Y	N		Resolved
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0001, Subject ID=001089, Gender=F, Race=White, Age=41 Years, Rel Day of Study Medication Discontinuance†=365										
001089	Treatment Cycle 4	56	Cardio-respiratory arrest	1.71 Weeks	Severe	4	Y	N	Interrupted	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0001, Subject ID=001530, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=134										
001530	Safety Follow-up	145	Dermatitis	4 Days	Severe	3	Y	N	Interrupted	Resolved
		153	Renal failure acute	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001554, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=43										
001554	Safety Follow-up	66	Fatigue	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001570, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=										
001570	Treatment Cycle 5	64	Pyrexia	5 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 7	92	Pyrexia	1 Weeks	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 15	219	Diverticulitis	5 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001734, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=										
001734	Treatment Cycle 1	9	Colitis	3 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0002, Subject ID=001014, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=155										
001014	Extended Safety Follow-up	198	Pneumonia	1.29 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=001074, Gender=M, Race=Black Or African American, Age=60 Years, Rel Day of Study Medication Discontinuance†=62										
001074	Treatment Cycle 2	31	Chronic obstructive pulmonary disease	6 Days	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001167, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=239										
001167	Treatment Cycle 9	114	Chest pain	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000927, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=										
000927	Treatment Cycle 33	462	Chronic obstructive pulmonary disease	2 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000931, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=170										
000931	Treatment Cycle 1	22	Femoral neck fracture	1.45 Months	Severe	3	Y	N		Resolved
		38	Pneumonia	2.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000934, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=404										
000934	Treatment Cycle 13	180	Chronic obstructive pulmonary disease	5 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	414	Death	1 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0011, Subject ID=000951, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=79										
000951	Treatment Cycle 3	43	Hyponatraemia	1.18 Months	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000954, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=85										
000954	Treatment Cycle 2	24	Malignant pleural effusion	1.86 Weeks	Moderate	2	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001002, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=										
001002	Treatment Cycle 9	119	Urinary tract infection	1.29 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001109, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=72										
001109	Treatment Cycle 1	2	Dyspnoea	2 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001156, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=										
001156	Treatment Cycle 1	8	Pleural effusion	1.57 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001542, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=58										
001542	Safety Follow-up	61	Cholecystitis	5 Days	Moderate	2	Y	N		Resolved
		88	Atrial flutter	2 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001720, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=1										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001720, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=1										
001720	Safety Follow-up	5	Hypoxia	2.17 Months	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001728, Gender=F, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=43										
001728	Safety Follow-up	46	Pneumonitis	1.71 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001743, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=1										
001743	Safety Follow-up	9	Erosive duodenitis	Continuing	Mild	1	Y	N		Not Resolved
		9	Gastritis erosive	Continuing	Mild	1	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=001730, Gender=M, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=160										
001730	Safety Follow-up	161	Hypoxia	Continuing	Severe	3	Y	N		Not Resolved
		161	Myocardial infarction	Continuing	Severe	3	Y	N		Not Resolved
		161	Respiratory failure	Continuing	Severe	4	Y	N		Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001731, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=35										
001731	Treatment Cycle 1	12	Chronic obstructive pulmonary disease	3 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	38	Haemoptysis	3 Days	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=001733, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=57										
001733	Safety Follow-up	68	Anaemia	1.43 Weeks	Severe	3	Y	N		Resolved
		68	Asthenia	Continuing	Severe	3	Y	N		Not Resolved
		68	Cachexia	Continuing	Severe	3	Y	N		Not Resolved
		68	Respiratory failure	Continuing	Severe	4	Y	N		Not Resolved
		68	Thrombocytopenia	3 Days	Severe	4	Y	N		Resolved
		71	Thrombocytopenia	1 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0013, Subject ID=001134, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0013, Subject ID=001134, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=										
001134	Treatment Cycle 3	43	Nausea	3 Days	Severe	3	Y	Y	Interrupted	Resolved
		43	Vomiting	3 Days	Severe	3	Y	Y	Interrupted	Resolved
	Treatment Cycle 18	267	Drug withdrawal syndrome	2 Days	Severe	3	Y	N		Resolved
		267	Nausea	2 Days	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000919, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=155										
000919	Safety Follow-up	162	Diffuse alveolar damage	1.29 Weeks		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000964, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=56										
000964	Treatment Cycle 3	35	Hypovolaemia	1 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000966, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=1										
000966	Safety Follow-up	15	Embolism	1 Weeks	Severe	5	Y	N	Discontinued	Fatal

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0015, Subject ID=000984, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=1										
000984	Safety Follow-up	7	Acute respiratory failure	4 Days	Severe	3	Y	N		Resolved
		7	Cerebrovascular accident	4 Days	Severe	3	Y	N		Resolved
		7	Pleural effusion	4 Days	Severe	3	Y	N		Resolved
		11	Pleural effusion	5 Days	Severe	3	Y	N		Resolved
		17	Malignant pleural effusion	Continuing	Severe	4	Y	N		Not Resolved
		17	Renal failure	Continuing	Severe	4	Y	N		Not Resolved
		17	Respiratory failure	3 Days	Severe	5	Y	N	Discontinued	Fatal
		17	Shock haemorrhagic	Continuing	Severe	4	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001032, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=55										
001032	Treatment Cycle 3	34	Pleural infection	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001114, Gender=F, Race=Asian, Age=52 Years, Rel Day of Study Medication Discontinuance†=14										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0015, Subject ID=001114, Gender=F, Race=Asian, Age=52 Years, Rel Day of Study Medication Discontinuance†=14										
001114	Safety Follow-up	22	Pneumonia	1.43 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001152, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=43										
001152	Safety Follow-up	46	Supraventricular tachycardia	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001534, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=364										
001534	Treatment Cycle 10	133	Asthenia	5 Days	Moderate	2	Y	N		Resolved
		133	Fatigue	5 Days	Moderate	2	Y	N		Resolved
		154	Oedema	1 Weeks	Severe	3	Y	N		Resolved
	Treatment Cycle 18	277	Asthenia	5 Days	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001553, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=225										
001553	Treatment Cycle 1	10	Pleural effusion	3 Days	Moderate	2	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0015, Subject ID=001553, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=225										
001553	Safety Follow-up	243	Pyrexia	1.71 Weeks	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001588, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=53										
001588	Treatment Cycle 2	22	Vasogenic cerebral oedema	4 Days	Severe	3	Y	N	Interrupted	Resolved
		50	Headache	1 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001592, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=15										
001592	Safety Follow-up	23	Death	1 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=001703, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=109										
001703	Treatment Cycle 3	44	Ascites	3 Days	Severe	3	Y	N		Resolved
		44	Renal failure acute	3 Days	Severe	3	Y	N		Resolved
		56	Acute respiratory failure	5 Days	Moderate	2	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0015, Subject ID=001703, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=109										
001703	Treatment Cycle 3	56	Oedema	5 Days	Moderate	2	Y	N		Resolved
		56	Pericardial effusion	5 Days	Severe	3	Y	N	Interrupted	Resolved
		56	Pleural effusion	5 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001718, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=142										
001718	Safety Follow-up	157	Acute respiratory failure	6 Days	Severe	3	Y	N		Resolved
		157	Pulmonary embolism	6 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001732, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=										
001732	Treatment Cycle 25	347	Chronic obstructive pulmonary disease	6 Days	Severe	4	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001737, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=57										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0015, Subject ID=001737, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=57										
001737	Treatment Cycle 2	16	Adrenal haemorrhage	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=001547, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=71										
001547	Treatment Cycle 2	23	Gastrointestinal pain	1 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001029, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=49										
001029	Treatment Cycle 1	15	Pleural effusion	4 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	56	Hypoxia	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001119, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=15										
001119	Safety Follow-up	29	Rash	3.29 Weeks	Severe	3	Y	Y		Resolved
		35	Embolism	2.43 Weeks	Severe	3	Y	N		Resolved
		35	Pneumonitis	2.43 Weeks	Severe	3	Y	Y		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001119, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=15										
001119	Extended Safety Follow-up	48	Sepsis	4 Days	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0019, Subject ID=001559, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=46										
001559	Safety Follow-up	57	Bone pain	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001574, Gender=F, Race=White, Age=93 Years, Rel Day of Study Medication Discontinuance†=114										
001574	Safety Follow-up	117	Hypoxia	2 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001709, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=15										
001709	Safety Follow-up	20	Dyspnoea	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000904, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=99										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0020, Subject ID=000904, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=99										
000904	Safety Follow-up	106	Gastrointestinal perforation	2 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0020, Subject ID=000987, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=272										
000987	Treatment Cycle 9	133	Convulsion	1 Days	Moderate	2	Y	N	Interrupted	Resolved
	Safety Follow-up	286	Autoimmune haemolytic anaemia	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001576, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=134										
001576	Safety Follow-up	148	Atrial flutter	1 Days	Severe	3	Y	N		Resolved
		149	Pulmonary embolism	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001710, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=40										
001710	Safety Follow-up	49	Pain	3 Days	Severe	3	Y	N		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0020, Subject ID=001735, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=50										
001735	Safety Follow-up	64	Neutropenia	1.31 Months	Severe	4	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001736, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=77										
001736	Safety Follow-up	91	Pulmonary embolism	Continuing	Severe	4	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001742, Gender=M, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†=71										
001742	Treatment Cycle 1	7	Deep vein thrombosis	Continuing	Severe	3	Y	N		Not Resolved
	Treatment Cycle 2	22	Depressed level of consciousness	3 Days	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000994, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=40										
000994	Treatment Cycle 2	19	Haemoptysis	1.14 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 4	40	Atrial fibrillation	3.86 Weeks	Moderate	2	Y	N		Resolved
		40	Pleural effusion	3.86 Weeks	Severe	3	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0023, Subject ID=000994, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=40										
000994	Safety Follow-up	47	Lymphadenopathy	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001006, Gender=M, Race=Asian, Age=67 Years, Rel Day of Study Medication Discontinuance†=1										
001006	Safety Follow-up	29	Back pain	1.86 Weeks	Moderate	2	Y	N		Resolved
		30	Pneumonitis	1.71 Weeks	Severe	4	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001509, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=										
001509	Treatment Cycle 3	45	Peripheral ischaemia	3 Days	Moderate	2	Y	N	Interrupted	Resolved
	Treatment Cycle 32	460	Bacterial sepsis	4 Days	Severe	3	Y	N		Resolved
		460	Pneumonia	4 Days	Severe	3	Y	N		Resolved
		467	Lower respiratory tract infection	3 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001511, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=29										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0023, Subject ID=001511, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=29										
001511	Safety Follow-up	42	Lymphangitis	Continuing	Moderate	2	Y	Y		Not Resolved
		42	Pathological fracture	Continuing	Moderate	2	Y	N		Not Resolved
		42	Pleural effusion	3.71 Weeks	Moderate	2	Y	N	Discontinued	Resolved
		42	Thoracic vertebral fracture	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001583, Gender=F, Race=Asian, Age=60 Years, Rel Day of Study Medication Discontinuance†=71										
001583	Treatment Cycle 1	5	Pneumonia	5 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 2	17	Pneumonia	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0026, Subject ID=000957, Gender=M, Race=Black Or African American, Age=52 Years, Rel Day of Study Medication Discontinuance†=15										
000957	Safety Follow-up	26	Neck pain	3.14 Weeks	Severe	3	Y	N	Discontinued	Resolved
		26	Pneumothorax	3.14 Weeks	Severe	3	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0026, Subject ID=001081, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=15										
001081	Safety Follow-up	29	Herpes zoster	1 Weeks	Moderate	2	Y	N	Discontinued	Resolved
		29	Hypoxia	4 Days	Moderate	2	Y	Y		Resolved
Trial Number=3475-001, Site Number=0027, Subject ID=001515, Gender=M, Race=Black Or African American, Age=72 Years, Rel Day of Study Medication Discontinuance†=253										
001515	Treatment Cycle 12	177	Pneumonia cryptococcal	5 Days	Moderate	2	Y	N	Interrupted	Resolved
	Safety Follow-up	269	Pleural effusion	2 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0028, Subject ID=000972, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=29										
000972	Safety Follow-up	43	Hypercalcaemia	1 Days	Severe	4	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0028, Subject ID=001507, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=										
001507	Treatment Cycle 14	211	Blood creatine phosphokinase increased	3 Weeks	Severe	4	Y	Y		Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0028, Subject ID=001507, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=										
001507	Treatment Cycle 24	374	Syncope	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0031, Subject ID=001041, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=										
001041	Treatment Cycle 9	129	General physical health deterioration	5 Days	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 20	294	Rectal haemorrhage	4 Days	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0031, Subject ID=001049, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=183										
001049	Safety Follow-up	202	Meningitis	4.29 Weeks	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0040, Subject ID=001019, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=27										
001019	Treatment Cycle 1	11	Dyspnoea	2.29 Weeks	Severe	3	Y	N	Interrupted	Resolved
	Safety Follow-up	41	Dyspnoea	4.14 Weeks	Severe	3	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0040, Subject ID=001141, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=57										
001141	Safety Follow-up	77	General physical health deterioration	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0070, Subject ID=000999, Gender=M, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†=										
000999	Treatment Cycle 16	217	Acute myocardial infarction	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0070, Subject ID=001034, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=436										
001034	Treatment Cycle 17	231	Haemoptysis	1 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0073, Subject ID=001111, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=										
001111	Treatment Cycle 1	1	Pneumonia	1.43 Weeks	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0073, Subject ID=001529, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=239										

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(All Subjects as Treated)

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=0073, Subject ID=001529, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=239										
001529	Safety Follow-up Extended Safety Follow-up	254 283	Lower respiratory tract infection Cholecystitis	1.43 Weeks 2.71 Weeks	Moderate Moderate	2 2	Y Y	N N		Resolved Resolved
Trial Number=3475-001, Site Number=0081, Subject ID=001062, Gender=F, Race=Asian, Age=65 Years, Rel Day of Study Medication Discontinuance†=183										
001062	Safety Follow-up	197	Pneumonia	3.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0081, Subject ID=001071, Gender=M, Race=Asian, Age=62 Years, Rel Day of Study Medication Discontinuance†=225										
001071	Safety Follow-up	239	Pneumonia	1.35 Months	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0081, Subject ID=001577, Gender=M, Race=Asian, Age=64 Years, Rel Day of Study Medication Discontinuance†=113										
001577	Safety Follow-up	119 125	Dysuria Pneumothorax	Continuing Continuing	Moderate Severe	2 3	Y Y	N N		Not Resolved Not Resolved

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0081, Subject ID=001577, Gender=M, Race=Asian, Age=64 Years, Rel Day of Study Medication Discontinuance†=113										
001577	Safety Follow-up	126	Pneumonitis	2 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0082, Subject ID=001565, Gender=M, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=1										
001565	Safety Follow-up	5	Pneumonia	3 Weeks	Severe	3	Y	N	Interrupted	Resolved
		31	Pneumonia	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001051, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
001051	Treatment Cycle 9	114	Dyspnoea	2 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001545, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
001545	Treatment Cycle 25	359	Right ventricular failure	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0091, Subject ID=001099, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=57										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0091, Subject ID=001099, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=57										
001099	Treatment Cycle 1	3	Abdominal pain	1 Weeks	Moderate	2	Y	N		Resolved
	Safety Follow-up	68	Cardiac tamponade	1.43 Weeks	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0091, Subject ID=001556, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=185										
001556	Safety Follow-up	214	Respiratory tract infection	5 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0112, Subject ID=001122, Gender=F, Race=Asian, Age=64 Years, Rel Day of Study Medication Discontinuance†=13										
001122	Treatment Cycle 1	2	Decreased appetite	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0120, Subject ID=001580, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=267										
001580	Safety Follow-up	268	Neuralgia	1 Weeks	Moderate	2	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001182, Gender=M, Race=Black Or African American, Age=59 Years, Rel Day of Study Medication Discontinuance†=292										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0134, Subject ID=001182, Gender=M, Race=Black Or African American, Age=59 Years, Rel Day of Study Medication Discontinuance†=292										
001182	Treatment Cycle 13	180	Erythema multiforme	2.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 18	262	Convulsion	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001572, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=										
001572	Treatment Cycle 1	12	Embolism	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001582, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=219										

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Listing of Subjects With Adverse Events Serious Adverse Events up to 90 Days after Last Dose
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0134, Subject ID=001582, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance[†]=219										
001582	Safety Follow-up	229	Chronic obstructive pulmonary disease	1 Weeks	Severe	3	Y	N	Discontinued	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.

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: [redacted])

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付録 2.7.4- 39　　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 C 及び F）（安全性解析対象集団）

Subjects With Drug-Related Serious Adverse Events Up to 90 Days after Last Dose
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	61		287		202		550	
with one or more adverse events	6	(9.8)	27	(9.4)	13	(6.4)	46	(8.4)
with no adverse events	55	(90.2)	260	(90.6)	189	(93.6)	504	(91.6)
Blood and lymphatic system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**2**	**(0.4)**
Autoimmune haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Neutropenia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Cardiac disorders	**1**	**(1.6)**	**3**	**(1.0)**	**0**	**(0.0)**	**4**	**(0.7)**
Acute myocardial infarction	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Angina unstable	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Cardiac tamponade	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Cardio-respiratory arrest	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Pericardial effusion	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Endocrine disorders	**0**	**(0.0)**	**4**	**(1.4)**	**0**	**(0.0)**	**4**	**(0.7)**
Adrenal insufficiency	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Hyperthyroidism	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Hypophysitis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Hypothyroidism	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Gastrointestinal disorders	**2**	**(3.3)**	**3**	**(1.0)**	**2**	**(1.0)**	**7**	**(1.3)**
Colitis	2	(3.3)	1	(0.3)	0	(0.0)	3	(0.5)
Diarrhoea	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Nausea	0	(0.0)	2	(0.7)	1	(0.5)	3	(0.5)
Rectal haemorrhage	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Vomiting	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days after Last Dose (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**1**	**(1.6)**	**2**	**(0.7)**	**0**	**(0.0)**	**3**	**(0.5)**
Chills	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Generalised oedema	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pyrexia	1	(1.6)	1	(0.3)	0	(0.0)	2	(0.4)
Infections and infestations	**0**	**(0.0)**	**2**	**(0.7)**	**2**	**(1.0)**	**4**	**(0.7)**
Listeriosis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Lymphangitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Meningitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Meningitis listeria	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pneumonia viral	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Investigations	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Blood bilirubin increased	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Blood creatine phosphokinase increased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Metabolism and nutrition disorders	**1**	**(1.6)**	**2**	**(0.7)**	**0**	**(0.0)**	**3**	**(0.5)**
Hyperkalaemia	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Hyponatraemia	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Nervous system disorders	**1**	**(1.6)**	**0**	**(0.0)**	**1**	**(0.5)**	**2**	**(0.4)**
Lethargy	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Neuralgia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days after Last Dose (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**1**	**(1.6)**	**1**	**(0.3)**	**0**	**(0.0)**	**2**	**(0.4)**
Dysuria	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Renal failure acute	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Respiratory, thoracic and mediastinal disorders	**2**	**(3.3)**	**12**	**(4.2)**	**5**	**(2.5)**	**19**	**(3.5)**
Hypoxia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Interstitial lung disease	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pleural effusion	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pneumonitis	2	(3.3)	8	(2.8)	4	(2.0)	14	(2.5)
Pneumothorax	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Respiratory failure	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Rash	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Vascular disorders	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.2)**
Vasculitis	0	(0.0)	1	(0.3)	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.
(Database Cutoff Date: [redacted])

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付録 2.7.4- 40　　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）
010 試験（MK-3475 併合、安全性解析対象集団）（PD-L1 発現陽性）

Subjects With Serious Adverse Events Up to 90 Days After Last Dose
(Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Subjects in population	309		682	
with one or more adverse events	107	(34.6)	246	(36.1)
with no adverse events	202	(65.4)	436	(63.9)
Blood and lymphatic system disorders	**19**	**(6.1)**	**12**	**(1.8)**
Anaemia	1	(0.3)	6	(0.9)
Bone marrow failure	1	(0.3)	0	(0.0)
Eosinophilia	0	(0.0)	1	(0.1)
Febrile neutropenia	11	(3.6)	2	(0.3)
Leukocytosis	1	(0.3)	0	(0.0)
Leukopenia	1	(0.3)	0	(0.0)
Lymph node pain	0	(0.0)	1	(0.1)
Microcytic anaemia	0	(0.0)	1	(0.1)
Neutropenia	5	(1.6)	0	(0.0)
Normochromic normocytic anaemia	0	(0.0)	1	(0.1)
Cardiac disorders	**8**	**(2.6)**	**28**	**(4.1)**
Acute coronary syndrome	0	(0.0)	1	(0.1)
Acute myocardial infarction	1	(0.3)	1	(0.1)
Arrhythmia	0	(0.0)	1	(0.1)
Arteriosclerosis coronary artery	1	(0.3)	0	(0.0)
Atrial fibrillation	2	(0.6)	3	(0.4)
Atrial flutter	0	(0.0)	2	(0.3)
Atrial thrombosis	0	(0.0)	1	(0.1)
Atrioventricular block complete	0	(0.0)	1	(0.1)
Bradycardia	0	(0.0)	1	(0.1)
Cardiac arrest	0	(0.0)	1	(0.1)
Cardiac failure	0	(0.0)	2	(0.3)
Cardiac failure acute	1	(0.3)	0	(0.0)
Cardiac tamponade	0	(0.0)	1	(0.1)
Cardio-respiratory arrest	1	(0.3)	0	(0.0)
Cardiomyopathy	0	(0.0)	1	(0.1)
Cardiopulmonary failure	0	(0.0)	1	(0.1)
Coronary artery disease	0	(0.0)	1	(0.1)
Myocardial infarction	0	(0.0)	2	(0.3)
Palpitations	0	(0.0)	1	(0.1)
Pericardial effusion	1	(0.3)	6	(0.9)
Pericarditis	1	(0.3)	1	(0.1)
Tachycardia	0	(0.0)	1	(0.1)
Ventricular fibrillation	1	(0.3)	0	(0.0)
Congenital, familial and genetic disorders	**0**	**(0.0)**	**3**	**(0.4)**

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups) MK-3475 Treatment Groups Pooled APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Congenital, familial and genetic disorders	**0**	**(0.0)**	**3**	**(0.4)**
Pyloric stenosis	0	(0.0)	1	(0.1)
Tracheo-oesophageal fistula	0	(0.0)	2	(0.3)
Endocrine disorders	**0**	**(0.0)**	**7**	**(1.0)**
Adrenal insufficiency	0	(0.0)	1	(0.1)
Hyperthyroidism	0	(0.0)	2	(0.3)
Hypopituitarism	0	(0.0)	2	(0.3)
Hypothyroidism	0	(0.0)	2	(0.3)
Gastrointestinal disorders	**13**	**(4.2)**	**21**	**(3.1)**
Abdominal pain	1	(0.3)	2	(0.3)
Abdominal pain lower	0	(0.0)	1	(0.1)
Ascites	1	(0.3)	0	(0.0)
Colitis	0	(0.0)	3	(0.4)
Colitis ischaemic	1	(0.3)	0	(0.0)
Constipation	2	(0.6)	2	(0.3)
Diarrhoea	2	(0.6)	0	(0.0)
Dysphagia	1	(0.3)	3	(0.4)
Faecaloma	0	(0.0)	2	(0.3)
Gastric haemorrhage	0	(0.0)	1	(0.1)
Gastritis	0	(0.0)	1	(0.1)
Gastrooesophageal reflux disease	0	(0.0)	1	(0.1)
Ileus	0	(0.0)	1	(0.1)
Inguinal hernia	0	(0.0)	1	(0.1)
Intra-abdominal haemorrhage	1	(0.3)	0	(0.0)
Large intestinal obstruction	0	(0.0)	2	(0.3)
Nausea	0	(0.0)	2	(0.3)
Oesophageal obstruction	0	(0.0)	1	(0.1)
Oesophageal stenosis	2	(0.6)	0	(0.0)
Pancreatitis	0	(0.0)	2	(0.3)
Upper gastrointestinal haemorrhage	1	(0.3)	0	(0.0)
Vomiting	1	(0.3)	1	(0.1)
General disorders and administration site conditions	**10**	**(3.2)**	**24**	**(3.5)**
Asthenia	0	(0.0)	1	(0.1)
Chest pain	0	(0.0)	3	(0.4)
Death	1	(0.3)	6	(0.9)
Device dislocation	0	(0.0)	1	(0.1)
Fatigue	0	(0.0)	2	(0.3)
General physical health deterioration	1	(0.3)	4	(0.6)

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose
(Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
General disorders and administration site conditions	**10**	**(3.2)**	**24**	**(3.5)**
Malaise	1	(0.3)	0	(0.0)
Mucosal inflammation	1	(0.3)	0	(0.0)
Multi-organ failure	0	(0.0)	1	(0.1)
Oedema	1	(0.3)	0	(0.0)
Oedema peripheral	0	(0.0)	1	(0.1)
Pain	1	(0.3)	3	(0.4)
Pyrexia	4	(1.3)	5	(0.7)
Hepatobiliary disorders	**0**	**(0.0)**	**5**	**(0.7)**
Autoimmune hepatitis	0	(0.0)	2	(0.3)
Hepatic failure	0	(0.0)	1	(0.1)
Hepatocellular injury	0	(0.0)	1	(0.1)
Jaundice cholestatic	0	(0.0)	1	(0.1)
Immune system disorders	**0**	**(0.0)**	**1**	**(0.1)**
Drug hypersensitivity	0	(0.0)	1	(0.1)
Infections and infestations	**38**	**(12.3)**	**66**	**(9.7)**
Bronchitis	3	(1.0)	1	(0.1)
Cellulitis	0	(0.0)	1	(0.1)
Clostridium difficile infection	1	(0.3)	0	(0.0)
Device related infection	0	(0.0)	1	(0.1)
Device related sepsis	0	(0.0)	1	(0.1)
Diverticulitis	1	(0.3)	0	(0.0)
Endocarditis	0	(0.0)	1	(0.1)
External ear cellulitis	1	(0.3)	0	(0.0)
Gastroenteritis	1	(0.3)	1	(0.1)
Gastrointestinal infection	0	(0.0)	1	(0.1)
Herpes zoster	1	(0.3)	0	(0.0)
Infectious colitis	0	(0.0)	1	(0.1)
Infectious pleural effusion	0	(0.0)	1	(0.1)
Influenza	0	(0.0)	2	(0.3)
Laryngitis	1	(0.3)	0	(0.0)
Lower respiratory tract infection	2	(0.6)	1	(0.1)
Lung infection	3	(1.0)	2	(0.3)
Mucosal infection	1	(0.3)	0	(0.0)
Nasopharyngitis	1	(0.3)	0	(0.0)
Osteomyelitis	0	(0.0)	1	(0.1)
Phlebitis infective	1	(0.3)	0	(0.0)
Pleural infection	1	(0.3)	0	(0.0)
Pneumocystis jirovecii pneumonia	0	(0.0)	1	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups) MK-3475 Treatment Groups Pooled APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Infections and infestations	**38**	**(12.3)**	**66**	**(9.7)**
Pneumonia	16	(5.2)	36	(5.3)
Pneumonia bacterial	1	(0.3)	2	(0.3)
Pneumonia haemophilus	0	(0.0)	1	(0.1)
Pneumonia pneumococcal	0	(0.0)	1	(0.1)
Pyelonephritis acute	0	(0.0)	1	(0.1)
Pyopneumothorax	0	(0.0)	1	(0.1)
Respiratory tract infection	3	(1.0)	6	(0.9)
Respiratory tract infection viral	0	(0.0)	1	(0.1)
Sepsis	1	(0.3)	0	(0.0)
Septic shock	2	(0.6)	0	(0.0)
Staphylococcal infection	1	(0.3)	1	(0.1)
Upper respiratory tract infection	3	(1.0)	0	(0.0)
Urinary tract infection	0	(0.0)	1	(0.1)
Urosepsis	1	(0.3)	1	(0.1)
Wound sepsis	0	(0.0)	1	(0.1)
Injury, poisoning and procedural complications	**6**	**(1.9)**	**14**	**(2.1)**
Accidental overdose	0	(0.0)	1	(0.1)
Contusion	1	(0.3)	1	(0.1)
Fall	0	(0.0)	2	(0.3)
Femur fracture	1	(0.3)	0	(0.0)
Hip fracture	1	(0.3)	0	(0.0)
Humerus fracture	1	(0.3)	0	(0.0)
Incisional hernia, obstructive	0	(0.0)	1	(0.1)
Pneumonitis chemical	0	(0.0)	2	(0.3)
Post procedural urine leak	0	(0.0)	1	(0.1)
Radiation pneumonitis	0	(0.0)	2	(0.3)
Seroma	0	(0.0)	1	(0.1)
Spinal compression fracture	0	(0.0)	1	(0.1)
Thoracic vertebral fracture	1	(0.3)	0	(0.0)
Traumatic intracranial haemorrhage	1	(0.3)	0	(0.0)
Upper limb fracture	0	(0.0)	2	(0.3)
Investigations	**1**	**(0.3)**	**7**	**(1.0)**
Alanine aminotransferase increased	0	(0.0)	1	(0.1)
Aspartate aminotransferase increased	0	(0.0)	1	(0.1)
Aspiration bronchial	0	(0.0)	1	(0.1)
Blood alkaline phosphatase increased	0	(0.0)	1	(0.1)
Blood bilirubin increased	0	(0.0)	1	(0.1)
Blood creatine phosphokinase increased	0	(0.0)	1	(0.1)
Blood creatinine increased	0	(0.0)	1	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups) MK-3475 Treatment Groups Pooled APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Investigations	**1**	**(0.3)**	**7**	**(1.0)**
C-reactive protein increased	0	(0.0)	1	(0.1)
Gamma-glutamyltransferase increased	0	(0.0)	1	(0.1)
Neutrophil count decreased	1	(0.3)	0	(0.0)
Metabolism and nutrition disorders	**8**	**(2.6)**	**19**	**(2.8)**
Decreased appetite	3	(1.0)	1	(0.1)
Dehydration	4	(1.3)	3	(0.4)
Diabetes mellitus	0	(0.0)	1	(0.1)
Diabetic ketoacidosis	0	(0.0)	1	(0.1)
Hypercalcaemia	0	(0.0)	6	(0.9)
Hypertriglyceridaemia	0	(0.0)	1	(0.1)
Hypoalbuminaemia	0	(0.0)	1	(0.1)
Hypokalaemia	0	(0.0)	1	(0.1)
Hypomagnesaemia	0	(0.0)	1	(0.1)
Hyponatraemia	1	(0.3)	3	(0.4)
Hypophosphataemia	0	(0.0)	1	(0.1)
Type 1 diabetes mellitus	0	(0.0)	2	(0.3)
Musculoskeletal and connective tissue disorders	**4**	**(1.3)**	**18**	**(2.6)**
Arthralgia	1	(0.3)	1	(0.1)
Arthritis	0	(0.0)	1	(0.1)
Back pain	1	(0.3)	4	(0.6)
Bone pain	0	(0.0)	1	(0.1)
Flank pain	0	(0.0)	1	(0.1)
Muscle fatigue	1	(0.3)	0	(0.0)
Muscle haemorrhage	0	(0.0)	1	(0.1)
Muscle necrosis	0	(0.0)	1	(0.1)
Musculoskeletal chest pain	0	(0.0)	1	(0.1)
Musculoskeletal pain	0	(0.0)	2	(0.3)
Myopathy	0	(0.0)	1	(0.1)
Neck pain	0	(0.0)	1	(0.1)
Osteoporosis	0	(0.0)	1	(0.1)
Osteoporotic fracture	0	(0.0)	1	(0.1)
Pain in extremity	0	(0.0)	1	(0.1)
Spinal column stenosis	0	(0.0)	1	(0.1)
Spinal osteoarthritis	1	(0.3)	0	(0.0)
Synovitis	0	(0.0)	1	(0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**2**	**(0.6)**	**10**	**(1.5)**
Basal cell carcinoma	0	(0.0)	1	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups) MK-3475 Treatment Groups Pooled APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**2**	**(0.6)**	**10**	**(1.5)**
Cancer pain	0	(0.0)	1	(0.1)
Gastric cancer	0	(0.0)	1	(0.1)
Lung neoplasm malignant	0	(0.0)	1	(0.1)
Malignant neoplasm progression	0	(0.0)	1	(0.1)
Malignant pleural effusion	0	(0.0)	1	(0.1)
Metastases to central nervous system	2	(0.6)	1	(0.1)
Metastatic pain	0	(0.0)	1	(0.1)
Tumour associated fever	0	(0.0)	1	(0.1)
Tumour pain	0	(0.0)	1	(0.1)
Nervous system disorders	**4**	**(1.3)**	**20**	**(2.9)**
Brain oedema	1	(0.3)	1	(0.1)
Cerebral ischaemia	0	(0.0)	1	(0.1)
Cerebrovascular accident	1	(0.3)	2	(0.3)
Cognitive disorder	1	(0.3)	0	(0.0)
Dizziness	0	(0.0)	1	(0.1)
Haemorrhage intracranial	0	(0.0)	1	(0.1)
Hemiparesis	0	(0.0)	1	(0.1)
Ischaemic stroke	0	(0.0)	3	(0.4)
Myelitis transverse	0	(0.0)	1	(0.1)
Neurological decompensation	0	(0.0)	1	(0.1)
Peripheral sensory neuropathy	0	(0.0)	1	(0.1)
Seizure	0	(0.0)	1	(0.1)
Spinal cord compression	0	(0.0)	2	(0.3)
Syncope	1	(0.3)	2	(0.3)
Toxic leukoencephalopathy	0	(0.0)	1	(0.1)
Transient ischaemic attack	0	(0.0)	1	(0.1)
Psychiatric disorders	**2**	**(0.6)**	**8**	**(1.2)**
Anxiety	0	(0.0)	1	(0.1)
Completed suicide	0	(0.0)	1	(0.1)
Confusional state	1	(0.3)	3	(0.4)
Delirium	1	(0.3)	1	(0.1)
Disorientation	0	(0.0)	1	(0.1)
Mental status changes	0	(0.0)	1	(0.1)
Renal and urinary disorders	**3**	**(1.0)**	**8**	**(1.2)**
Acute kidney injury	1	(0.3)	4	(0.6)
Bladder hypertrophy	1	(0.3)	0	(0.0)
Haematuria	1	(0.3)	0	(0.0)
Renal failure	0	(0.0)	1	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups) MK-3475 Treatment Groups Pooled APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Renal and urinary disorders	**3**	**(1.0)**	**8**	**(1.2)**
Tubulointerstitial nephritis	0	(0.0)	1	(0.1)
Urinary bladder polyp	0	(0.0)	1	(0.1)
Urinary retention	1	(0.3)	1	(0.1)
Reproductive system and breast disorders	**0**	**(0.0)**	**1**	**(0.1)**
Erectile dysfunction	0	(0.0)	1	(0.1)
Respiratory, thoracic and mediastinal disorders	**24**	**(7.8)**	**65**	**(9.5)**
Acute respiratory failure	0	(0.0)	1	(0.1)
Chronic obstructive pulmonary disease	1	(0.3)	7	(1.0)
Dyspnoea	6	(1.9)	8	(1.2)
Haemoptysis	0	(0.0)	4	(0.6)
Hypoxia	0	(0.0)	2	(0.3)
Interstitial lung disease	1	(0.3)	1	(0.1)
Painful respiration	0	(0.0)	1	(0.1)
Pleural effusion	3	(1.0)	8	(1.2)
Pleurisy	1	(0.3)	0	(0.0)
Pleuritic pain	1	(0.3)	0	(0.0)
Pneumonia aspiration	1	(0.3)	3	(0.4)
Pneumonitis	2	(0.6)	17	(2.5)
Pneumothorax	3	(1.0)	0	(0.0)
Pulmonary embolism	5	(1.6)	15	(2.2)
Pulmonary haemorrhage	2	(0.6)	2	(0.3)
Pulmonary hypertension	0	(0.0)	1	(0.1)
Pulmonary oedema	0	(0.0)	2	(0.3)
Pulmonary vascular disorder	0	(0.0)	1	(0.1)
Respiratory distress	0	(0.0)	1	(0.1)
Respiratory failure	2	(0.6)	3	(0.4)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**2**	**(0.3)**
Drug eruption	0	(0.0)	1	(0.1)
Rash maculo-papular	0	(0.0)	1	(0.1)
Vascular disorders	**5**	**(1.6)**	**11**	**(1.6)**
Deep vein thrombosis	2	(0.6)	1	(0.1)
Embolism	0	(0.0)	2	(0.3)
Femoral artery occlusion	0	(0.0)	1	(0.1)
Hypertension	1	(0.3)	0	(0.0)
Hypotension	2	(0.6)	1	(0.1)
Peripheral ischaemia	0	(0.0)	1	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days After Last Dose
(Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Vascular disorders	**5**	**(1.6)**	**11**	**(1.6)**
Superior vena cava occlusion	0	(0.0)	1	(0.1)
Superior vena cava syndrome	1	(0.3)	2	(0.3)
Thrombosis	0	(0.0)	1	(0.1)
Vena cava thrombosis	0	(0.0)	1	(0.1)

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.
SAE is monitored until 90 days after last dose.
(Database Cutoff Date: 30SEP2015)

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付録 2.7.4- 41　　最終投与後 90 日までに発現した重篤な有害事象の一覧

010 試験（安全性解析対象集団）（PD-L1 発現陽性）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0002, AN=310915, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=127								
310915	Treatment Cycle 1	4	Clostridium difficile infection	1.14 Weeks	Y	N	None	Resolved
	Safety Follow-up	131	Febrile neutropenia	1 Weeks	Y	Y	None	Resolved
		131	Hypotension	2 Hours	Y	Y	None	Resolved
		131	Pneumonia	Continuing	Y	Y	None	Resolving
		146	Pneumonitis	Continuing	Y	Y	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0004, AN=309836, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=99								
309836	Treatment Cycle 5	99	Constipation	4 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0015, AN=310885, Gender=F, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=146								
310885	Safety Follow-up	150	Urosepsis	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0017, AN=309938, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=205								
309938	Treatment Cycle 7	146	Abdominal pain	2.71 Weeks	Y	N	None	Resolved
	Treatment Cycle 8	160	Leukopenia	5 Days	Y	Y	None	Resolved
		160	Neutropenia	5 Days	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0026, AN=310973, Gender=F, Race=White, Age=81 Years, Rel Day of Study Medication Discontinuance†=1								
310973	Safety Follow-up	4	Syncope	1.29 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0027, AN=301906, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=1								
301906	Extended Safety Follow-up	33	Back pain	2 Days	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0040, AN=302628, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=1								
302628	Safety Follow-up	22	Humerus fracture	3 Days	Y	N	None	Resolved
		22	Pneumonia	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0040, AN=305127, Gender=M, Race=Black Or African American, Age=81 Years, Rel Day of Study Medication Discontinuance†=86								
305127	Safety Follow-up	89	Dyspnoea	6 Days	Y	Y	None	Resolved
		96	Dyspnoea	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0046, AN=305963, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=92								
305963	Treatment Cycle 3	60	Dyspnoea	4 Days	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=0047, AN=308729, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=106								
308729	Treatment Cycle 1	6	Diverticulitis	2.43 Weeks	Y	N	None	Resolved
		9	Neutropenia	2 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0048, AN=301916, Gender=M, Race=Black Or African American, Age=62 Years, Rel Day of Study Medication Discontinuance†=45								
301916	Safety Follow-up	55	Pericardial effusion	Continuing	Y	N	None	Not Resolved
		68	Pneumonia	3 Days	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0051, AN=303197, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=127								
303197	Treatment Cycle 5	105	Bronchitis	1.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0051, AN=304906, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=232								
304906	Treatment Cycle 1	8	Dehydration	4 Days	Y	Y	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0051, AN=304906, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=232								
304906	Treatment Cycle 1	8	Upper respiratory tract infection	4 Days	Y	Y	None	Resolved
	Treatment Cycle 12	232	Pleural effusion	1 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0051, AN=306663, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=127								
306663	Safety Follow-up	146	Pleural effusion	3 Days	Y	Y	Discontinued	Resolved
Study Number=3475-010, Site Number=0051, AN=307442, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=63								
307442	Safety Follow-up	69	Cognitive disorder	Continuing	Y	Y	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0051, AN=313974, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=20								
313974	Treatment Cycle 1	8	Neutropenia	4 Days	Y	Y	Interrupted	Resolved
	Safety Follow-up	33	Deep vein thrombosis	3 Days	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0052, AN=304865, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=43								
304865	Treatment Cycle 1	17	Pneumonia	1.43 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0055, AN=303539, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=29								
303539	Treatment Cycle 1	7	Febrile neutropenia	6 Days	Y	Y	Reduced	Resolved
	Safety Follow-up	37	Pneumonia	4 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0063, AN=309676, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=92								
309676	Treatment Cycle 1	22	Pulmonary embolism	1.14 Weeks	Y	N	Interrupted	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0081, AN=301651, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=189								
301651	Treatment Cycle 9	189	Superior vena cava syndrome	2.07 Months	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0082, AN=304902, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=22								
304902	Safety Follow-up	26	Oesophageal stenosis	2 Weeks	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0082, AN=307310, Gender=M, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=83								
307310	Safety Follow-up	96	Arteriosclerosis coronary artery	1.29 Weeks	Y	Y	Discontinued	Sequelae
Study Number=3475-010, Site Number=0085, AN=303940, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=43								
303940	Safety Follow-up	55	Bronchitis	Unknown	Y	N	N/A	Unknown
Study Number=3475-010, Site Number=0086, AN=304216, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=1								
304216	Safety Follow-up	2	General physical health deterioration	Continuing	Y	Y	N/A	Not Resolved
Study Number=3475-010, Site Number=0088, AN=309010, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=149								
309010	Treatment Cycle 3 Treatment Cycle 4	62 78	Pulmonary embolism Dysphagia	4 Days 2.92 Months	Y Y	N N	None None	Resolved Sequelae
Study Number=3475-010, Site Number=0089, AN=302678, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=86								
302678	Safety Follow-up	100	Oedema	2.99 Months	Y	Y	Discontinued	Resolved
Study Number=3475-010, Site Number=0091, AN=301577, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=40								
301577	Safety Follow-up	55	Pyrexia	3.14 Weeks	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0094, AN=302688, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=217								
302688	Treatment Cycle 9 Safety Follow-up	194 223	Acute myocardial infarction Pleurisy	5 Days Continuing	Y Y	N N	None None	Resolved Resolving
Study Number=3475-010, Site Number=0095, AN=300863, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=1								
300863	Safety Follow-up	7	Bone marrow failure	6 Days	Y	Y	None	Sequelae
Study Number=3475-010, Site Number=0095, AN=304130, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=169								
304130	Treatment Cycle 4	81	Pain	2 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0096, AN=305891, Gender=M, Race=, Age=64 Years, Rel Day of Study Medication Discontinuance†=1								
305891	Safety Follow-up	6	Pyrexia	2.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0096, AN=308089, Gender=M, Race=, Age=56 Years, Rel Day of Study Medication Discontinuance†=43								
308089	Safety Follow-up	58	Oesophageal stenosis	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0096, AN=309496, Gender=F, Race=, Age=54 Years, Rel Day of Study Medication Discontinuance†=1								
309496	Safety Follow-up	17	Pneumonia	2.86 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0130, AN=307952, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=64								
307952	Extended Safety Follow-up	110	Death	23 Hours	Y	N	None	Fatal
Study Number=3475-010, Site Number=0136, AN=307842, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0136, AN=307842, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1								
307842	Safety Follow-up	11	Dehydration	2 Days	Y	Y	N/A	Fatal
Study Number=3475-010, Site Number=0160, AN=302004, Gender=F, Race=Asian, Age=54 Years, Rel Day of Study Medication Discontinuance†=114								
302004	Extended Safety Follow-up	168	Contusion	24 Hours	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0160, AN=305711, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=1								
305711	Safety Follow-up	20	Pneumothorax	Continuing	Y	N	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0166, AN=301698, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=113								
301698	Treatment Cycle 4	84	Decreased appetite	Continuing	Y	N	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0167, AN=300143, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=1								
300143	Safety Follow-up	6	Colitis ischaemic	2 Weeks	Y	Y	Discontinued	Resolved
Study Number=3475-010, Site Number=0180, AN=300441, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=155								
300441	Treatment Cycle 1	8	Pleuritic pain	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0181, AN=302502, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=29								
302502	Safety Follow-up	47	Brain oedema	2 Days	Y	N	None	Fatal
Study Number=3475-010, Site Number=0182, AN=303567, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=64								
303567	Safety Follow-up	88	Chronic obstructive pulmonary disease	1.28 Months	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0182, AN=303567, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=64								
303567	Extended Safety Follow-up	140	Pneumothorax	1.02 Months	Y	N	None	Resolved
Study Number=3475-010, Site Number=0183, AN=309268, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=71								
309268	Treatment Cycle 1	22	Thoracic vertebral fracture	Continuing	Y	N	None	Not Resolved
	Treatment Cycle 4	71	Pneumonia	2.43 Weeks	Y	N	None	Fatal
Study Number=3475-010, Site Number=0184, AN=307849, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=72								
307849	Treatment Cycle 2	36	Atrial fibrillation	3 Days	Y	N	None	Resolved
		36	Dehydration	4 Days	Y	N	None	Resolved
	Safety Follow-up	80	Lower respiratory tract infection	1 Weeks	Y	N	None	Resolved
		81	Anaemia	Continuing	Y	N	None	Not Resolved
	Extended Safety Follow-up	115	Constipation	5 Days	Y	N	N/A	Resolved
		120	Confusional state	4 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0184, AN=308281, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=50								
308281	Treatment Cycle 2	35	Urinary retention	4 Days	Y	N	None	Resolved
		40	Spinal osteoarthritis	5 Days	Y	N	Interrupted	Sequelae
	Extended Safety Follow-up	81	Bladder hypertrophy	23 Hours	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0185, AN=313294, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=131								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0185, AN=313294, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=131								
313294	Treatment Cycle 1	15	Lower respiratory tract infection	6 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0200, AN=300589, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=149								
300589	Treatment Cycle 1	7	Neutropenia	2.14 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0200, AN=302610, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=64								
302610	Safety Follow-up	90	Delirium	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0200, AN=309408, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=40								
309408	Treatment Cycle 1	13	Haematuria	Continuing	Y	N	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0200, AN=313162, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=42								
313162	Safety Follow-up	63	Metastases to central nervous system	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0200, AN=313799, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=44								
313799	Treatment Cycle 2	23	Femur fracture	1 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0201, AN=300727, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=45								
300727	Treatment Cycle 1	4	Pulmonary haemorrhage	2 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0201, AN=303362, Gender=F, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=42								
303362	Safety Follow-up	66	Metastases to central nervous system	23 Hours	Y	N	Discontinued	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0201, AN=312546, Gender=M, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=52								
312546	Extended Safety Follow-up	87	Septic shock	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0201, AN=312670, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=42								
312670	Safety Follow-up	53	Bronchitis	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0202, AN=311034, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=1								
311034	Safety Follow-up	4	Pulmonary embolism	1.43 Weeks	Y	N	None	Resolved
		20	Respiratory failure	1.29 Weeks	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=0205, AN=301943, Gender=M, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=22								
301943	Safety Follow-up	40	Pneumothorax	1.71 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0207, AN=303419, Gender=M, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=1								
303419	Safety Follow-up	7	Febrile neutropenia	1.22 Months	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0208, AN=306146, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=169								
306146	Extended Safety Follow-up	235	Respiratory tract infection	2.57 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0211, AN=300914, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=43								
300914	Safety Follow-up	56	Lung infection	2.29 Weeks	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0283, AN=302405, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=1								
302405	Safety Follow-up	8	Decreased appetite	2.57 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0284, AN=302057, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=127								
302057	Treatment Cycle 3	47	Pneumonia	1.71 Weeks	Y	N	None	Resolved
	Safety Follow-up	148	Ventricular fibrillation	1.14 Weeks	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0326, AN=304848, Gender=F, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=22								
304848	Safety Follow-up	32	Diarrhoea	Continuing	Y	Y	N/A	Not Resolved
Study Number=3475-010, Site Number=0326, AN=313199, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=22								
313199	Safety Follow-up	26	Cerebrovascular accident	1.48 Months	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=0360, AN=312975, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=113								
312975	Treatment Cycle 2	22	Dyspnoea	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0400, AN=305384, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=1								
305384	Safety Follow-up	17	Cardio-respiratory arrest	23 Hours	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0401, AN=300174, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1								
300174	Safety Follow-up	6	Respiratory tract infection	1 Weeks	Y	Y	Discontinued	Fatal
		6	Upper gastrointestinal haemorrhage	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0407, AN=310834, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=22								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0407, AN=310834, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=22								
310834	Safety Follow-up	24	Respiratory tract infection	1.57 Weeks	Y	N	None	Resolved
		46	Hypotension	2 Hours	Y	N	None	Resolved
Study Number=3475-010, Site Number=0440, AN=309531, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=106								
309531	Treatment Cycle 4	75	Pneumonia	1.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0441, AN=310131, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=85								
310131	Treatment Cycle 3	49	Deep vein thrombosis	1.29 Weeks	Y	N	None	Resolved
	Treatment Cycle 4	76	Hypertension	Continuing	Y	N	None	Resolving
	Safety Follow-up	91	Vomiting	3 Days	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0444, AN=312765, Gender=M, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=22								
312765	Safety Follow-up	32	Lung infection	3.71 Weeks	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0522, AN=310853, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=112								
310853	Treatment Cycle 2	27	Febrile neutropenia	1.43 Weeks	Y	Y	None	Resolved
	Treatment Cycle 4	72	Pneumonia	2 Weeks	Y	Y	Interrupted	Resolved
	Safety Follow-up	130	Pneumonia	1.97 Months	Y	Y	None	Sequelae
Study Number=3475-010, Site Number=0560, AN=303847, Gender=M, Race=White, Age=37 Years, Rel Day of Study Medication Discontinuance†=23								
303847	Safety Follow-up	39	Pneumonia	1.18 Months	Y	Y	None	Resolved
	Extended Safety Follow-up	104	Dyspnoea	Continuing	Y	N	N/A	Resolving

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0560, AN=308319, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=22								
308319	Treatment Cycle 1	12	Hip fracture	2.86 Weeks	Y	N	N/A	Resolved
	Safety Follow-up	51	Arthralgia	1.57 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0560, AN=310979, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=73								
310979	Safety Follow-up	78	Phlebitis infective	1.15 Months	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0561, AN=304604, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=104								
304604	Treatment Cycle 5	94	Pericarditis	2 Days	Y	N	None	Resolved
	Safety Follow-up	109	Pericarditis	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0561, AN=306386, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=104								
306386	Treatment Cycle 1	6	Muscle fatigue	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0562, AN=304804, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=1								
304804	Safety Follow-up	14	Ascites	5 Days	Y	N	None	Resolved
		18	Malaise	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0563, AN=310498, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=22								
310498	Safety Follow-up	47	Hyponatraemia	3 Days	Y	N	None	Resolved
		47	Leukocytosis	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0604, AN=305125, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=42								
305125	Safety Follow-up	52	Pulmonary embolism	1.71 Weeks	Y	N	Discontinued	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=0760, AN=306274, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=191								
306274	Treatment Cycle 1	8	Febrile neutropenia	3 Days	Y	Y	Reduced	Resolved
Study Number=3475-010, Site Number=0764, AN=300266, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
300266	Safety Follow-up	6	Febrile neutropenia	5 Days	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0764, AN=302112, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=150								
302112	Treatment Cycle 1	8	Neutropenia	4 Days	Y	Y	None	Resolved
	Safety Follow-up	154	Intra-abdominal haemorrhage	3.57 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0764, AN=305414, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=64								
305414	Treatment Cycle 1	9	Dyspnoea	2 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0960, AN=308933, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=								
308933	Treatment Cycle 4	69	Febrile neutropenia	4 Days	Y	Y	None	Resolved
	Treatment Cycle 8	162	Pneumonia	1.29 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 10	203	Pneumonia	5 Days	Y	N	None	Resolved
		209	Mucosal inflammation	Continuing	Y	Y	None	Not Resolved
Study Number=3475-010, Site Number=1004, AN=309747, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=113								
309747	Treatment Cycle 1	13	Pleural effusion	1.57 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 3	64	Pleural infection	4.57 Months	Y	N	Interrupted	Resolved
	Safety Follow-up	119	Pneumonia	Continuing	Y	N	None	Resolving

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=1080, AN=307406, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=41								
307406	Treatment Cycle 2	25	Pyrexia	1.29 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=1081, AN=301965, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=175								
301965	Treatment Cycle 4	75	Pneumonia	1.43 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 7	159	Gastroenteritis	5 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=1083, AN=309376, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=22								
309376	Safety Follow-up	32	Febrile neutropenia	5 Days	Y	N	None	Resolved
		40	Herpes zoster	2.57 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1240, AN=311863, Gender=M, Race=Asian, Age=74 Years, Rel Day of Study Medication Discontinuance†=								
311863	Treatment Cycle 13	302	Diarrhoea	1.86 Weeks	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=1241, AN=305727, Gender=M, Race=Asian, Age=64 Years, Rel Day of Study Medication Discontinuance†=64								
305727	Safety Follow-up	85	Pneumonitis	Continuing	Y	Y	Discontinued	Resolving
Study Number=3475-010, Site Number=1241, AN=307953, Gender=M, Race=Asian, Age=72 Years, Rel Day of Study Medication Discontinuance†=64								
307953	Safety Follow-up	74	Pneumonia	Continuing	Y	Y	Discontinued	Resolving
Study Number=3475-010, Site Number=1243, AN=301184, Gender=F, Race=Asian, Age=74 Years, Rel Day of Study Medication Discontinuance†=150								
301184	Safety Follow-up	159	Febrile neutropenia	1.43 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=1243, AN=302438, Gender=M, Race=Asian, Age=63 Years, Rel Day of Study Medication Discontinuance†=27								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=1243, AN=302438, Gender=M, Race=Asian, Age=63 Years, Rel Day of Study Medication Discontinuance†=27								
302438	Treatment Cycle 1	6	Laryngitis	2.14 Weeks	Y	Y	Interrupted	Resolved
		8	Mucosal infection	1.86 Weeks	Y	Y	None	Resolved
		8	Neutrophil count decreased	4 Days	Y	Y	None	Resolved
Study Number=3475-010, Site Number=1243, AN=312969, Gender=M, Race=Asian, Age=78 Years, Rel Day of Study Medication Discontinuance†=206								
312969	Treatment Cycle 4	82	Upper respiratory tract infection	1.86 Weeks	Y	Y	Interrupted	Resolved
	Treatment Cycle 6	119	Lung infection	3.57 Weeks	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=1243, AN=313082, Gender=F, Race=Asian, Age=62 Years, Rel Day of Study Medication Discontinuance†=246								
313082	Treatment Cycle 1	12	Sepsis	2 Weeks	Y	Y	Interrupted	Resolved
	Treatment Cycle 11	233	Upper respiratory tract infection	1.14 Weeks	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=1245, AN=307607, Gender=M, Race=Asian, Age=72 Years, Rel Day of Study Medication Discontinuance†=1								
307607	Safety Follow-up	4	Febrile neutropenia	3 Days	Y	Y	N/A	Fatal
Study Number=3475-010, Site Number=1245, AN=309049, Gender=M, Race=Asian, Age=60 Years, Rel Day of Study Medication Discontinuance†=40								
309049	Safety Follow-up	57	Pneumonia	2.1 Months	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=1366, AN=311525, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=1								
311525	Safety Follow-up	7	Pulmonary embolism	2 Hours	Y	N	None	Fatal
Study Number=3475-010, Site Number=1366, AN=312557, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=								
312557	Treatment Cycle 2	31	Febrile neutropenia	5 Days	Y	Y	Reduced	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=1403, AN=309360, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=30								
309360	Treatment Cycle 1	9	Pneumonia bacterial	3.14 Weeks	Y	Y	Reduced	Resolved
	Safety Follow-up	41	Interstitial lung disease	1.86 Weeks	Y	Y	Discontinued	Fatal
Study Number=3475-010, Site Number=1405, AN=312181, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=106								
312181	Extended Safety Follow-up	145	Pulmonary haemorrhage	1.22 Months	Y	N	None	Resolved
Study Number=3475-010, Site Number=1419, AN=301064, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=81								
301064	Treatment Cycle 1	3	Dyspnoea	Continuing	Y	Y	Interrupted	Resolving
	Treatment Cycle 3	59	Decreased appetite	Continuing	Y	Y	Interrupted	Not Resolved
	Safety Follow-up	87	Pneumonia aspiration	Continuing	Y	Y	None	Resolving
		88	Respiratory failure	4 Weeks	Y	N	None	Fatal
		88	Septic shock	Continuing	Y	Y	Discontinued	Resolving
Study Number=3475-010, Site Number=1420, AN=304509, Gender=M, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=127								
304509	Treatment Cycle 1	7	Dehydration	1.29 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=1421, AN=309956, Gender=M, Race=Asian, Age=77 Years, Rel Day of Study Medication Discontinuance†=109								
309956	Treatment Cycle 2	41	Pyrexia	6 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=1422, AN=310046, Gender=M, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
310046	Safety Follow-up	10	Atrial fibrillation	Continuing	Y	Y	N/A	Not Resolved
		12	Acute kidney injury	Continuing	Y	Y	N/A	Not Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
Docetaxel 75 mg/m2 Q3W								
Study Number=3475-010, Site Number=1422, AN=310046, Gender=M, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
310046	Safety Follow-up	19	Cardiac failure acute	6 Hours	Y	Y	N/A	Fatal
Study Number=3475-010, Site Number=1437, AN=311287, Gender=M, Race=Asian, Age=34 Years, Rel Day of Study Medication Discontinuance†=159								
311287	Treatment Cycle 3	45	Staphylococcal infection	4.14 Weeks	Y	N	Interrupted	Resolved
	Safety Follow-up	164	Nasopharyngitis	6 Days	Y	N	N/A	Resolved
		176	External ear cellulitis	1.14 Weeks	Y	N	N/A	Resolved
	Extended Safety Follow-up	214	Traumatic intracranial haemorrhage	Continuing	Y	N	N/A	Resolving
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0003, AN=300621, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=1								
300621	Safety Follow-up	8	Malignant pleural effusion	3.43 Weeks	Y	N	None	Resolved
	Extended Safety Follow-up	33	Malignant pleural effusion	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0003, AN=310279, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=20								
310279	Safety Follow-up	40	Pulmonary embolism	4 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0004, AN=300573, Gender=M, Race=, Age=70 Years, Rel Day of Study Medication Discontinuance†=28								
300573	Treatment Cycle 1	6	Pneumonitis	3 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0004, AN=301679, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=49								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0004, AN=301679, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=49								
301679	Safety Follow-up	67	Blood alkaline phosphatase increased	1.57 Weeks	Y	N	Interrupted	Resolved
		67	Blood bilirubin increased	1.57 Weeks	Y	N	None	Resolved
		76	Acute kidney injury	2 Days	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0004, AN=309510, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=22								
309510	Safety Follow-up	37	Pericarditis	Continuing	Y	N	None	Resolving
		39	Musculoskeletal pain	Continuing	Y	N	N/A	Resolving
Study Number=3475-010, Site Number=0005, AN=306197, Gender=F, Race=White, Age=29 Years, Rel Day of Study Medication Discontinuance†=43								
306197	Safety Follow-up	66	Pneumonia	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0005, AN=311089, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=								
311089	Treatment Cycle 12	253	Chronic obstructive pulmonary disease	1.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0006, AN=307697, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=138								
307697	Treatment Cycle 5	104	Arthritis	3.14 Weeks	Y	Y	Interrupted	Resolved
		104	Pleural effusion	3.14 Weeks	Y	Y	Interrupted	Resolved
		113	Muscle haemorrhage	3.71 Weeks	Y	N	None	Resolved
	Safety Follow-up	160	Dyspnoea	Continuing	Y	Y	Interrupted	Not Resolved
		160	Pericardial effusion	Continuing	Y	N	Interrupted	Not Resolved
		160	Pleural effusion	Continuing	Y	N	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0007, AN=307955, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=239								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0007, AN=307955, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=239								
307955	Treatment Cycle 1	20	Gastric haemorrhage	6 Days	Y	N	Interrupted	Resolved
	Treatment Cycle 6	134	Dehydration	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0014, AN=301535, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=232								
301535	Safety Follow-up	243	Pneumonia	1.29 Weeks	Y	N	None	Resolved
		253	Acute myocardial infarction	3.14 Weeks	Y	N	Discontinued	Resolved
		253	Chronic obstructive pulmonary disease	4 Days	Y	N	N/A	Resolved
	Extended Safety Follow-up	286	Pneumonia	6 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0015, AN=306432, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=109								
306432	Treatment Cycle 4	70	Abdominal pain lower	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0024, AN=302527, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=22								
302527	Treatment Cycle 1	11	Superior vena cava syndrome	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0026, AN=304255, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=51								
304255	Treatment Cycle 2	39	Influenza	1.29 Weeks	Y	N	Interrupted	Resolved
	Safety Follow-up	58	Pneumonitis	1.15 Months	Y	Y	Discontinued	Resolved
		58	Pulmonary embolism	Continuing	Y	N	N/A	Resolving
Study Number=3475-010, Site Number=0026, AN=308278, Gender=M, Race=Black Or African American, Age=77 Years, Rel Day of Study Medication Discontinuance†=63								
308278	Safety Follow-up	72	Transient ischaemic attack	30 Minutes	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0028, AN=308356, Gender=M, Race=American Indian Or Alaska Native, Age=62 Years, Rel Day of Study Medication Discontinuance†=1								
308356	Safety Follow-up	10	Blood creatine phosphokinase increased	Continuing	Y	N	None	Not Resolved
		10	Hyponatraemia	Continuing	Y	N	None	Not Resolved
		10	Myocardial infarction	2 Days	Y	N	N/A	Resolved
		10	Pneumonia	1.14 Weeks	Y	Y	Discontinued	Fatal
Study Number=3475-010, Site Number=0028, AN=313159, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=22								
313159	Safety Follow-up	30	Dyspnoea	3 Days	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0037, AN=310781, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=43								
310781	Safety Follow-up	50	Cardiomyopathy	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0040, AN=307770, Gender=F, Race=Black Or African American, Age=78 Years, Rel Day of Study Medication Discontinuance†=149								
307770	Treatment Cycle 5	99	Musculoskeletal chest pain	4 Days	Y	N	None	Resolved
		106	Musculoskeletal chest pain	2 Days	Y	N	Interrupted	Resolved
	Treatment Cycle 7	149	Nausea	3.57 Weeks	Y	N	None	Resolved
	Extended Safety Follow-up	192	Faecaloma	23 Hours	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0046, AN=309525, Gender=M, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=68								
309525	Extended Safety Follow-up	119	Pneumonia	2.29 Weeks	Y	N	N/A	Sequelae
		122	Pneumonitis	1.57 Weeks	Y	Y	N/A	Resolved
		133	Pulmonary embolism	3 Days	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0046, AN=314043, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=417								
314043	Treatment Cycle 18	389	Anaemia	2 Days	Y	N	Interrupted	Sequelae
Study Number=3475-010, Site Number=0050, AN=306601, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=169								
306601	Treatment Cycle 3	44	Large intestinal obstruction	2 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0050, AN=313837, Gender=F, Race=Black Or African American, Age=73 Years, Rel Day of Study Medication Discontinuance†=1								
313837	Safety Follow-up	11	Pneumonia	Continuing	Y	N	None	Not Resolved
	Extended Safety Follow-up	32	Multi-organ failure	1.14 Weeks	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=0051, AN=303260, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=68								
303260	Treatment Cycle 3	53	Flank pain	Unknown	Y	N	None	Unknown
	Safety Follow-up	84	Jaundice cholestatic	1.57 Weeks	Y	N	N/A	Unknown
Study Number=3475-010, Site Number=0058, AN=312963, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=								
312963	Treatment Cycle 2	40	Pericardial effusion	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0059, AN=307425, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=105								
307425	Treatment Cycle 1	6	Nausea	4 Days	Y	N	None	Resolved
		6	Vomiting	4 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0063, AN=303281, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=178								
303281	Treatment Cycle 5	96	Pulmonary embolism	4 Days	Y	Y	Interrupted	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0063, AN=303281, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=178								
303281	Treatment Cycle 7	155	Hypoxia	4 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0084, AN=302927, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=218								
302927	Treatment Cycle 11 Safety Follow-up	218 229	Confusional state Fatigue	Continuing Continuing	Y Y	N Y	None Discontinued	Resolving Not Resolved
Study Number=3475-010, Site Number=0088, AN=311561, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=212								
311561	Treatment Cycle 1	8	Anxiety	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0089, AN=311406, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=41								
311406	Safety Follow-up	57	Atrial fibrillation	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0094, AN=302933, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=								
302933	Treatment Cycle 14	295	Hemiparesis	Continuing	Y	N	Interrupted	Resolving
Study Number=3475-010, Site Number=0094, AN=303077, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=219								
303077	Safety Follow-up	245	Febrile neutropenia	1.43 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0094, AN=303099, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=84								
303099	Safety Follow-up	105	Vena cava thrombosis	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0096, AN=304814, Gender=M, Race=, Age=67 Years, Rel Day of Study Medication Discontinuance†=1								
304814	Safety Follow-up	31	Type 1 diabetes mellitus	1.15 Months	Y	Y	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0123, AN=314063, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=176								
314063	Treatment Cycle 1	5	Chronic obstructive pulmonary disease	1.94 Months	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0129, AN=304272, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43								
304272	Safety Follow-up	56	Radiation pneumonitis	4.24 Months	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0130, AN=308513, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=246								
308513	Extended Safety Follow-up	298	Seizure	2.86 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0131, AN=307729, Gender=M, Race=White, Age=39 Years, Rel Day of Study Medication Discontinuance†=43								
307729	Safety Follow-up	69	Bronchitis	3.57 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0135, AN=305284, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=								
305284	Treatment Cycle 10	191	Lung infection	1.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0136, AN=306797, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=23								
306797	Safety Follow-up	32	Pneumonitis	2.29 Weeks	Y	Y	N/A	Resolved
Study Number=3475-010, Site Number=0138, AN=310772, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=173								
310772	Treatment Cycle 7	136	Infectious colitis	1.61 Months	Y	N	Interrupted	Resolved
	Safety Follow-up	181	Toxic leukoencephalopathy	Continuing	Y	Y	Discontinued	Resolving
Study Number=3475-010, Site Number=0162, AN=302404, Gender=F, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=22								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0162, AN=302404, Gender=F, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=22								
302404	Safety Follow-up	32	Ischaemic stroke	Continuing	Y	N	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0162, AN=309544, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=121								
309544	Treatment Cycle 3	53	Pulmonary embolism	2.14 Months	Y	N	Interrupted	Resolved
	Treatment Cycle 5	100	Lymph node pain	1.86 Weeks	Y	N	None	Resolved
	Safety Follow-up	145	Device related sepsis	3.29 Weeks	Y	N	N/A	Resolved
	Extended Safety Follow-up	168	Pyrexia	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0167, AN=310382, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=								
310382	Treatment Cycle 5	108	Back pain	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0180, AN=310957, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=84								
310957	Safety Follow-up	93	Cerebrovascular accident	Continuing	Y	Y	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0180, AN=311647, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=1								
311647	Safety Follow-up	4	Dyspnoea	Continuing	Y	N	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0181, AN=303188, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=64								
303188	Safety Follow-up	82	Alanine aminotransferase increased	2 Weeks	Y	Y	N/A	Resolved
		82	Aspartate aminotransferase increased	1.43 Weeks	Y	Y	Discontinued	Resolved
	Extended Safety Follow-up	116	Pneumonia bacterial	2.14 Weeks	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0183, AN=314351, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=1								
314351	Safety Follow-up	21	Autoimmune hepatitis	Continuing	Y	Y	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0184, AN=309469, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=								
309469	Treatment Cycle 1	3	Chest pain	2 Weeks	Y	N	None	Resolved
		3	Dyspnoea	Continuing	Y	N	Interrupted	Resolving
Study Number=3475-010, Site Number=0185, AN=301233, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=92								
301233	Treatment Cycle 4	76	Confusional state	3 Days	Y	N	None	Resolved
	Safety Follow-up	104	Confusional state	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0185, AN=307250, Gender=M, Race=Asian, Age=60 Years, Rel Day of Study Medication Discontinuance†=1								
307250	Safety Follow-up	8	Abdominal pain	3 Days	Y	N	None	Resolved
		18	Abdominal pain	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0185, AN=307585, Gender=F, Race=Black Or African American, Age=54 Years, Rel Day of Study Medication Discontinuance†=105								
307585	Treatment Cycle 5	90	Musculoskeletal pain	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0200, AN=306250, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=21								
306250	Treatment Cycle 1	20	Respiratory tract infection	Continuing	Y	N	None	Resolving
	Safety Follow-up	26	Brain oedema	3.71 Weeks	Y	N	None	Fatal
Study Number=3475-010, Site Number=0200, AN=306369, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=21								
306369	Safety Follow-up	39	Pneumonitis	1.15 Months	Y	Y	Discontinued	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0200, AN=311151, Gender=F, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=1								
311151	Safety Follow-up	6	Respiratory failure	2 Days	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=0201, AN=300176, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=368								
300176	Safety Follow-up	388	Pulmonary embolism	1.02 Months	Y	N	None	Resolved
	Extended Safety Follow-up	418	Respiratory failure	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0201, AN=309551, Gender=M, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=100								
309551	Treatment Cycle 2	44	Superior vena cava occlusion	1.61 Months	Y	N	Interrupted	Resolved
	Treatment Cycle 3	73	Pancreatitis	2 Weeks	Y	Y	Interrupted	Resolved
		86	Pulmonary embolism	1.18 Months	Y	N	None	Resolved
	Safety Follow-up	105	Pericardial effusion	1.57 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0202, AN=301353, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=21								
301353	Safety Follow-up	42	Hypercalcaemia	1.14 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0204, AN=306723, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=154								
306723	Treatment Cycle 5	116	Pyrexia	4 Days	Y	N	None	Resolved
	Treatment Cycle 6	133	Pneumonia	1.29 Weeks	Y	N	None	Resolved
	Extended Safety Follow-up	223	Tracheo-oesophageal fistula	4 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0204, AN=312519, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=93								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0204, AN=312519, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=93								
312519	Treatment Cycle 2	43	Pneumonia	1.14 Weeks	Y	N	Reduced	Resolved
Study Number=3475-010, Site Number=0205, AN=304062, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=1								
304062	Safety Follow-up	13	Haemoptysis	2 Days	Y	N	None	Resolved
		14	Atrial flutter	Continuing	Y	N	None	Not Resolved
		14	Dyspnoea	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0207, AN=311261, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=21								
311261	Safety Follow-up	46	Respiratory tract infection	1.22 Months	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0208, AN=308277, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=85								
308277	Safety Follow-up	97	Haemoptysis	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0209, AN=307769, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=110								
307769	Safety Follow-up	117	Back pain	2.71 Weeks	Y	N	None	Resolved
		117	Chest pain	2.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0209, AN=310671, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=22								
310671	Safety Follow-up	35	Death	23 Hours	Y	N	None	Fatal
Study Number=3475-010, Site Number=0209, AN=313318, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=279								
313318	Treatment Cycle 3	42	Gamma-glutamyltransferase increased	3.43 Weeks	Y	N	None	Resolved
	Treatment Cycle 13	271	Respiratory tract infection	1.43 Weeks	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0209, AN=313318, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=279								
313318	Safety Follow-up	283	Pneumonitis	3.71 Weeks	Y	Y	Discontinued	Resolved
		283	Pulmonary hypertension	3.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0209, AN=314106, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=133								
314106	Extended Safety Follow-up	211	Atrial thrombosis	2.86 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0211, AN=302459, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=								
302459	Treatment Cycle 8	175	Chronic obstructive pulmonary disease	5 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0211, AN=310073, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=21								
310073	Safety Follow-up	23	Muscle necrosis	3.14 Weeks	Y	Y	Discontinued	Resolved
Study Number=3475-010, Site Number=0282, AN=307169, Gender=M, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=331								
307169	Treatment Cycle 8	179	Colitis	2 Weeks	Y	Y	None	Resolved
	Treatment Cycle 11	273	Acute kidney injury	3 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0283, AN=303552, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
303552	Safety Follow-up	12	Fall	2 Days	Y	N	None	Resolved
		13	Confusional state	Continuing	Y	Y	None	Not Resolved
Study Number=3475-010, Site Number=0284, AN=307284, Gender=M, Race=Asian, Age=47 Years, Rel Day of Study Medication Discontinuance†=29								
307284	Treatment Cycle 1	11	Tumour pain	3.14 Weeks	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0284, AN=307284, Gender=M, Race=Asian, Age=47 Years, Rel Day of Study Medication Discontinuance†=29								
307284	Treatment Cycle 1	12	Pneumonitis	1.71 Weeks	Y	N	Interrupted	Resolved
	Safety Follow-up	41	Pneumonitis	3 Days	Y	Y	None	Fatal
Study Number=3475-010, Site Number=0284, AN=309628, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=40								
309628	Safety Follow-up	52	General physical health deterioration	6 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0324, AN=303296, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=323								
303296	Treatment Cycle 2	27	Anaemia	4.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0360, AN=309611, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=42								
309611	Safety Follow-up	56	Pneumonitis chemical	Continuing	Y	Y	N/A	Not Resolved
Study Number=3475-010, Site Number=0361, AN=300231, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=21								
300231	Safety Follow-up	30	Pulmonary embolism	2.57 Weeks	Y	N	None	Sequelae
Study Number=3475-010, Site Number=0401, AN=311762, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=								
311762	Treatment Cycle 3	60	Gastrointestinal infection	4 Days	Y	N	None	Resolved
		64	Staphylococcal infection	1.86 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0407, AN=305019, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=22								
305019	Treatment Cycle 1	7	Pain	3 Days	Y	N	None	Resolved
	Safety Follow-up	36	Pneumocystis jirovecii pneumonia	1.14 Weeks	Y	N	None	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0407, AN=306573, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=								
306573	Treatment Cycle 11	241	Blood creatinine increased	Continuing	Y	N	N/A	Not Resolved
		241	Hypothyroidism	Continuing	Y	Y	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0440, AN=310818, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=296								
310818	Treatment Cycle 13	270	Cardiac failure	1.02 Months	Y	N	None	Fatal
	Treatment Cycle 14	294	General physical health deterioration	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0441, AN=301317, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=43								
301317	Treatment Cycle 2	36	Upper limb fracture	2.29 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0443, AN=301653, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=								
301653	Treatment Cycle 23	480	Upper limb fracture	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0443, AN=310105, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=43								
310105	Safety Follow-up	51	Pneumonia	2.14 Weeks	Y	N	None	Fatal
Study Number=3475-010, Site Number=0444, AN=312030, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=22								
312030	Treatment Cycle 1	11	Lung infection	3.29 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0522, AN=302311, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=1								
302311	Safety Follow-up	4	Haemoptysis	5 Minutes	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0561, AN=311714, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=49								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0561, AN=311714, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=49								
311714	Treatment Cycle 1	16	Superior vena cava syndrome	4.14 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0562, AN=301548, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=1								
301548	Safety Follow-up	20	Tubulointerstitial nephritis	Continuing	Y	Y	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0563, AN=308798, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=								
308798	Treatment Cycle 1	20	C-reactive protein increased	2.6 Months	Y	N	Interrupted	Resolved
		20	Normochromic normocytic anaemia	3.29 Months	Y	N	Interrupted	Resolved
	Treatment Cycle 6	133	Chronic obstructive pulmonary disease	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0563, AN=313241, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=1								
313241	Safety Follow-up	15	General physical health deterioration	Continuing	Y	N	None	Not Resolved
		23	Femoral artery occlusion	2.14 Weeks	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0764, AN=305926, Gender=M, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=43								
305926	Safety Follow-up	45	Respiratory tract infection viral	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0764, AN=307665, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=43								
307665	Safety Follow-up	55	Atrial fibrillation	1.29 Weeks	Y	N	None	Resolved
		70	Atrial fibrillation	2 Weeks	Y	N	Discontinued	Resolved
Study Number=3475-010, Site Number=0805, AN=310425, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=296								
310425	Safety Follow-up	316	Acute coronary syndrome	25 Minutes	Y	N	Discontinued	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=0836, AN=305281, Gender=M, Race=Asian, Age=67 Years, Rel Day of Study Medication Discontinuance†=167								
305281	Safety Follow-up	189	Death	2.29 Weeks	Y	N	None	Fatal
Study Number=3475-010, Site Number=0926, AN=307528, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=407								
307528	Treatment Cycle 13	290	Pericardial effusion	6 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0964, AN=311245, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=104								
311245	Safety Follow-up	118	Pleural effusion	Continuing	Y	N	Discontinued	Resolving
Study Number=3475-010, Site Number=1000, AN=305693, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=150								
305693	Safety Follow-up	170	Pleural effusion	1.29 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1080, AN=304049, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=64								
304049	Treatment Cycle 1	13	Synovitis	4.29 Weeks	Y	Y	Interrupted	Resolved
		33	Faecaloma	5 Days	Y	N	None	Resolved
	Safety Follow-up	79	Colitis	3.29 Weeks	Y	Y	N/A	Resolved
		79	Constipation	3.29 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=1080, AN=305559, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=1								
305559	Safety Follow-up	5	Pneumonia	Continuing	Y	N	None	Not Resolved
		16	Pneumonitis	Continuing	Y	Y	Discontinued	Resolving
Study Number=3475-010, Site Number=1080, AN=312970, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=94								
312970	Treatment Cycle 4	86	Myopathy	Continuing	Y	Y	Interrupted	Resolving

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=1241, AN=301658, Gender=M, Race=Asian, Age=77 Years, Rel Day of Study Medication Discontinuance†=50								
301658	Safety Follow-up	60	Pneumonia aspiration	1.12 Months	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=1241, AN=306873, Gender=M, Race=Asian, Age=77 Years, Rel Day of Study Medication Discontinuance†=106								
306873	Safety Follow-up	122	Death	23 Hours	Y		N/A	Fatal
Study Number=3475-010, Site Number=1242, AN=304109, Gender=M, Race=Asian, Age=55 Years, Rel Day of Study Medication Discontinuance†=44								
304109	Treatment Cycle 1	12	Oedema peripheral	Continuing	Y	N	None	Resolving
		12	Pain	6 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=1243, AN=309997, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=								
309997	Treatment Cycle 2	23	Haemorrhage intracranial	1.71 Weeks	Y	N	None	Resolved
	Treatment Cycle 3	44	Embolism	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=1245, AN=301979, Gender=M, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=								
301979	Treatment Cycle 5	89	Dyspnoea	1.41 Years	Y	N	None	Resolved
	Treatment Cycle 12	249	Gastroenteritis	1.71 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 15	320	Drug hypersensitivity	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=1245, AN=308516, Gender=M, Race=Asian, Age=55 Years, Rel Day of Study Medication Discontinuance†=113								
308516	Treatment Cycle 1	10	Pneumonia	3.29 Weeks	Y	N	N/A	Resolved
		26	Rash maculo-papular	1.43 Weeks	Y	Y	Interrupted	Resolved
	Extended Safety Follow-up	200	Urinary retention	5 Days	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=1245, AN=308563, Gender=M, Race=Asian, Age=77 Years, Rel Day of Study Medication Discontinuance†=1								
308563	Safety Follow-up	4	Pneumonia	2.29 Weeks	Y	N	None	Resolved
		22	Lung neoplasm malignant	2.14 Weeks	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=1322, AN=306739, Gender=M, Race=Asian, Age=75 Years, Rel Day of Study Medication Discontinuance†=234								
306739	Safety Follow-up	242	Pneumonia	1.58 Months	Y	N	None	Resolved
Study Number=3475-010, Site Number=1366, AN=311976, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=21								
311976	Safety Follow-up	27	Pneumonia	1.41 Months	Y	N	None	Resolved
Study Number=3475-010, Site Number=1374, AN=304914, Gender=M, Race=Asian, Age=73 Years, Rel Day of Study Medication Discontinuance†=22								
304914	Safety Follow-up	31	Chronic obstructive pulmonary disease	1.14 Weeks	Y	Y	N/A	Resolved
		31	Pneumonia	1.57 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=1403, AN=301594, Gender=M, Race=Asian, Age=78 Years, Rel Day of Study Medication Discontinuance†=								
301594	Treatment Cycle 5	106	Hypopituitarism	Continuing	Y	Y	Reduced	Not Resolved
Study Number=3475-010, Site Number=1405, AN=304574, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=								
304574	Treatment Cycle 4	118	Colitis	Continuing	Y	Y	Interrupted	Resolving
Study Number=3475-010, Site Number=1417, AN=309855, Gender=M, Race=Asian, Age=64 Years, Rel Day of Study Medication Discontinuance†=110								
309855	Extended Safety Follow-up	149	Pancreatitis	1.81 Months	Y	N	N/A	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W								
Study Number=3475-010, Site Number=1422, AN=308873, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=								
308873	Treatment Cycle 1	10	Pneumonia	3.86 Weeks	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=1423, AN=301923, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=85								
301923	Extended Safety Follow-up	141	Gastric cancer	Continuing	Y	N	Discontinued	Not Resolved
Study Number=3475-010, Site Number=1434, AN=302434, Gender=M, Race=Asian, Age=69 Years, Rel Day of Study Medication Discontinuance†=								
302434	Treatment Cycle 1	3	Decreased appetite	3.57 Weeks	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=1438, AN=307840, Gender=M, Race=Asian, Age=50 Years, Rel Day of Study Medication Discontinuance†=								
307840	Treatment Cycle 2	40	Pleural effusion	Continuing	Y	Y	None	Not Resolved
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0002, AN=301310, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=1								
301310	Safety Follow-up	5	Fatigue	Continuing	Y	Y	Interrupted	Not Resolved
Study Number=3475-010, Site Number=0003, AN=300217, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=99								
300217	Treatment Cycle 1	13	Pneumonia	5 Days	Y	N	N/A	Resolved
	Treatment Cycle 2	38	Ischaemic stroke	2.14 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0003, AN=305802, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=36								
305802	Safety Follow-up	37	Mental status changes	4 Days	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0004, AN=305817, Gender=F, Race=Black Or African American, Age=63 Years, Rel Day of Study Medication Discontinuance†=								
305817	Treatment Cycle 7	142	Coronary artery disease	1.86 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0005, AN=303231, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=232								
303231	Treatment Cycle 2	46	Pneumonia	2.71 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0006, AN=306565, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=107								
306565	Treatment Cycle 3	57	Pneumonia	1.29 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0014, AN=302077, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=141								
302077	Safety Follow-up	160	Diabetic ketoacidosis	1 Weeks	Y	Y	N/A	Resolved
		160	Hypertriglyceridaemia	2 Days	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0015, AN=314201, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=148								
314201	Treatment Cycle 1	9	Atrial fibrillation	3 Days	Y	N	None	Resolved
		9	Pneumonia	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0017, AN=312527, Gender=M, Race=Asian, Age=76 Years, Rel Day of Study Medication Discontinuance†=1								
312527	Safety Follow-up	2	Pyrexia	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0024, AN=302763, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=1								
302763	Safety Follow-up	14	Cardiac arrest	1 Seconds	Y	N	None	Fatal
Study Number=3475-010, Site Number=0028, AN=303736, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=25								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0028, AN=303736, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=25								
303736	Treatment Cycle 1	6	Back pain	Continuing	Y	N	None	Resolving
		6	Chest pain	2.27 Months	Y	N	N/A	Resolved
		6	Hypoxia	3 Days	Y	N	None	Resolved
		6	Pain	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0033, AN=311270, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=50								
311270	Treatment Cycle 1	3	Pneumonia	6 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0037, AN=305210, Gender=F, Race=Black Or African American, Age=60 Years, Rel Day of Study Medication Discontinuance†=								
305210	Treatment Cycle 6	126	Chronic obstructive pulmonary disease	3.43 Weeks	Y	N	None	Resolved
	Treatment Cycle 7	147	Palpitations	3 Days	Y	N	Interrupted	Resolved
	Treatment Cycle 11	229	Chronic obstructive pulmonary disease	4 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0037, AN=309567, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=1								
309567	Safety Follow-up	10	Asthenia	Continuing	Y	Y	N/A	Resolving
		22	Malignant neoplasm progression	Continuing	Y	Y	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0045, AN=300012, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=45								
300012	Safety Follow-up	64	Atrial flutter	3.14 Weeks	Y	N	None	Resolved
		64	Pneumonitis	2.29 Weeks	Y	Y	Discontinued	Resolved
		66	Acute kidney injury	2 Weeks	Y	N	None	Resolved
		66	Acute respiratory failure	5 Days	Y	N	None	Resolved
		66	Pulmonary oedema	Continuing	Y	N	None	Not Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0046, AN=305415, Gender=M, Race=Black Or African American, Age=20 Years, Rel Day of Study Medication Discontinuance†=302								
305415	Safety Follow-up	307	Pneumonia aspiration	1.43 Weeks	Y	N	N/A	Resolved
		317	Pneumonia	1.43 Weeks	Y	Y	N/A	Resolved
	Extended Safety Follow-up	359	Hypercalcaemia	2.43 Weeks	Y	N	N/A	Resolved
		362	Pneumonia	2 Weeks	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0046, AN=310887, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=1								
310887	Safety Follow-up	19	Cerebrovascular accident	5 Days	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0047, AN=310066, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=62								
310066	Treatment Cycle 2	20	Spinal compression fracture	3.14 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0048, AN=301360, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=50								
301360	Extended Safety Follow-up	89	Cardiopulmonary failure	23 Hours	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0050, AN=309308, Gender=F, Race=Black Or African American, Age=77 Years, Rel Day of Study Medication Discontinuance†=								
309308	Treatment Cycle 1	2	Anaemia	Continuing	Y	Y	None	Not Resolved
		2	Pyrexia	6 Hours	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0055, AN=300953, Gender=M, Race=, Age=37 Years, Rel Day of Study Medication Discontinuance†=91								
300953	Safety Follow-up	98	Myelitis transverse	Continuing	Y	Y	Discontinued	Resolving

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0055, AN=311446, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=								
311446	Treatment Cycle 3	44	Hyperthyroidism	2 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0055, AN=312063, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=315								
312063	Safety Follow-up	331	Post procedural urine leak	1.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0057, AN=309753, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=64								
309753	Safety Follow-up	67	Pneumonia	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0058, AN=305706, Gender=M, Race=Black Or African American, Age=76 Years, Rel Day of Study Medication Discontinuance†=								
305706	Treatment Cycle 7	143	Haemoptysis	1.71 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0063, AN=308627, Gender=F, Race=, Age=59 Years, Rel Day of Study Medication Discontinuance†=85								
308627	Safety Follow-up	88 88	Cardiac tamponade Pericardial effusion	1 Minutes 4 Hours	Y Y	N N	N/A N/A	Fatal Resolved
Study Number=3475-010, Site Number=0063, AN=313118, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=302								
313118	Treatment Cycle 8	189	Thrombosis	4 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0063, AN=313714, Gender=M, Race=White, Age=84 Years, Rel Day of Study Medication Discontinuance†=211								
313714	Treatment Cycle 2	45	Pneumonitis	Continuing	Y	Y	Reduced	Resolving
Study Number=3475-010, Site Number=0081, AN=301391, Gender=M, Race=Multiple, Age=62 Years, Rel Day of Study Medication Discontinuance†=43								
301391	Safety Follow-up	52	Spinal cord compression	3.75 Months	Y	N	Discontinued	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0081, AN=305369, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=130								
305369	Safety Follow-up	136 140	Gastrooesophageal reflux disease Gastritis	1.71 Weeks 7.49 Months	Y Y	Y Y	N/A Discontinued	Resolved Sequelae
Study Number=3475-010, Site Number=0081, AN=305939, Gender=M, Race=Asian, Age=57 Years, Rel Day of Study Medication Discontinuance†=471								
305939	Treatment Cycle 3	60	Hepatocellular injury	1.54 Months	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0081, AN=307798, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=43								
307798	Extended Safety Follow-up	74	Respiratory distress	3.14 Weeks	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=0082, AN=304831, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=170								
304831	Treatment Cycle 6	106	Pyopneumothorax	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0082, AN=308795, Gender=M, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=62								
308795	Safety Follow-up	88	Influenza	1.86 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0084, AN=312799, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=227								
312799	Treatment Cycle 1 Treatment Cycle 6	23 124	Eosinophilia Pneumonia	Continuing 1.86 Weeks	Y Y	Y N	None Interrupted	Not Resolved Resolved
Study Number=3475-010, Site Number=0085, AN=302387, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=43								
302387	Extended Safety Follow-up	80	Pneumonia	2.46 Months	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0085, AN=312745, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=113								
312745	Safety Follow-up	123	Pulmonary embolism	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0088, AN=311348, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=190								
311348	Treatment Cycle 5	88	Erectile dysfunction	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0092, AN=307409, Gender=M, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=22								
307409	Safety Follow-up	40	Hyperthyroidism	3.86 Weeks	Y	Y	N/A	Resolved
Study Number=3475-010, Site Number=0094, AN=300608, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=23								
300608	Safety Follow-up	43	Hyponatraemia	Continuing	Y	Y	Discontinued	Not Resolved
		50	Myocardial infarction	10 Minutes	Y	Y	N/A	Fatal
Study Number=3475-010, Site Number=0095, AN=313597, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=55								
313597	Treatment Cycle 1	28	Hypercalcaemia	1 Weeks	Y	N	None	Resolved
	Treatment Cycle 2	48	Hypercalcaemia	3.38 Months	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0096, AN=309695, Gender=M, Race=, Age=38 Years, Rel Day of Study Medication Discontinuance†=43								
309695	Treatment Cycle 2	26	Delirium	5 Days	Y	N	None	Resolved
	Safety Follow-up	57	Metastatic pain	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0096, AN=313979, Gender=M, Race=, Age=60 Years, Rel Day of Study Medication Discontinuance†=65								
313979	Treatment Cycle 1	3	Tumour associated fever	1.43 Weeks	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0122, AN=304572, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=								
304572	Treatment Cycle 7	135	Inguinal hernia	6 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0122, AN=310300, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=248								
310300	Treatment Cycle 3	64	Infectious pleural effusion	3.94 Months	Y	N	Interrupted	Sequelae
	Treatment Cycle 6	130	Tracheo-oesophageal fistula	4.99 Months	Y	N	None	Resolved
	Treatment Cycle 8	182	Device dislocation	2 Days	Y	N	None	Resolved
	Treatment Cycle 12	248	Device dislocation	3 Days	Y	N	None	Resolved
	Extended Safety Follow-up	281	General physical health deterioration	Continuing	Y	N	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0136, AN=305862, Gender=M, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†=237								
305862	Treatment Cycle 3	54	Pulmonary embolism	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0136, AN=308375, Gender=F, Race=White, Age=39 Years, Rel Day of Study Medication Discontinuance†=43								
308375	Treatment Cycle 3	43	Pneumonia	1 Weeks	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0136, AN=310655, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
310655	Safety Follow-up	2	Tachycardia	2 Weeks	Y	N	None	Resolved
		6	Pneumonia	1.43 Weeks	Y	N	None	Sequelae
Study Number=3475-010, Site Number=0138, AN=305038, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=106								
305038	Treatment Cycle 4	70	Anaemia	1.74 Months	Y	N	None	Resolved
	Safety Follow-up	121	Autoimmune hepatitis	Continuing	Y	Y	N/A	Resolving

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0138, AN=308814, Gender=M, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=								
308814	Treatment Cycle 1	3	Device related infection	1.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0181, AN=300961, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=1								
300961	Safety Follow-up	13	Lower respiratory tract infection	2.29 Weeks	Y	N	N/A	Resolved
	Extended Safety Follow-up	55	Pneumonia	1.86 Weeks	Y	Y	N/A	Fatal
Study Number=3475-010, Site Number=0181, AN=307020, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=105								
307020	Treatment Cycle 4	89	Dysphagia	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0181, AN=313988, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=								
313988	Treatment Cycle 3	61	Pyloric stenosis	3.29 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 5	113	Peripheral sensory neuropathy	2.71 Weeks	Y	N	None	Resolved
	Treatment Cycle 6	137	Hypothyroidism	Continuing	Y	Y	None	Not Resolved
Study Number=3475-010, Site Number=0182, AN=311519, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=182								
311519	Safety Follow-up	193	Incisional hernia, obstructive	1.86 Weeks	Y	N	None	Resolved
	Extended Safety Follow-up	222	Wound sepsis	6 Days	Y	N	N/A	Resolved
		253	Wound sepsis	1 Weeks	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0183, AN=301027, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=								
301027	Treatment Cycle 11	239	Bradycardia	1 Weeks	Y	N	Interrupted	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0183, AN=301027, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=								
301027	Treatment Cycle 11	239	Hypotension	1 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0183, AN=306910, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=190								
306910	Safety Follow-up	202	Dysphagia	2.43 Weeks	Y	N	None	Sequelae
		219	Dysphagia	1.71 Weeks	Y	N	None	Resolved
	Extended Safety Follow-up	255	Pulmonary embolism	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0183, AN=307906, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=225								
307906	Treatment Cycle 6	208	Pulmonary embolism	5 Days	Y	N	Interrupted	Resolved
	Safety Follow-up	226	Dizziness	1 Weeks	Y	N	None	Resolved
		226	Dyspnoea	1 Weeks	Y	N	None	Resolved
		255	Fall	2 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0183, AN=311755, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=323								
311755	Treatment Cycle 8	160	Pneumonia	1.29 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0184, AN=307958, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=155								
307958	Treatment Cycle 7	138	Dehydration	1.29 Weeks	Y	N	None	Resolved
		140	Hypokalaemia	3 Days	Y	N	None	Resolved
		144	Hypomagnesaemia	1.02 Months	Y	N	None	Resolved
		145	Hypokalaemia	23 Hours	Y	N	None	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0200, AN=300253, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
300253	Safety Follow-up	4	Pneumonia	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0200, AN=308329, Gender=M, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=469								
308329	Treatment Cycle 2	24	Syncope	20 Hours	Y	N	None	Resolved
	Safety Follow-up	479	Pneumonia	1.29 Weeks	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0200, AN=309392, Gender=M, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=302								
309392	Treatment Cycle 2	31	Hypercalcaemia	1.86 Weeks	Y	N	None	Resolved
		60	Hypercalcaemia	3.84 Months	Y	N	None	Resolved
	Treatment Cycle 3	81	Seroma	1.54 Months	Y	N	None	Resolved
	Treatment Cycle 7	169	Renal failure	1.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0201, AN=302829, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=42								
302829	Safety Follow-up	50	Bone pain	Continuing	Y	N	None	Not Resolved
		67	Pneumonia aspiration	23 Hours	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0201, AN=305454, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=238								
305454	Treatment Cycle 9	188	Acute kidney injury	Continuing	Y	N	Interrupted	Resolving
		199	Constipation	3.71 Weeks	Y	N	N/A	Resolved
	Complete Response Follow-up	265	Febrile neutropenia	4 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0201, AN=306439, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0201, AN=306439, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43								
306439	Safety Follow-up	46	Back pain	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=0201, AN=313931, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=22								
313931	Safety Follow-up	31	Neck pain	1.86 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0202, AN=301495, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=551								
301495	Treatment Cycle 18	372	Pneumonia	1.71 Weeks	Y	N	None	Resolved
	Treatment Cycle 23	491	Pain in extremity	4 Days	Y	N	None	Resolved
	Treatment Cycle 24	523	Cardiac failure	3 Days	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=0204, AN=307524, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=204								
307524	Safety Follow-up	209	Pneumonitis chemical	4 Weeks	Y	Y	Discontinued	Sequelae
Study Number=3475-010, Site Number=0206, AN=301738, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=								
301738	Treatment Cycle 14	296	Urinary bladder polyp	1 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 20	418	Syncope	2 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0207, AN=310100, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1								
310100	Safety Follow-up	17	Respiratory tract infection	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0208, AN=302999, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=22								
302999	Safety Follow-up	38	Disorientation	3.14 Weeks	Y	Y	Discontinued	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0209, AN=305467, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=1								
305467	Safety Follow-up	2	Aspiration bronchial	2 Days	Y	N	None	Fatal
Study Number=3475-010, Site Number=0209, AN=308247, Gender=F, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†=22								
308247	Safety Follow-up	42	Anaemia	2.43 Weeks	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0209, AN=309351, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=22								
309351	Treatment Cycle 1	8	Spinal column stenosis	2.14 Weeks	Y	N	None	Resolved
	Extended Safety Follow-up	71	Death	23 Hours	Y	N	None	Fatal
Study Number=3475-010, Site Number=0209, AN=310208, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=68								
310208	Treatment Cycle 1	10	Respiratory tract infection	1.05 Months	Y	N	Interrupted	Resolved
		55	Pyrexia	1.38 Months	Y	N	None	Resolved
Study Number=3475-010, Site Number=0211, AN=308531, Gender=M, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=								
308531	Treatment Cycle 1	16	Pericardial effusion	1.29 Weeks	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=0211, AN=313739, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=1								
313739	Safety Follow-up	8	Neurological decompensation	Continuing	Y	N	N/A	Not Resolved
Study Number=3475-010, Site Number=0283, AN=314399, Gender=M, Race=White, Age=36 Years, Rel Day of Study Medication Discontinuance†=22								
314399	Safety Follow-up	29	Pulmonary embolism	1 Weeks	Y	N	None	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0322, AN=306291, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=41								
306291	Treatment Cycle 1	6	Respiratory tract infection	3 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0324, AN=300779, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=109								
300779	Safety Follow-up	120	Metastases to central nervous system	2.43 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0360, AN=312585, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=63								
312585	Treatment Cycle 2	39	Pleural effusion	2 Days	Y	N	None	Resolved
	Treatment Cycle 4	63	Pleural effusion	Continuing	Y	N	None	Not Resolved
	Safety Follow-up	71	Hypoalbuminaemia	Continuing	Y	N	None	Not Resolved
		86	Pulmonary oedema	3 Days	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0360, AN=313958, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=1								
313958	Safety Follow-up	8	Pneumonitis	Continuing	Y	Y	Discontinued	Resolving
	Extended Safety Follow-up	86	Spinal cord compression	2.14 Weeks	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=0361, AN=310171, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=169								
310171	Treatment Cycle 2	30	Painful respiration	3 Days	Y	N	None	Resolved
	Treatment Cycle 3	43	Accidental overdose	1 Hours	Y	N	None	Resolved
	Treatment Cycle 4	64	Accidental overdose	1 Hours	Y	N	None	Resolved
	Treatment Cycle 5	85	Accidental overdose	1 Hours	Y	N	None	Resolved
Study Number=3475-010, Site Number=0452, AN=309774, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=170								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0452, AN=309774, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=170								
309774	Treatment Cycle 8	169	Microcytic anaemia	1.22 Months	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0452, AN=311424, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=191								
311424	Treatment Cycle 3	52	Dehydration	1.43 Weeks	Y	N	None	Resolved
	Treatment Cycle 4	75	Cancer pain	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0560, AN=307270, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=								
307270	Treatment Cycle 19	436	Hypophosphataemia	Continuing	Y	Y	None	Not Resolved
Study Number=3475-010, Site Number=0560, AN=309087, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=359								
309087	Treatment Cycle 16	319	Pneumonitis	1.35 Months	Y	Y	Interrupted	Resolved
Study Number=3475-010, Site Number=0560, AN=309906, Gender=F, Race=White, Age=40 Years, Rel Day of Study Medication Discontinuance†=67								
309906	Treatment Cycle 1	10	Pneumonia haemophilus	2.29 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=0560, AN=310393, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=64								
310393	Safety Follow-up	85	Hypercalcaemia	2.14 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=0561, AN=300941, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=45								
300941	Safety Follow-up	64	Pneumonitis	Continuing	Y	Y	Discontinued	Not Resolved
Study Number=3475-010, Site Number=0561, AN=303230, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=								
303230	Treatment Cycle 16	319	Pulmonary vascular disorder	3 Weeks	Y	N	Interrupted	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0561, AN=303230, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=								
303230	Treatment Cycle 26	541	Basal cell carcinoma	Continuing	Y	N	None	Not Resolved
Study Number=3475-010, Site Number=0561, AN=306075, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=64								
306075	Extended Safety Follow-up	120	Pneumonitis	1.29 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=0561, AN=313427, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=365								
313427	Safety Follow-up	386	Arrhythmia	2 Days	Y	N	None	Resolved
	Extended Safety Follow-up	437	Hyponatraemia	1.29 Weeks	Y	Y	N/A	Resolved
Study Number=3475-010, Site Number=0563, AN=303832, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=43								
303832	Treatment Cycle 1	20	Pulmonary embolism	3 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0563, AN=310319, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=50								
310319	Treatment Cycle 1	8	Urosepsis	1.57 Weeks	Y	N	Interrupted	Resolved
	Treatment Cycle 2	35	Osteoporosis	Continuing	Y	N	None	Not Resolved
		35	Osteoporotic fracture	6 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=0563, AN=312499, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=281								
312499	Treatment Cycle 7	154	Pleural effusion	1 Weeks	Y	N	Interrupted	Resolved
	Safety Follow-up	287	Pneumonia	12.17 Hours	Y	N	Discontinued	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=0602, AN=304067, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=20								
304067	Safety Follow-up	32	Death	1 Days	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=0920, AN=308160, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=120								
308160	Safety Follow-up	133	Pneumonitis	2 Days	Y	Y	Discontinued	Fatal
Study Number=3475-010, Site Number=0964, AN=307384, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=1								
307384	Safety Follow-up	3	Endocarditis	Continuing	Y	N	N/A	Not Resolved
		3	Ischaemic stroke	Continuing	Y	N	N/A	Not Resolved
		3	Pleural effusion	Continuing	Y	N	N/A	Not Resolved
		3	Respiratory failure	3.14 Weeks	Y	N	N/A	Fatal
Study Number=3475-010, Site Number=0964, AN=309164, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=25								
309164	Safety Follow-up	41	Pulmonary embolism	Continuing	Y	N	None	Not Resolved
	Extended Safety Follow-up	75	Hepatic failure	23 Hours	Y	N	None	Fatal
Study Number=3475-010, Site Number=0968, AN=300014, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=								
300014	Treatment Cycle 8	168	Deep vein thrombosis	Continuing	Y	N	None	Resolving
Study Number=3475-010, Site Number=1003, AN=310688, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=47								
310688	Safety Follow-up	56	Pneumonitis	1.29 Weeks	Y	Y	Discontinued	Resolved
Study Number=3475-010, Site Number=1080, AN=312055, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=106								

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=1080, AN=312055, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=106								
312055	Treatment Cycle 2	34	Abdominal pain	Continuing	Y	N	Interrupted	Not Resolved
		57	Hypercalcaemia	1.58 Months	Y	N	Interrupted	Resolved
	Treatment Cycle 3	85	Arthralgia	Continuing	Y	Y	None	Not Resolved
Study Number=3475-010, Site Number=1081, AN=308580, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=43								
308580	Treatment Cycle 2	34	Urinary tract infection	1.43 Weeks	Y	N	None	Resolved
	Safety Follow-up	53	Pneumonia	3.14 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1084, AN=301742, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=1								
301742	Safety Follow-up	2	Dysphagia	3 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1240, AN=303343, Gender=M, Race=Asian, Age=67 Years, Rel Day of Study Medication Discontinuance†=82								
303343	Treatment Cycle 1	8	Pleural effusion	1.71 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1242, AN=314137, Gender=F, Race=Asian, Age=63 Years, Rel Day of Study Medication Discontinuance†=64								
314137	Safety Follow-up	81	Embolism	1.25 Months	Y	N	Discontinued	Fatal
Study Number=3475-010, Site Number=1243, AN=302791, Gender=M, Race=Asian, Age=73 Years, Rel Day of Study Medication Discontinuance†=								
302791	Treatment Cycle 22	454	Large intestinal obstruction	1.29 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=1243, AN=313804, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=220								
313804	Safety Follow-up	228	Pulmonary haemorrhage	23 Hours	Y	N	Discontinued	Fatal

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=1243, AN=314100, Gender=M, Race=Asian, Age=66 Years, Rel Day of Study Medication Discontinuance†=								
314100	Treatment Cycle 4	86	Radiation pneumonitis	1.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=1244, AN=305539, Gender=M, Race=Asian, Age=73 Years, Rel Day of Study Medication Discontinuance†=								
305539	Treatment Cycle 16	332	Contusion	1.57 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1245, AN=306495, Gender=M, Race=Asian, Age=50 Years, Rel Day of Study Medication Discontinuance†=43								
306495	Treatment Cycle 1	13	Pyelonephritis acute	1.43 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1245, AN=309919, Gender=M, Race=Asian, Age=59 Years, Rel Day of Study Medication Discontinuance†=106								
309919	Treatment Cycle 5	89	Oesophageal obstruction	1.86 Weeks	Y	N	None	Resolved
Study Number=3475-010, Site Number=1245, AN=310534, Gender=M, Race=Asian, Age=67 Years, Rel Day of Study Medication Discontinuance†=								
310534	Treatment Cycle 7 Treatment Cycle 8	127 156	Type 1 diabetes mellitus Cellulitis	Continuing 2.57 Weeks	Y Y	Y N	Interrupted None	Not Resolved Resolved
Study Number=3475-010, Site Number=1320, AN=309190, Gender=M, Race=Asian, Age=55 Years, Rel Day of Study Medication Discontinuance†=66								
309190	Treatment Cycle 1	19	Pneumonia	2.2 Months	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=1322, AN=311967, Gender=M, Race=Asian, Age=72 Years, Rel Day of Study Medication Discontinuance†=20								
311967	Safety Follow-up	39	Death	23 Hours	Y	N	None	Fatal
Study Number=3475-010, Site Number=1400, AN=302342, Gender=M, Race=Asian, Age=54 Years, Rel Day of Study Medication Discontinuance†=								
302342	Treatment Cycle 1	6	Pneumonia pneumococcal	3.29 Weeks	Y	N	Interrupted	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=1400, AN=302342, Gender=M, Race=Asian, Age=54 Years, Rel Day of Study Medication Discontinuance†=								
302342	Treatment Cycle 1	14	Anaemia	2.14 Weeks	Y	N	Interrupted	Resolved
Study Number=3475-010, Site Number=1400, AN=308317, Gender=M, Race=Asian, Age=73 Years, Rel Day of Study Medication Discontinuance†=53								
308317	Treatment Cycle 1	5	Pneumonia bacterial	1.86 Weeks	Y	N	None	Resolved
		9	Cerebral ischaemia	2.57 Weeks	Y	N	Interrupted	Resolved
	Extended Safety Follow-up	97	Ileus	3 Weeks	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=1401, AN=301977, Gender=M, Race=Asian, Age=63 Years, Rel Day of Study Medication Discontinuance†=137								
301977	Treatment Cycle 7	137	Diabetes mellitus	1.71 Weeks	Y	Y	None	Resolved
Study Number=3475-010, Site Number=1401, AN=311426, Gender=F, Race=Asian, Age=74 Years, Rel Day of Study Medication Discontinuance†=1								
311426	Extended Safety Follow-up	50	Pneumonitis	1.87 Months	Y	N	N/A	Sequelae
Study Number=3475-010, Site Number=1405, AN=312141, Gender=M, Race=Asian, Age=74 Years, Rel Day of Study Medication Discontinuance†=40								
312141	Safety Follow-up	57	Pneumonia	2.57 Weeks	Y	N	None	Fatal
Study Number=3475-010, Site Number=1410, AN=307796, Gender=M, Race=Asian, Age=69 Years, Rel Day of Study Medication Discontinuance†=								
307796	Treatment Cycle 4	102	Interstitial lung disease	Continuing	Y	Y	Interrupted	Not Resolved
Study Number=3475-010, Site Number=1410, AN=308147, Gender=M, Race=Asian, Age=78 Years, Rel Day of Study Medication Discontinuance†=22								
308147	Safety Follow-up	39	Atrioventricular block complete	Continuing	Y	Y	Discontinued	Not Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=1411, AN=303388, Gender=F, Race=Asian, Age=45 Years, Rel Day of Study Medication Discontinuance†=24								
303388	Treatment Cycle 1	3	Osteomyelitis	5 Days	Y	N	None	Resolved
Study Number=3475-010, Site Number=1412, AN=306857, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=149								
306857	Extended Safety Follow-up	183	Pulmonary haemorrhage	6 Days	Y	N	N/A	Resolved
Study Number=3475-010, Site Number=1421, AN=311479, Gender=M, Race=Asian, Age=49 Years, Rel Day of Study Medication Discontinuance†=								
311479	Treatment Cycle 11	278	Hypopituitarism	Continuing	Y	Y	Interrupted	Not Resolved
Study Number=3475-010, Site Number=1422, AN=313656, Gender=M, Race=Asian, Age=42 Years, Rel Day of Study Medication Discontinuance†=148								
313656	Treatment Cycle 1	15	Pneumonia	Continuing	Y	Y	Interrupted	Resolving
Study Number=3475-010, Site Number=1424, AN=301369, Gender=F, Race=Asian, Age=74 Years, Rel Day of Study Medication Discontinuance†=								
301369	Treatment Cycle 16	323	Adrenal insufficiency	Continuing	Y	Y	Interrupted	Not Resolved
Study Number=3475-010, Site Number=1430, AN=304201, Gender=F, Race=Asian, Age=54 Years, Rel Day of Study Medication Discontinuance†=29								
304201	Safety Follow-up Extended Safety Follow-up	36 80	Drug eruption Completed suicide	Continuing 23 Hours	Y Y	Y N	Interrupted N/A	Resolving Fatal
Study Number=3475-010, Site Number=1434, AN=314187, Gender=M, Race=Asian, Age=60 Years, Rel Day of Study Medication Discontinuance†=70								
314187	Safety Follow-up	75	Peripheral ischaemia	2.63 Months	Y	Y	Discontinued	Resolved

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Listing of Subjects With Serious Adverse Events Up to 90 Days of Last Dose
APaT Population (TPS ≥1%)

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W								
Study Number=3475-010, Site Number=1435, AN=308529, Gender=F, Race=Asian, Age=76 Years, Rel Day of Study Medication Discontinuance†=128								
308529	Treatment Cycle 4	67	Dyspnoea	Continuing	Y	Y	None	Not 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' ,'Neoplasm Progression' and 'Disease Progression' not related to the drug are excluded.
After the end of treatment, each subject will be followed for a minimum of 30 days for adverse event monitoring. SAE is monitored until 90 days after last dose.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 42　　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）
010 試験（MK-3475 併合、安全性解析対象集団）（PD-L1 発現陽性）

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Subjects in population	309		682	
with one or more adverse events	42	(13.6)	71	(10.4)
with no adverse events	267	(86.4)	611	(89.6)
Blood and lymphatic system disorders	**15**	**(4.9)**	**3**	**(0.4)**
Anaemia	0	(0.0)	1	(0.1)
Bone marrow failure	1	(0.3)	0	(0.0)
Eosinophilia	0	(0.0)	1	(0.1)
Febrile neutropenia	10	(3.2)	0	(0.0)
Leukopenia	1	(0.3)	0	(0.0)
Microcytic anaemia	0	(0.0)	1	(0.1)
Neutropenia	4	(1.3)	0	(0.0)
Cardiac disorders	**2**	**(0.6)**	**3**	**(0.4)**
Arteriosclerosis coronary artery	1	(0.3)	0	(0.0)
Atrial fibrillation	1	(0.3)	0	(0.0)
Atrioventricular block complete	0	(0.0)	1	(0.1)
Cardiac failure acute	1	(0.3)	0	(0.0)
Myocardial infarction	0	(0.0)	1	(0.1)
Pericardial effusion	0	(0.0)	1	(0.1)
Endocrine disorders	**0**	**(0.0)**	**7**	**(1.0)**
Adrenal insufficiency	0	(0.0)	1	(0.1)
Hyperthyroidism	0	(0.0)	2	(0.3)
Hypopituitarism	0	(0.0)	2	(0.3)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Endocrine disorders	**0**	**(0.0)**	**7**	**(1.0)**
Hypothyroidism	0	(0.0)	2	(0.3)
Gastrointestinal disorders	**4**	**(1.3)**	**5**	**(0.7)**
Colitis	0	(0.0)	3	(0.4)
Colitis ischaemic	1	(0.3)	0	(0.0)
Diarrhoea	2	(0.6)	0	(0.0)
Gastritis	0	(0.0)	1	(0.1)
Gastrooesophageal reflux disease	0	(0.0)	1	(0.1)
Pancreatitis	0	(0.0)	1	(0.1)
Vomiting	1	(0.3)	0	(0.0)
General disorders and administration site conditions	**4**	**(1.3)**	**4**	**(0.6)**
Asthenia	0	(0.0)	1	(0.1)
Fatigue	0	(0.0)	2	(0.3)
General physical health deterioration	1	(0.3)	0	(0.0)
Mucosal inflammation	1	(0.3)	0	(0.0)
Oedema	1	(0.3)	0	(0.0)
Pyrexia	1	(0.3)	1	(0.1)
Hepatobiliary disorders	**0**	**(0.0)**	**2**	**(0.3)**
Autoimmune hepatitis	0	(0.0)	2	(0.3)
Infections and infestations	**12**	**(3.9)**	**6**	**(0.9)**
Laryngitis	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Infections and infestations	**12**	**(3.9)**	**6**	**(0.9)**
Lung infection	1	(0.3)	0	(0.0)
Mucosal infection	1	(0.3)	0	(0.0)
Phlebitis infective	1	(0.3)	0	(0.0)
Pneumonia	4	(1.3)	6	(0.9)
Pneumonia bacterial	1	(0.3)	0	(0.0)
Respiratory tract infection	1	(0.3)	0	(0.0)
Sepsis	1	(0.3)	0	(0.0)
Septic shock	1	(0.3)	0	(0.0)
Upper respiratory tract infection	3	(1.0)	0	(0.0)
Injury, poisoning and procedural complications	**1**	**(0.3)**	**2**	**(0.3)**
Femur fracture	1	(0.3)	0	(0.0)
Pneumonitis chemical	0	(0.0)	2	(0.3)
Investigations	**1**	**(0.3)**	**1**	**(0.1)**
Alanine aminotransferase increased	0	(0.0)	1	(0.1)
Aspartate aminotransferase increased	0	(0.0)	1	(0.1)
Neutrophil count decreased	1	(0.3)	0	(0.0)
Metabolism and nutrition disorders	**4**	**(1.3)**	**8**	**(1.2)**
Decreased appetite	1	(0.3)	1	(0.1)
Dehydration	3	(1.0)	0	(0.0)
Diabetes mellitus	0	(0.0)	1	(0.1)
Diabetic ketoacidosis	0	(0.0)	1	(0.1)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Metabolism and nutrition disorders	**4**	**(1.3)**	**8**	**(1.2)**
Hypertriglyceridaemia	0	(0.0)	1	(0.1)
Hyponatraemia	0	(0.0)	2	(0.3)
Hypophosphataemia	0	(0.0)	1	(0.1)
Type 1 diabetes mellitus	0	(0.0)	2	(0.3)
Musculoskeletal and connective tissue disorders	**0**	**(0.0)**	**5**	**(0.7)**
Arthralgia	0	(0.0)	1	(0.1)
Arthritis	0	(0.0)	1	(0.1)
Muscle necrosis	0	(0.0)	1	(0.1)
Myopathy	0	(0.0)	1	(0.1)
Synovitis	0	(0.0)	1	(0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**1**	**(0.1)**
Malignant neoplasm progression	0	(0.0)	1	(0.1)
Nervous system disorders	**1**	**(0.3)**	**3**	**(0.4)**
Cerebrovascular accident	0	(0.0)	1	(0.1)
Cognitive disorder	1	(0.3)	0	(0.0)
Myelitis transverse	0	(0.0)	1	(0.1)
Toxic leukoencephalopathy	0	(0.0)	1	(0.1)
Psychiatric disorders	**0**	**(0.0)**	**2**	**(0.3)**
Confusional state	0	(0.0)	1	(0.1)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Psychiatric disorders	**0**	**(0.0)**	**2**	**(0.3)**
Disorientation	0	(0.0)	1	(0.1)
Renal and urinary disorders	**1**	**(0.3)**	**1**	**(0.1)**
Acute kidney injury	1	(0.3)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	1	(0.1)
Respiratory, thoracic and mediastinal disorders	**8**	**(2.6)**	**21**	**(3.1)**
Chronic obstructive pulmonary disease	0	(0.0)	1	(0.1)
Dyspnoea	3	(1.0)	2	(0.3)
Interstitial lung disease	1	(0.3)	1	(0.1)
Pleural effusion	2	(0.6)	2	(0.3)
Pneumonia aspiration	1	(0.3)	0	(0.0)
Pneumonitis	2	(0.6)	15	(2.2)
Pulmonary embolism	0	(0.0)	1	(0.1)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**2**	**(0.3)**
Drug eruption	0	(0.0)	1	(0.1)
Rash maculo-papular	0	(0.0)	1	(0.1)
Vascular disorders	**1**	**(0.3)**	**1**	**(0.1)**
Hypotension	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Serious Adverse Events Up to 90 Days After Last Dose (Incidence > 0% in One or More Treatment Groups)
MK-3475 Treatment Groups Pooled
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W		MK-3475 Pooled	
	n	(%)	n	(%)
Vascular disorders	**1**	**(0.3)**	**1**	**(0.1)**
Peripheral ischaemia	0	(0.0)	1	(0.1)

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.
SAE is monitored until 90 days after last dose.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 43　　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＋002 試験＋006 試験＋010 試験
MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	682		1,232		1,567		2,799	
with one or more adverse events	246	(36.1)	474	(38.5)	567	(36.2)	1,041	(37.2)
with no adverse events	436	(63.9)	758	(61.5)	1,000	(63.8)	1,758	(62.8)
Blood and lymphatic system disorders	**12**	**(1.8)**	**16**	**(1.3)**	**36**	**(2.3)**	**52**	**(1.9)**
Anaemia	6	(0.9)	7	(0.6)	24	(1.5)	31	(1.1)
Autoimmune haemolytic anaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Disseminated intravascular coagulation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eosinophilia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Febrile neutropenia	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Iron deficiency anaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Leukocytosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymph node pain	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Lymphadenopathy	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Microcytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neutropenia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Normochromic normocytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pancytopenia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Splenic infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thrombocytopenia	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Cardiac disorders	**28**	**(4.1)**	**54**	**(4.4)**	**36**	**(2.3)**	**90**	**(3.2)**
Acute coronary syndrome	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Acute myocardial infarction	1	(0.1)	4	(0.3)	3	(0.2)	7	(0.3)
Angina pectoris	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Angina unstable	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Arrhythmia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Atrial fibrillation	3	(0.4)	5	(0.4)	8	(0.5)	13	(0.5)
Atrial flutter	2	(0.3)	4	(0.3)	1	(0.1)	5	(0.2)
Atrial thrombosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**28**	**(4.1)**	**54**	**(4.4)**	**36**	**(2.3)**	**90**	**(3.2)**
Atrioventricular block complete	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Bradycardia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cardiac arrest	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac failure	2	(0.3)	2	(0.2)	5	(0.3)	7	(0.3)
Cardiac failure congestive	0	(0.0)	3	(0.2)	6	(0.4)	9	(0.3)
Cardiac tamponade	1	(0.1)	6	(0.5)	0	(0.0)	6	(0.2)
Cardiac ventricular disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cardio-respiratory arrest	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Cardiogenic shock	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cardiomyopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cardiopulmonary failure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Coronary artery disease	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Myocardial infarction	2	(0.3)	3	(0.2)	2	(0.1)	5	(0.2)
Palpitations	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pericardial effusion	6	(0.9)	11	(0.9)	5	(0.3)	16	(0.6)
Pericarditis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Right ventricular failure	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Supraventricular tachycardia	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Tachycardia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Congenital, familial and genetic disorders	**3**	**(0.4)**	**3**	**(0.2)**	**0**	**(0.0)**	**3**	**(0.1)**
Pyloric stenosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tracheo-oesophageal fistula	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Ear and labyrinth disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.0)**
Vertigo positional	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Endocrine disorders	**7**	**(1.0)**	**12**	**(1.0)**	**19**	**(1.2)**	**31**	**(1.1)**
Adrenal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Adrenal insufficiency	1	(0.1)	3	(0.2)	5	(0.3)	8	(0.3)
Adrenocortical insufficiency acute	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**7**	**(1.0)**	**12**	**(1.0)**	**19**	**(1.2)**	**31**	**(1.1)**
Hyperparathyroidism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperthyroidism	2	(0.3)	3	(0.2)	3	(0.2)	6	(0.2)
Hypophysitis	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Hypopituitarism	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Hypothyroidism	2	(0.3)	4	(0.3)	1	(0.1)	5	(0.2)
Secondary adrenocortical insufficiency	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thyroiditis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eye disorders	**0**	**(0.0)**	**0**	**(0.0)**	**4**	**(0.3)**	**4**	**(0.1)**
Eye movement disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Glaucoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Visual acuity reduced	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal disorders	**21**	**(3.1)**	**47**	**(3.8)**	**138**	**(8.8)**	**185**	**(6.6)**
Abdominal distension	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Abdominal mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Abdominal pain	2	(0.3)	5	(0.4)	17	(1.1)	22	(0.8)
Abdominal pain lower	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Anal fistula	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ascites	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Colitis	3	(0.4)	7	(0.6)	24	(1.5)	31	(1.1)
Colitis microscopic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Constipation	2	(0.3)	2	(0.2)	8	(0.5)	10	(0.4)
Diarrhoea	0	(0.0)	1	(0.1)	25	(1.6)	26	(0.9)
Diverticulitis intestinal haemorrhagic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diverticulum	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dysphagia	3	(0.4)	3	(0.2)	2	(0.1)	5	(0.2)
Enterocolitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erosive duodenitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Faecaloma	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Gastric disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastric haemorrhage	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Gastric perforation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**21**	**(3.1)**	**47**	**(3.8)**	**138**	**(8.8)**	**185**	**(6.6)**
Gastric ulcer haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastritis	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Gastritis erosive	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal haemorrhage	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Gastrointestinal pain	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal perforation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrointestinal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrooesophageal reflux disease	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Haematemesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haematochezia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ileus	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Inguinal hernia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Intestinal obstruction	0	(0.0)	0	(0.0)	7	(0.4)	7	(0.3)
Intestinal perforation	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Intussusception	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Large intestinal obstruction	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Large intestinal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Large intestine perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Malabsorption	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nausea	2	(0.3)	9	(0.7)	9	(0.6)	18	(0.6)
Obstruction gastric	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oesophageal obstruction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Oesophagitis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Pancreatitis	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Proctalgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rectal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Retroperitoneal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Small intestinal obstruction	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**21**	**(3.1)**	**47**	**(3.8)**	**138**	**(8.8)**	**185**	**(6.6)**
Small intestinal perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stomatitis necrotising	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vomiting	1	(0.1)	4	(0.3)	14	(0.9)	18	(0.6)
General disorders and administration site conditions	**24**	**(3.5)**	**56**	**(4.5)**	**77**	**(4.9)**	**133**	**(4.8)**
Adverse drug reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Asthenia	1	(0.1)	4	(0.3)	8	(0.5)	12	(0.4)
Chest pain	3	(0.4)	6	(0.5)	3	(0.2)	9	(0.3)
Chills	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Death	6	(0.9)	8	(0.6)	9	(0.6)	17	(0.6)
Device dislocation	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Drug withdrawal syndrome	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Face oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fatigue	2	(0.3)	7	(0.6)	5	(0.3)	12	(0.4)
Gait disturbance	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
General physical health deterioration	4	(0.6)	6	(0.5)	13	(0.8)	19	(0.7)
Generalised oedema	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Impaired healing	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infusion site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Malaise	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Multi-organ failure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Non-cardiac chest pain	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Oedema	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Oedema peripheral	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Pain	3	(0.4)	7	(0.6)	5	(0.3)	12	(0.4)
Pyrexia	5	(0.7)	16	(1.3)	19	(1.2)	35	(1.3)
Hepatobiliary disorders	**5**	**(0.7)**	**8**	**(0.6)**	**23**	**(1.5)**	**31**	**(1.1)**
Autoimmune hepatitis	2	(0.3)	2	(0.2)	6	(0.4)	8	(0.3)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**5**	**(0.7)**	**8**	**(0.6)**	**23**	**(1.5)**	**31**	**(1.1)**
Bile duct obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bile duct stone	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Biliary dilatation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cholangitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cholecystitis	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Drug-induced liver injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hepatic failure	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Hepatic function abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatitis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Hepatocellular injury	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Jaundice cholestatic	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Liver disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune system disorders	**1**	**(0.1)**	**1**	**(0.1)**	**5**	**(0.3)**	**6**	**(0.2)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Drug hypersensitivity	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Hypersensitivity	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Infections and infestations	**66**	**(9.7)**	**119**	**(9.7)**	**114**	**(7.3)**	**233**	**(8.3)**
Appendicitis perforated	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arthritis bacterial	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Bacillus bacteraemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Bacterial sepsis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Bronchitis	1	(0.1)	4	(0.3)	5	(0.3)	9	(0.3)
Candida infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Catheter site infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cellulitis	1	(0.1)	1	(0.1)	14	(0.9)	15	(0.5)
Cellulitis streptococcal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Clostridium difficile colitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Clostridium difficile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Device related infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Device related sepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Diverticulitis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**66**	**(9.7)**	**119**	**(9.7)**	**114**	**(7.3)**	**233**	**(8.3)**
Endocarditis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Enterocolitis infectious	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erysipelas	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Escherichia bacteraemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastroenteritis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Gastroenteritis viral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Herpes simplex encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Herpes zoster	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Infected cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infectious colitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Infectious pleural effusion	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Infective exacerbation of chronic obstructive airways disease	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Influenza	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Listeriosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Liver abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lobar pneumonia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Localised infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lower respiratory tract infection	1	(0.1)	6	(0.5)	0	(0.0)	6	(0.2)
Lung infection	2	(0.3)	6	(0.5)	3	(0.2)	9	(0.3)
Lyme disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymph gland infection	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Lymphangitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Mastitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meningitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Meningitis listeria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Oesophageal candidiasis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Osteomyelitis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Pelvic abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pleural infection	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**66**	**(9.7)**	**119**	**(9.7)**	**114**	**(7.3)**	**233**	**(8.3)**
Pneumocystis jirovecii pneumonia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia	36	(5.3)	56	(4.5)	28	(1.8)	84	(3.0)
Pneumonia bacterial	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Pneumonia cryptococcal	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia haemophilus	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia pneumococcal	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia viral	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pulmonary sepsis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pyelonephritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pyelonephritis acute	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pyopneumothorax	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory tract infection	6	(0.9)	8	(0.6)	1	(0.1)	9	(0.3)
Respiratory tract infection viral	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Salmonellosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sepsis	0	(0.0)	3	(0.2)	11	(0.7)	14	(0.5)
Septic shock	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Sinusitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Skin infection	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Soft tissue infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Staphylococcal bacteraemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Staphylococcal infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Thrombophlebitis septic	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper respiratory tract infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Urinary tract infection	1	(0.1)	2	(0.2)	13	(0.8)	15	(0.5)
Urosepsis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Viral infection	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Wound infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Wound sepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**13**	**(1.9)**	**16**	**(1.3)**	**22**	**(1.4)**	**38**	**(1.4)**
Contusion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Facial bones fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fall	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Femoral neck fracture	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Femur fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fracture displacement	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hip fracture	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Humerus fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Incisional hernia, obstructive	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Joint injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lower limb fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pneumonitis chemical	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Post procedural urine leak	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Radiation necrosis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Radiation pneumonitis	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Rib fracture	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Seroma	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Spinal compression fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Spinal fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thoracic vertebral fracture	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Traumatic intracranial haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper limb fracture	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Wound	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Wound decomposition	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Wound haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Investigations	**7**	**(1.0)**	**11**	**(0.9)**	**13**	**(0.8)**	**24**	**(0.9)**
Alanine aminotransferase increased	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Aspartate aminotransferase increased	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Aspiration bronchial	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**7**	**(1.0)**	**11**	**(0.9)**	**13**	**(0.8)**	**24**	**(0.9)**
Bilirubin conjugated increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood alkaline phosphatase increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood bilirubin increased	1	(0.1)	3	(0.2)	1	(0.1)	4	(0.1)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood creatine phosphokinase increased	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Blood creatinine increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood prolactin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
C-reactive protein increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Electrocardiogram change	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gamma-glutamyltransferase increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Intraocular pressure decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Liver function test abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Medical observation	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Neutrophil count decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolism and nutrition disorders	**19**	**(2.8)**	**39**	**(3.2)**	**60**	**(3.8)**	**99**	**(3.5)**
Cachexia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Decreased appetite	1	(0.1)	3	(0.2)	1	(0.1)	4	(0.1)
Dehydration	3	(0.4)	8	(0.6)	16	(1.0)	24	(0.9)
Diabetes mellitus	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Diabetic ketoacidosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Diabetic metabolic decompensation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Electrolyte imbalance	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**19**	**(2.8)**	**39**	**(3.2)**	**60**	**(3.8)**	**99**	**(3.5)**
Failure to thrive	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Fluid overload	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Gout	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypercalcaemia	6	(0.9)	10	(0.8)	2	(0.1)	12	(0.4)
Hyperglycaemia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Hyperkalaemia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Hypertriglyceridaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hyperuricaemia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hypoalbuminaemia	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Hypoglycaemia	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Hypokalaemia	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Hypomagnesaemia	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Hyponatraemia	3	(0.4)	6	(0.5)	15	(1.0)	21	(0.8)
Hypophosphataemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hypovolaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Insulin resistant diabetes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Malnutrition	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolic acidosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Type 1 diabetes mellitus	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Musculoskeletal and connective tissue disorders	**18**	**(2.6)**	**33**	**(2.7)**	**42**	**(2.7)**	**75**	**(2.7)**
Arthralgia	1	(0.1)	5	(0.4)	4	(0.3)	9	(0.3)
Arthritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Back pain	4	(0.6)	7	(0.6)	8	(0.5)	15	(0.5)
Bone pain	1	(0.1)	3	(0.2)	0	(0.0)	3	(0.1)
Costochondritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Flank pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Groin pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intervertebral disc protrusion	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Muscle haemorrhage	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Muscle necrosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Muscular weakness	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Musculoskeletal chest pain	1	(0.1)	3	(0.2)	1	(0.1)	4	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**18**	**(2.6)**	**33**	**(2.7)**	**42**	**(2.7)**	**75**	**(2.7)**
Musculoskeletal pain	2	(0.3)	4	(0.3)	4	(0.3)	8	(0.3)
Myalgia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Myopathy	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Myositis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neck pain	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Osteolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Osteoporosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Osteoporotic fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pain in extremity	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Pathological fracture	0	(0.0)	1	(0.1)	6	(0.4)	7	(0.3)
Polyarthritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Spinal column stenosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Spinal pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Spondylolisthesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Synovial cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Synovitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**10**	**(1.5)**	**25**	**(2.0)**	**71**	**(4.5)**	**96**	**(3.4)**
Adenocarcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Adenocarcinoma gastric	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Basal cell carcinoma	1	(0.1)	3	(0.2)	15	(1.0)	18	(0.6)
Basosquamous carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bowen's disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Breast cancer	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Cancer pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Colon cancer metastatic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Desmoplastic melanoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastric cancer	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrointestinal carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intracranial tumour haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**10**	**(1.5)**	**25**	**(2.0)**	**71**	**(4.5)**	**96**	**(3.4)**
Invasive ductal breast carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Leiomyosarcoma	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Lung neoplasm malignant	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Lymphangiosis carcinomatosa	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Malignant melanoma	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Malignant neoplasm progression	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Malignant pleural effusion	1	(0.1)	4	(0.3)	0	(0.0)	4	(0.1)
Metastases to central nervous system	1	(0.1)	2	(0.2)	5	(0.3)	7	(0.3)
Metastases to large intestine	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metastases to lymph nodes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metastases to meninges	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metastatic malignant melanoma	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Metastatic pain	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Neoplasm malignant	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Papillary thyroid cancer	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Papilloma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pericardial effusion malignant	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Prostate cancer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rectal cancer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Squamous cell carcinoma	0	(0.0)	1	(0.1)	14	(0.9)	15	(0.5)
Squamous cell carcinoma of skin	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Tumour associated fever	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tumour haemorrhage	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Tumour pain	1	(0.1)	5	(0.4)	5	(0.3)	10	(0.4)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**20**	**(2.9)**	**36**	**(2.9)**	**70**	**(4.5)**	**106**	**(3.8)**
Amnesia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ataxia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Axonal neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Brain oedema	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Cerebral haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Cerebral ischaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cerebrovascular accident	2	(0.3)	5	(0.4)	5	(0.3)	10	(0.4)
Depressed level of consciousness	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Dizziness	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Dysarthria	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Embolic stroke	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Encephalopathy	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Epilepsy	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhage intracranial	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Haemorrhagic stroke	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Headache	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Hemiparesis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Hemiplegia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hydrocephalus	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Ischaemic stroke	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Lethargy	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Lumbar radiculopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Migraine	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myelitis transverse	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neuralgia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Neurological decompensation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neuropathy peripheral	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Paraesthesia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Partial seizures	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**20**	**(2.9)**	**36**	**(2.9)**	**70**	**(4.5)**	**106**	**(3.8)**
Peripheral sensory neuropathy	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Presyncope	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Sciatica	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Seizure	1	(0.1)	3	(0.2)	8	(0.5)	11	(0.4)
Spinal cord compression	2	(0.3)	2	(0.2)	8	(0.5)	10	(0.4)
Syncope	2	(0.3)	5	(0.4)	5	(0.3)	10	(0.4)
Toxic leukoencephalopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Transient ischaemic attack	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Vasogenic cerebral oedema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Psychiatric disorders	**8**	**(1.2)**	**10**	**(0.8)**	**17**	**(1.1)**	**27**	**(1.0)**
Anxiety	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Completed suicide	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Confusional state	3	(0.4)	4	(0.3)	11	(0.7)	15	(0.5)
Delirium	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Depression	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Disorientation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dysphoria	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Mental status changes	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Renal and urinary disorders	**8**	**(1.2)**	**18**	**(1.5)**	**36**	**(2.3)**	**54**	**(1.9)**
Acute kidney injury	4	(0.6)	7	(0.6)	15	(1.0)	22	(0.8)
Calculus ureteric	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Dysuria	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Hydronephrosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Obstructive uropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Postrenal failure	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Renal failure	1	(0.1)	3	(0.2)	12	(0.8)	15	(0.5)
Renal infarct	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tubulointerstitial nephritis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Urge incontinence	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Urinary bladder polyp	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**8**	**(1.2)**	**18**	**(1.5)**	**36**	**(2.3)**	**54**	**(1.9)**
Urinary incontinence	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urinary retention	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Urinary tract obstruction	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Reproductive system and breast disorders	**1**	**(0.1)**	**1**	**(0.1)**	**3**	**(0.2)**	**4**	**(0.1)**
Erectile dysfunction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Metrorrhagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pelvic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Prostatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Respiratory, thoracic and mediastinal disorders	**65**	**(9.5)**	**158**	**(12.8)**	**89**	**(5.7)**	**247**	**(8.8)**
Acute respiratory failure	1	(0.1)	6	(0.5)	1	(0.1)	7	(0.3)
Atelectasis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Bronchial obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bronchospasm	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chronic obstructive pulmonary disease	7	(1.0)	13	(1.1)	3	(0.2)	16	(0.6)
Cough	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Diffuse alveolar damage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Dyspnoea	8	(1.2)	23	(1.9)	22	(1.4)	45	(1.6)
Dyspnoea exertional	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Epistaxis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemoptysis	4	(0.6)	7	(0.6)	5	(0.3)	12	(0.4)
Haemothorax	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hiccups	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypoxia	2	(0.3)	8	(0.6)	4	(0.3)	12	(0.4)
Interstitial lung disease	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Laryngeal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lung consolidation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lung disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Obstructive airways disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Painful respiration	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pleural effusion	8	(1.2)	34	(2.8)	14	(0.9)	48	(1.7)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**65**	**(9.5)**	**158**	**(12.8)**	**89**	**(5.7)**	**247**	**(8.8)**
Pleuritic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pneumonia aspiration	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Pneumonitis	17	(2.5)	31	(2.5)	15	(1.0)	46	(1.6)
Pneumothorax	0	(0.0)	7	(0.6)	2	(0.1)	9	(0.3)
Pneumothorax spontaneous	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pulmonary embolism	15	(2.2)	28	(2.3)	13	(0.8)	41	(1.5)
Pulmonary haemorrhage	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Pulmonary hypertension	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Pulmonary oedema	2	(0.3)	4	(0.3)	0	(0.0)	4	(0.1)
Pulmonary thrombosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pulmonary vascular disorder	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory distress	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory failure	3	(0.4)	12	(1.0)	2	(0.1)	14	(0.5)
Wheezing	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin and subcutaneous tissue disorders	**2**	**(0.3)**	**6**	**(0.5)**	**13**	**(0.8)**	**19**	**(0.7)**
Dermatitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Drug eruption	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Erythema multiforme	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Haemorrhage subcutaneous	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lichenoid keratosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Rash generalised	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash maculo-papular	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Skin mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stevens-Johnson syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Surgical and medical procedures	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.1)**	**2**	**(0.1)**

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Surgical and medical procedures	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.1)**	**2**	**(0.1)**
Mitral valve replacement	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin neoplasm excision	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vascular disorders	**11**	**(1.6)**	**25**	**(2.0)**	**29**	**(1.9)**	**54**	**(1.9)**
Aortic stenosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arterial stenosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arterial thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Deep vein thrombosis	1	(0.1)	4	(0.3)	4	(0.3)	8	(0.3)
Embolism	2	(0.3)	7	(0.6)	2	(0.1)	9	(0.3)
Femoral artery occlusion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhagic infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypotension	1	(0.1)	3	(0.2)	4	(0.3)	7	(0.3)
Intra-abdominal haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphoedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Orthostatic hypotension	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Peripheral ischaemia	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Phlebitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Poor venous access	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Shock haemorrhagic	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Superior vena cava occlusion	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Superior vena cava syndrome	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Thrombosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Vasculitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Vein disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vena cava thrombosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Venous thrombosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
NULL	**0**	**(0.0)**	**1**	**(0.1)**	**0**	**(0.0)**	**1**	**(0.0)**

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
NULL	**0**	**(0.0)**	**1**	**(0.1)**	**0**	**(0.0)**	**1**	**(0.0)**
NULL	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted].

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 44　　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 1%以上）
001 試験＋002 試験＋006 試験＋010 試験
MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence ≥ 1% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	682		1,232		1,567		2,799	
with one or more adverse events	246	(36.1)	474	(38.5)	567	(36.2)	1,041	(37.2)
with no adverse events	436	(63.9)	758	(61.5)	1,000	(63.8)	1,758	(62.8)
Blood and lymphatic system disorders	**12**	**(1.8)**	**16**	**(1.3)**	**36**	**(2.3)**	**52**	**(1.9)**
Anaemia	6	(0.9)	7	(0.6)	24	(1.5)	31	(1.1)
Cardiac disorders	**28**	**(4.1)**	**54**	**(4.4)**	**36**	**(2.3)**	**90**	**(3.2)**
Endocrine disorders	**7**	**(1.0)**	**12**	**(1.0)**	**19**	**(1.2)**	**31**	**(1.1)**
Gastrointestinal disorders	**21**	**(3.1)**	**47**	**(3.8)**	**138**	**(8.8)**	**185**	**(6.6)**
Abdominal pain	2	(0.3)	5	(0.4)	17	(1.1)	22	(0.8)
Colitis	3	(0.4)	7	(0.6)	24	(1.5)	31	(1.1)
Diarrhoea	0	(0.0)	1	(0.1)	25	(1.6)	26	(0.9)
General disorders and administration site conditions	**24**	**(3.5)**	**56**	**(4.5)**	**77**	**(4.9)**	**133**	**(4.8)**
Pyrexia	5	(0.7)	16	(1.3)	19	(1.2)	35	(1.3)
Hepatobiliary disorders	**5**	**(0.7)**	**8**	**(0.6)**	**23**	**(1.5)**	**31**	**(1.1)**
Infections and infestations	**66**	**(9.7)**	**119**	**(9.7)**	**114**	**(7.3)**	**233**	**(8.3)**
Pneumonia	36	(5.3)	56	(4.5)	28	(1.8)	84	(3.0)
Injury, poisoning and procedural complications	**13**	**(1.9)**	**16**	**(1.3)**	**22**	**(1.4)**	**38**	**(1.4)**
Investigations	**7**	**(1.0)**	**11**	**(0.9)**	**13**	**(0.8)**	**24**	**(0.9)**
Metabolism and nutrition disorders	**19**	**(2.8)**	**39**	**(3.2)**	**60**	**(3.8)**	**99**	**(3.5)**
Dehydration	3	(0.4)	8	(0.6)	16	(1.0)	24	(0.9)
Hyponatraemia	3	(0.4)	6	(0.5)	15	(1.0)	21	(0.8)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose (Incidence ≥ 1% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**18**	**(2.6)**	**33**	**(2.7)**	**42**	**(2.7)**	**75**	**(2.7)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**10**	**(1.5)**	**25**	**(2.0)**	**71**	**(4.5)**	**96**	**(3.4)**
Basal cell carcinoma	1	(0.1)	3	(0.2)	15	(1.0)	18	(0.6)
Nervous system disorders	**20**	**(2.9)**	**36**	**(2.9)**	**70**	**(4.5)**	**106**	**(3.8)**
Psychiatric disorders	**8**	**(1.2)**	**10**	**(0.8)**	**17**	**(1.1)**	**27**	**(1.0)**
Renal and urinary disorders	**8**	**(1.2)**	**18**	**(1.5)**	**36**	**(2.3)**	**54**	**(1.9)**
Acute kidney injury	4	(0.6)	7	(0.6)	15	(1.0)	22	(0.8)
Respiratory, thoracic and mediastinal disorders	**65**	**(9.5)**	**158**	**(12.8)**	**89**	**(5.7)**	**247**	**(8.8)**
Chronic obstructive pulmonary disease	7	(1.0)	13	(1.1)	3	(0.2)	16	(0.6)
Dyspnoea	8	(1.2)	23	(1.9)	22	(1.4)	45	(1.6)
Pleural effusion	8	(1.2)	34	(2.8)	14	(0.9)	48	(1.7)
Pneumonitis	17	(2.5)	31	(2.5)	15	(1.0)	46	(1.6)
Pulmonary embolism	15	(2.2)	28	(2.3)	13	(0.8)	41	(1.5)
Respiratory failure	3	(0.4)	12	(1.0)	2	(0.1)	14	(0.5)

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Subjects With Serious Adverse Events Up to 90 Days of Last Dose
(Incidence ≥ 1% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**11**	**(1.6)**	**25**	**(2.0)**	**29**	**(1.9)**	**54**	**(1.9)**

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.
Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.
(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).
(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).
(MK-3475 PN002 Database Cutoff Date: [redacted]).
(MK-3475 PN006 Database Cutoff Date: 03MAR2015).
(MK-3475 PN010 Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 45　　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＋002 試験＋006 試験＋010 試験
MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	682		1,232		1,567		2,799	
with one or more adverse events	71	(10.4)	117	(9.5)	164	(10.5)	281	(10.0)
with no adverse events	611	(89.6)	1,115	(90.5)	1,403	(89.5)	2,518	(90.0)
Blood and lymphatic system disorders	**3**	**(0.4)**	**5**	**(0.4)**	**8**	**(0.5)**	**13**	**(0.5)**
Anaemia	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Autoimmune haemolytic anaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Eosinophilia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Microcytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neutropenia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pancytopenia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thrombocytopenia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Cardiac disorders	**3**	**(0.4)**	**7**	**(0.6)**	**2**	**(0.1)**	**9**	**(0.3)**
Acute myocardial infarction	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Angina unstable	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Atrioventricular block complete	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cardiac tamponade	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Cardio-respiratory arrest	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Myocardial infarction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pericardial effusion	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Pericarditis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Endocrine disorders	**7**	**(1.0)**	**11**	**(0.9)**	**16**	**(1.0)**	**27**	**(1.0)**
Adrenal insufficiency	1	(0.1)	3	(0.2)	4	(0.3)	7	(0.3)
Hyperthyroidism	2	(0.3)	3	(0.2)	3	(0.2)	6	(0.2)
Hypophysitis	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Hypopituitarism	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Hypothyroidism	2	(0.3)	4	(0.3)	1	(0.1)	5	(0.2)
Secondary adrenocortical insufficiency	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**7**	**(1.0)**	**11**	**(0.9)**	**16**	**(1.0)**	**27**	**(1.0)**
Thyroiditis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eye disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.0)**
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastrointestinal disorders	**5**	**(0.7)**	**12**	**(1.0)**	**48**	**(3.1)**	**60**	**(2.1)**
Abdominal pain	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Colitis	3	(0.4)	6	(0.5)	19	(1.2)	25	(0.9)
Colitis microscopic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diarrhoea	0	(0.0)	1	(0.1)	16	(1.0)	17	(0.6)
Dysphagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Enterocolitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gastritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrooesophageal reflux disease	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Ileus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intestinal obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nausea	0	(0.0)	3	(0.2)	3	(0.2)	6	(0.2)
Oesophagitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pancreatitis	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Rectal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Small intestinal perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vomiting	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
General disorders and administration site conditions	**4**	**(0.6)**	**7**	**(0.6)**	**17**	**(1.1)**	**24**	**(0.9)**
Asthenia	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Chest pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chills	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Face oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fatigue	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
General physical health deterioration	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Generalised oedema	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Pyrexia	1	(0.1)	3	(0.2)	7	(0.4)	10	(0.4)

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Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**2**	**(0.3)**	**2**	**(0.2)**	**13**	**(0.8)**	**15**	**(0.5)**
Autoimmune hepatitis	2	(0.3)	2	(0.2)	6	(0.4)	8	(0.3)
Cholangitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Drug-induced liver injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hepatic function abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatitis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Liver disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Immune system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(0.2)**	**3**	**(0.1)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infections and infestations	**6**	**(0.9)**	**10**	**(0.8)**	**10**	**(0.6)**	**20**	**(0.7)**
Bacterial sepsis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diverticulitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erysipelas	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Listeriosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Liver abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphangitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Meningitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Meningitis listeria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia	6	(0.9)	6	(0.5)	2	(0.1)	8	(0.3)
Pneumonia viral	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Injury, poisoning and procedural complications	**2**	**(0.3)**	**2**	**(0.2)**	**0**	**(0.0)**	**2**	**(0.1)**
Pneumonitis chemical	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Investigations	**1**	**(0.1)**	**3**	**(0.2)**	**7**	**(0.4)**	**10**	**(0.4)**
Alanine aminotransferase increased	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)

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Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose (Incidence > 0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**1**	**(0.1)**	**3**	**(0.2)**	**7**	**(0.4)**	**10**	**(0.4)**
Aspartate aminotransferase increased	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Blood bilirubin increased	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood creatine phosphokinase increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood prolactin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intraocular pressure decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Liver function test abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolism and nutrition disorders	**8**	**(1.2)**	**11**	**(0.9)**	**14**	**(0.9)**	**25**	**(0.9)**
Decreased appetite	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dehydration	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Diabetes mellitus	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Diabetic ketoacidosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Failure to thrive	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperglycaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperkalaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Hypertriglyceridaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hypoalbuminaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypokalaemia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hyponatraemia	2	(0.3)	4	(0.3)	3	(0.2)	7	(0.3)
Hypophosphataemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Insulin resistant diabetes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Type 1 diabetes mellitus	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Musculoskeletal and connective tissue disorders	**5**	**(0.7)**	**5**	**(0.4)**	**8**	**(0.5)**	**13**	**(0.5)**
Arthralgia	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)

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Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**5**	**(0.7)**	**5**	**(0.4)**	**8**	**(0.5)**	**13**	**(0.5)**
Arthritis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Muscle necrosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Muscular weakness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myalgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myopathy	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Myositis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Polyarthritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Synovitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(0.1)**	**1**	**(0.1)**	**1**	**(0.1)**	**2**	**(0.1)**
Malignant melanoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Malignant neoplasm progression	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Nervous system disorders	**3**	**(0.4)**	**5**	**(0.4)**	**13**	**(0.8)**	**18**	**(0.6)**
Amnesia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Brain oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cerebrovascular accident	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dysarthria	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Encephalopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Epilepsy	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lethargy	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myelitis transverse	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neuralgia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Neuropathy peripheral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Partial seizures	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**3**	**(0.4)**	**5**	**(0.4)**	**13**	**(0.8)**	**18**	**(0.6)**
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Peripheral sensory neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Presyncope	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Toxic leukoencephalopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Psychiatric disorders	**2**	**(0.3)**	**2**	**(0.2)**	**5**	**(0.3)**	**7**	**(0.3)**
Confusional state	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Disorientation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dysphoria	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Renal and urinary disorders	**1**	**(0.1)**	**3**	**(0.2)**	**10**	**(0.6)**	**13**	**(0.5)**
Acute kidney injury	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Dysuria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Renal failure	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Tubulointerstitial nephritis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Urinary incontinence	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Respiratory, thoracic and mediastinal disorders	**21**	**(3.1)**	**40**	**(3.2)**	**26**	**(1.7)**	**66**	**(2.4)**
Chronic obstructive pulmonary disease	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cough	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Dyspnoea	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Hypoxia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Interstitial lung disease	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Laryngeal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lung disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pleural effusion	2	(0.3)	3	(0.2)	0	(0.0)	3	(0.1)
Pleuritic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pneumonitis	15	(2.2)	29	(2.4)	15	(1.0)	44	(1.6)
Pneumothorax	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pulmonary embolism	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory failure	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**2**	**(0.3)**	**4**	**(0.3)**	**5**	**(0.3)**	**9**	**(0.3)**
Drug eruption	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lichenoid keratosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Rash maculo-papular	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Stevens-Johnson syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vascular disorders	**1**	**(0.1)**	**2**	**(0.2)**	**2**	**(0.1)**	**4**	**(0.1)**
Arterial thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Peripheral ischaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Vasculitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted]).

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).

C Confidential

付録 2.7.4- 46　　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 1%以上）
001 試験＋002 試験＋006 試験＋010 試験
MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Serious Drug-Related Adverse Events Up to 90 Days of Last Dose
(Incidence ≥ 1% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	682		1,232		1,567		2,799	
with one or more adverse events	71	(10.4)	117	(9.5)	164	(10.5)	281	(10.0)
with no adverse events	611	(89.6)	1,115	(90.5)	1,403	(89.5)	2,518	(90.0)
Endocrine disorders	**7**	**(1.0)**	**11**	**(0.9)**	**16**	**(1.0)**	**27**	**(1.0)**
Gastrointestinal disorders	**5**	**(0.7)**	**12**	**(1.0)**	**48**	**(3.1)**	**60**	**(2.1)**
Colitis	3	(0.4)	6	(0.5)	19	(1.2)	25	(0.9)
Diarrhoea	0	(0.0)	1	(0.1)	16	(1.0)	17	(0.6)
General disorders and administration site conditions	**4**	**(0.6)**	**7**	**(0.6)**	**17**	**(1.1)**	**24**	**(0.9)**
Metabolism and nutrition disorders	**8**	**(1.2)**	**11**	**(0.9)**	**14**	**(0.9)**	**25**	**(0.9)**
Respiratory, thoracic and mediastinal disorders	**21**	**(3.1)**	**40**	**(3.2)**	**26**	**(1.7)**	**66**	**(2.4)**
Pneumonitis	15	(2.2)	29	(2.4)	15	(1.0)	44	(1.6)

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.
Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.
(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).
(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).
(MK-3475 PN002 Database Cutoff Date: [redacted]).
(MK-3475 PN006 Database Cutoff Date: 03MAR2015).
(MK-3475 PN010 Database Cutoff Date: 30SEP2015).

C Confidential

付録 2.7.4- 47　　治験薬の投与中止に至った有害事象

（いずれかの投与群で発現割合 0%超）

001 試験（パート C 及び F）（安全性解析対象集団）

Subjects With Adverse Events Resulting in Discontinuation
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	61		287		202		550	
with one or more adverse events	9	(14.8)	40	(13.9)	30	(14.9)	79	(14.4)
with no adverse events	52	(85.2)	247	(86.1)	172	(85.1)	471	(85.6)
Blood and lymphatic system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**2**	**(0.4)**
Autoimmune haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Neutropenia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Cardiac disorders	**1**	**(1.6)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.2)**
Cardio-respiratory arrest	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Gastrointestinal disorders	**0**	**(0.0)**	**2**	**(0.7)**	**3**	**(1.5)**	**5**	**(0.9)**
Abdominal pain upper	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Colitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Gastrointestinal perforation	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Impaired gastric emptying	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Intestinal perforation	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
General disorders and administration site conditions	**1**	**(1.6)**	**8**	**(2.8)**	**6**	**(3.0)**	**15**	**(2.7)**
Death	0	(0.0)	0	(0.0)	2	(1.0)	2	(0.4)
Fatigue	0	(0.0)	4	(1.4)	0	(0.0)	4	(0.7)
General physical health deterioration	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Generalised oedema	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Malaise	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)

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Subjects With Adverse Events Resulting in Discontinuation (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**1**	**(1.6)**	**8**	**(2.8)**	**6**	**(3.0)**	**15**	**(2.7)**
Oedema	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Pain	1	(1.6)	2	(0.7)	1	(0.5)	4	(0.7)
Hepatobiliary disorders	**1**	**(1.6)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.2)**
Hepatic failure	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Immune system disorders	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.2)**
Serum sickness	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Infections and infestations	**4**	**(6.6)**	**2**	**(0.7)**	**4**	**(2.0)**	**10**	**(1.8)**
Bronchitis	1	(1.6)	1	(0.3)	0	(0.0)	2	(0.4)
Herpes zoster	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Pneumonia	1	(1.6)	0	(0.0)	3	(1.5)	4	(0.7)
Pulmonary sepsis	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Respiratory tract infection	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Thrombophlebitis septic	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Investigations	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**2**	**(0.4)**
Blood bilirubin increased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Weight decreased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Metabolism and nutrition disorders	**0**	**(0.0)**	**3**	**(1.0)**	**0**	**(0.0)**	**3**	**(0.5)**
Failure to thrive	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Hypercalcaemia	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)

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Subjects With Adverse Events Resulting in Discontinuation (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**0**	**(0.0)**	**3**	**(1.0)**	**2**	**(1.0)**	**5**	**(0.9)**
Arthralgia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Back pain	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Bone pain	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Joint stiffness	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Neck pain	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**2**	**(0.7)**	**0**	**(0.0)**	**2**	**(0.4)**
Squamous cell carcinoma	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Tumour pain	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Nervous system disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Embolic stroke	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Neuralgia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Renal and urinary disorders	**1**	**(1.6)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.2)**
Renal failure acute	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Respiratory, thoracic and mediastinal disorders	**3**	**(4.9)**	**17**	**(5.9)**	**11**	**(5.4)**	**31**	**(5.6)**
Acute respiratory failure	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)

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Subjects With Adverse Events Resulting in Discontinuation
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**3**	**(4.9)**	**17**	**(5.9)**	**11**	**(5.4)**	**31**	**(5.6)**
Diffuse alveolar damage	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Dyspnoea	1	(1.6)	2	(0.7)	1	(0.5)	4	(0.7)
Haemoptysis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Interstitial lung disease	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pleural effusion	0	(0.0)	2	(0.7)	2	(1.0)	4	(0.7)
Pneumonitis	2	(3.3)	6	(2.1)	3	(1.5)	11	(2.0)
Pneumothorax	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Respiratory failure	0	(0.0)	3	(1.0)	1	(0.5)	4	(0.7)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**2**	**(0.7)**	**0**	**(0.0)**	**2**	**(0.4)**
Hyperkeratosis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Rash	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Vascular disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Embolism	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)

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: [redacted])

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付録 2.7.4- 48　　治験薬の投与中止に至った副作用

（いずれかの投与群で発現割合 0%超）

001 試験（パート C 及び F）（安全性解析対象集団）

Subjects With Drug-Related Adverse Events Resulting in Discontinuation
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	61		287		202		550	
with one or more adverse events	4	(6.6)	11	(3.8)	8	(4.0)	23	(4.2)
with no adverse events	57	(93.4)	276	(96.2)	194	(96.0)	527	(95.8)
Blood and lymphatic system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**2**	**(0.4)**
Autoimmune haemolytic anaemia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Neutropenia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Cardiac disorders	**1**	**(1.6)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.2)**
Cardio-respiratory arrest	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Gastrointestinal disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**2**	**(0.4)**
Colitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Impaired gastric emptying	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
General disorders and administration site conditions	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.2)**
Generalised oedema	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Immune system disorders	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.2)**
Serum sickness	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Investigations	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.5)**	**1**	**(0.2)**
Weight decreased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)

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Subjects With Drug-Related Adverse Events Resulting in Discontinuation
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.2)**
Joint stiffness	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Nervous system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.5)**	**1**	**(0.2)**
Neuralgia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Renal and urinary disorders	**1**	**(1.6)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.2)**
Renal failure acute	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Respiratory, thoracic and mediastinal disorders	**2**	**(3.3)**	**7**	**(2.4)**	**3**	**(1.5)**	**12**	**(2.2)**
Interstitial lung disease	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pneumonitis	2	(3.3)	6	(2.1)	3	(1.5)	11	(2.0)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**2**	**(0.7)**	**0**	**(0.0)**	**2**	**(0.4)**
Hyperkeratosis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Rash	0	(0.0)	1	(0.3)	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.
(Database Cutoff Date: [redacted])

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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

001 試験（パート C 及び F）（安全性解析対象集団）

Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000605, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=105										
000605	Safety Follow-up	107	Renal failure acute	3 Days	Moderate	2	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=003015, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=21										
003015	Safety Follow-up	37	Pain	4 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=003034, Gender=M, Race=Asian, Age=76 Years, Rel Day of Study Medication Discontinuance†=22										
003034	Safety Follow-up	32	Cardio-respiratory arrest	1 Days		5	Y	Y	Discontinued	Fatal
Trial Number=3475-001, Site Number=0028, Subject ID=003020, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=22										
003020	Safety Follow-up	37	Dyspnoea	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0031, Subject ID=003021, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=22										
003021	Safety Follow-up	41	Thrombophlebitis septic	1.57 Weeks	Moderate	2	Y	N	Discontinued	Resolved

Confidential

Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0073, Subject ID=003007, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=72										
003007	Safety Follow-up	82	Pneumonia	1.14 Weeks		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0091, Subject ID=003019, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=207										
003019	Treatment Cycle 7	147	Bronchitis	3.57 Weeks	Moderate	2		N	Discontinued	Resolved
	Safety Follow-up	226	Pneumonitis	Continuing	Severe	4	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0092, Subject ID=003037, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=43										
003037	Safety Follow-up	51	Hepatic failure	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
		51	Pulmonary sepsis	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=003045, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
003045	Safety Follow-up	13	Pneumonitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved

Confidential

Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001519, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=1										
001519	Safety Follow-up	12	Fatigue	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=000169, Gender=F, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1										
000169	Safety Follow-up	19	Hypercalcaemia	1.43 Weeks	Severe	4	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=000971, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=114										
000971	Safety Follow-up	135	Pleural effusion	2 Days	Moderate	2		N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000180, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
000180	Safety Follow-up	4	Pneumonitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000181, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=85										
000181	Safety Follow-up	106	Pneumonitis	Continuing	Moderate	2	Y	Y	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001022, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=22										
001022	Safety Follow-up	41	Failure to thrive	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000814, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43										
000814	Safety Follow-up	54	Generalised oedema	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000952, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=1										
000952	Safety Follow-up	14	Tumour pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=000997, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=1										
000997	Safety Follow-up	2	Back pain	2 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000801, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=20										
000801	Safety Follow-up	33	Pneumonitis	4 Days	Severe	4	Y	Y	Discontinued	Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000807, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=22										
000807	Safety Follow-up	37	Respiratory failure	1 Days	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000816, Gender=M, Race=Asian, Age=38 Years, Rel Day of Study Medication Discontinuance†=23										
000816	Safety Follow-up	52	Intestinal perforation	2 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000820, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=51										
000820	Safety Follow-up	55	Respiratory failure	2 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000824, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=43										
000824	Treatment Cycle 2	37	Fatigue	Continuing	Moderate	2		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000905, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=189										
000905	Treatment Cycle 10	189	Abdominal pain upper	Continuing	Severe	3		N	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000913, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=232										
000913	Safety Follow-up	233	Acute respiratory failure	2.43 Weeks	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000918, Gender=M, Race=White, Age=32 Years, Rel Day of Study Medication Discontinuance†=20										
000918	Safety Follow-up	35	Pain	Continuing	Severe	3		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000943, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=1										
000943	Safety Follow-up	2	Pneumothorax	3 Days	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=001023, Gender=M, Race=Asian, Age=61 Years, Rel Day of Study Medication Discontinuance†=85										
001023	Treatment Cycle 5	85	Fatigue	Continuing	Moderate	2		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001581, Gender=M, Race=Asian, Age=68 Years, Rel Day of Study Medication Discontinuance†=1										
001581	Safety Follow-up	12	Embolic stroke	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0016, Subject ID=000945, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=22										
000945	Safety Follow-up	36	Dyspnoea	4 Days	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000199, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=22										
000199	Safety Follow-up	34	Fatigue	4 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000827, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=240										
000827	Safety Follow-up	261	Pneumonitis	2.04 Months	Mild	1		Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000928, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=428										
000928	Safety Follow-up	453	Rash	1.43 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001552, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=1										
001552	Safety Follow-up	19	Respiratory failure	2.86 Weeks	Severe	4	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=000908, Gender=F, Race=Black Or African American, Age=28 Years, Rel Day of Study Medication Discontinuance†=71										
000908	Safety Follow-up	86	Dyspnoea	Continuing	Severe	3		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000911, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=324										
000911	Safety Follow-up	342	Serum sickness	1.51 Months	Severe	3		Y	Discontinued	Resolved
		354	Joint stiffness	Continuing	Moderate	2		Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001566, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=300										
001566	Safety Follow-up	302	Hyperkeratosis	Continuing	Severe	3		Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000825, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=1										
000825	Safety Follow-up	11	Embolism	3 Days	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0023, Subject ID=001163, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=85										

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001163, Gender=M, Race=Asian, Age=70 Years, Rel Day of Study Medication Discontinuance†=85										
001163	Safety Follow-up	102	Acute respiratory failure	1 Days	Severe	4	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001508, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=98										
001508	Safety Follow-up	99	Pleural effusion	1.29 Weeks	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0026, Subject ID=000968, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=43										
000968	Safety Follow-up	51	Pneumonitis	1 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0026, Subject ID=001510, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=169										
001510	Safety Follow-up	179	Pneumonitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0033, Subject ID=001060, Gender=M, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=1										
001060	Safety Follow-up	12	Interstitial lung disease	5 Days	Severe	5	Y	Y	Discontinued	Fatal

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0036, Subject ID=001058, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=23										
001058	Treatment Cycle 1	17	General physical health deterioration	Continuing	Severe	3		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0036, Subject ID=001557, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=316										
001557	Treatment Cycle 15	309	Squamous cell carcinoma	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001067, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=50										
001067	Safety Follow-up	59	Respiratory tract infection	3 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001133, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=1										
001133	Safety Follow-up	28	Pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0090, Subject ID=001551, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=85										

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0090, Subject ID=001551, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=85										
001551	Safety Follow-up	105	Hypercalcaemia	1.29 Weeks	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0091, Subject ID=001573, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=22										
001573	Treatment Cycle 1	18	Bone pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
	Safety Follow-up	38	Bronchitis	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0011, Subject ID=000934, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=404										
000934	Safety Follow-up	414	Death	1 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0011, Subject ID=001728, Gender=F, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=43										
001728	Safety Follow-up	46	Pneumonitis	1.71 Weeks	Severe	3	Y	Y	Discontinued	Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001731, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=35										
001731	Safety Follow-up	38	Haemoptysis	3 Days	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0013, Subject ID=001159, Gender=F, Race=Black Or African American, Age=54 Years, Rel Day of Study Medication Discontinuance†=90										
001159	Safety Follow-up	104	Impaired gastric emptying	Unknown	Severe	3		Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000901, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=29										
000901	Safety Follow-up	43	Oedema	Continuing	Moderate	2		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000914, Gender=F, Race=White, Age=41 Years, Rel Day of Study Medication Discontinuance†=85										
000914	Treatment Cycle 6	85	Malaise	Continuing	Severe	3		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000919, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=155										
000919	Safety Follow-up	162	Diffuse alveolar damage	1.29 Weeks		5	Y	N	Discontinued	Fatal

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0015, Subject ID=000966, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=1										
000966	Safety Follow-up	15	Embolism	1 Weeks	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=000984, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=1										
000984	Safety Follow-up	17	Respiratory failure	3 Days	Severe	5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=001114, Gender=F, Race=Asian, Age=52 Years, Rel Day of Study Medication Discontinuance†=14										
001114	Safety Follow-up	31	Pneumonia	Continuing	Moderate	2		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001592, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=15										
001592	Safety Follow-up	23	Death	1 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0015, Subject ID=001712, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=140										
001712	Treatment Cycle 11	140	Pain	Continuing	Severe	3		N	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=001724, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=1										
001724	Safety Follow-up	15	Blood bilirubin increased	Continuing	Severe	3		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000904, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=99										
000904	Safety Follow-up	106	Gastrointestinal perforation	2 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0020, Subject ID=000987, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=272										
000987	Safety Follow-up	286	Autoimmune haemolytic anaemia	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001715, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=56										
001715	Safety Follow-up	68	Colitis	1 Weeks	Moderate	2		Y	Discontinued	Resolved
		69	Weight decreased	Continuing	Moderate	2		Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001735, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=50										

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0020, Subject ID=001735, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=50										
001735	Safety Follow-up	64	Neutropenia	1.31 Months	Severe	4	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001742, Gender=M, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†=71										
001742	Safety Follow-up	76	Arthralgia	Continuing	Moderate	2		N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000994, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=40										
000994	Treatment Cycle 4	40	Pleural effusion	3.86 Weeks	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001006, Gender=M, Race=Asian, Age=67 Years, Rel Day of Study Medication Discontinuance†=1										
001006	Safety Follow-up	30	Pneumonitis	1.71 Weeks	Severe	4	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001511, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=29										
001511	Safety Follow-up	42	Pleural effusion	3.71 Weeks	Moderate	2	Y	N	Discontinued	Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0026, Subject ID=000957, Gender=M, Race=Black Or African American, Age=52 Years, Rel Day of Study Medication Discontinuance†=15										
000957	Safety Follow-up	26	Neck pain	3.14 Weeks	Severe	3	Y	N	Discontinued	Resolved
		26	Pneumothorax	3.14 Weeks	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0026, Subject ID=001081, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=15										
001081	Safety Follow-up	29	Herpes zoster	1 Weeks	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0040, Subject ID=001019, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=27										
001019	Safety Follow-up	41	Dyspnoea	4.14 Weeks	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0040, Subject ID=001141, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=57										
001141	Safety Follow-up	77	General physical health deterioration	Continuing	Severe	3	Y	N	Discontinued	Not Resolved

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0081, Subject ID=001071, Gender=M, Race=Asian, Age=62 Years, Rel Day of Study Medication Discontinuance†=225										
001071	Safety Follow-up	239	Pneumonia	1.35 Months	Moderate	2	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0081, Subject ID=001577, Gender=M, Race=Asian, Age=64 Years, Rel Day of Study Medication Discontinuance†=113										
001577	Safety Follow-up	126	Pneumonitis	2 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0082, Subject ID=001565, Gender=M, Race=Asian, Age=71 Years, Rel Day of Study Medication Discontinuance†=1										
001565	Safety Follow-up	31	Pneumonia	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0120, Subject ID=001580, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=267										
001580	Safety Follow-up	268	Neuralgia	1 Weeks	Moderate	2	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0134, Subject ID=001582, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=219										

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Listing of Subjects With Adverse Events Resulting in Discontinuation
All Subjects with NSCLC by Dose
(All Subjects as Treated)

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=0134, Subject ID=001582, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance[†]=219										
001582	Safety Follow-up	229	Chronic obstructive pulmonary disease	1 Weeks	Severe	3	Y	N	Discontinued	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.
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: [redacted])

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付録 2.7.4- 50　　治験薬の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）
001 試験（パート C 及び F）（安全性解析対象集団）

Subjects With Adverse Events Resulting in Treatment Interruption
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	61		287		202		550	
with one or more adverse events	9	(14.8)	57	(19.9)	43	(21.3)	109	(19.8)
with no adverse events	52	(85.2)	230	(80.1)	159	(78.7)	441	(80.2)
Blood and lymphatic system disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Anaemia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Splenomegaly	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Cardiac disorders	**0**	**(0.0)**	**2**	**(0.7)**	**2**	**(1.0)**	**4**	**(0.7)**
Acute coronary syndrome	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Cardiac tamponade	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Cardio-respiratory arrest	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Pericardial effusion	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Endocrine disorders	**0**	**(0.0)**	**5**	**(1.7)**	**0**	**(0.0)**	**5**	**(0.9)**
Adrenal insufficiency	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Hypophysitis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Hypothyroidism	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Myxoedema	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Gastrointestinal disorders	**0**	**(0.0)**	**11**	**(3.8)**	**5**	**(2.5)**	**16**	**(2.9)**
Colitis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Diarrhoea	0	(0.0)	4	(1.4)	2	(1.0)	6	(1.1)
Gastric perforation	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Irritable bowel syndrome	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Nausea	0	(0.0)	3	(1.0)	1	(0.5)	4	(0.7)
Rectal haemorrhage	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)

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Subjects With Adverse Events Resulting in Treatment Interruption (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**0**	**(0.0)**	**11**	**(3.8)**	**5**	**(2.5)**	**16**	**(2.9)**
Small intestinal obstruction	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Vomiting	0	(0.0)	1	(0.3)	2	(1.0)	3	(0.5)
General disorders and administration site conditions	**3**	**(4.9)**	**6**	**(2.1)**	**6**	**(3.0)**	**15**	**(2.7)**
Asthenia	1	(1.6)	1	(0.3)	2	(1.0)	4	(0.7)
Chest pain	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Chills	1	(1.6)	1	(0.3)	0	(0.0)	2	(0.4)
Fatigue	1	(1.6)	2	(0.7)	2	(1.0)	5	(0.9)
General physical health deterioration	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Pyrexia	2	(3.3)	1	(0.3)	2	(1.0)	5	(0.9)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.5)**	**1**	**(0.2)**
Hepatic pain	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Immune system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**2**	**(0.4)**
Hypersensitivity	0	(0.0)	0	(0.0)	2	(1.0)	2	(0.4)
Infections and infestations	**3**	**(4.9)**	**15**	**(5.2)**	**9**	**(4.5)**	**27**	**(4.9)**
Arthritis bacterial	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Bronchitis	1	(1.6)	1	(0.3)	0	(0.0)	2	(0.4)
Diverticulitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Infective exacerbation of chronic obstructive airways disease	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)

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Subjects With Adverse Events Resulting in Treatment Interruption (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**3**	**(4.9)**	**15**	**(5.2)**	**9**	**(4.5)**	**27**	**(4.9)**
Lower respiratory tract infection	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Lung infection	0	(0.0)	2	(0.7)	1	(0.5)	3	(0.5)
Oesophageal candidiasis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pneumonia	2	(3.3)	5	(1.7)	2	(1.0)	9	(1.6)
Pneumonia cryptococcal	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Pneumonia viral	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Sepsis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Sinusitis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Tooth infection	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Upper respiratory tract infection	0	(0.0)	2	(0.7)	1	(0.5)	3	(0.5)
Viral infection	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Injury, poisoning and procedural complications	**0**	**(0.0)**	**3**	**(1.0)**	**3**	**(1.5)**	**6**	**(1.1)**
Hip fracture	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Infusion related reaction	0	(0.0)	1	(0.3)	3	(1.5)	4	(0.7)
Laceration	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Investigations	**0**	**(0.0)**	**7**	**(2.4)**	**3**	**(1.5)**	**10**	**(1.8)**
Alanine aminotransferase increased	0	(0.0)	3	(1.0)	2	(1.0)	5	(0.9)
Aspartate aminotransferase increased	0	(0.0)	3	(1.0)	1	(0.5)	4	(0.7)

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Subjects With Adverse Events Resulting in Treatment Interruption (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**0**	**(0.0)**	**7**	**(2.4)**	**3**	**(1.5)**	**10**	**(1.8)**
Blood bilirubin increased	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Blood creatine phosphokinase increased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Transaminases increased	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Weight decreased	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Metabolism and nutrition disorders	**1**	**(1.6)**	**4**	**(1.4)**	**3**	**(1.5)**	**8**	**(1.5)**
Decreased appetite	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Dehydration	1	(1.6)	1	(0.3)	0	(0.0)	2	(0.4)
Hypercalcaemia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Hypokalaemia	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Hypomagnesaemia	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Hyponatraemia	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Musculoskeletal and connective tissue disorders	**0**	**(0.0)**	**7**	**(2.4)**	**2**	**(1.0)**	**9**	**(1.6)**
Arthralgia	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Arthritis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Back pain	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Intervertebral disc protrusion	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Musculoskeletal pain	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Myalgia	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Tendonitis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)

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Subjects With Adverse Events Resulting in Treatment Interruption (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(1.6)**	**2**	**(0.7)**	**1**	**(0.5)**	**4**	**(0.7)**
Leiomyosarcoma	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Malignant pleural effusion	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pericardial effusion malignant	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Tumour pain	1	(1.6)	0	(0.0)	1	(0.5)	2	(0.4)
Nervous system disorders	**1**	**(1.6)**	**3**	**(1.0)**	**3**	**(1.5)**	**7**	**(1.3)**
Cerebrovascular accident	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Convulsion	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Myasthenic syndrome	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Presyncope	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Restless legs syndrome	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Syncope	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Vasogenic cerebral oedema	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Psychiatric disorders	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.2)**
Confusional state	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Renal and urinary disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Dysuria	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Microalbuminuria	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Respiratory, thoracic and mediastinal disorders	**3**	**(4.9)**	**13**	**(4.5)**	**8**	**(4.0)**	**24**	**(4.4)**

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Subjects With Adverse Events Resulting in Treatment Interruption (Incidence > 0% in One or More Treatment Groups) All Subjects with NSCLC by Dose (All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**3**	**(4.9)**	**13**	**(4.5)**	**8**	**(4.0)**	**24**	**(4.4)**
Atelectasis	1	(1.6)	0	(0.0)	0	(0.0)	1	(0.2)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	2	(1.0)	2	(0.4)
Cough	1	(1.6)	1	(0.3)	1	(0.5)	3	(0.5)
Dyspnoea	0	(0.0)	2	(0.7)	3	(1.5)	5	(0.9)
Hypoxia	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Obstructive airways disorder	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Pleural effusion	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Pneumonitis	1	(1.6)	3	(1.0)	1	(0.5)	5	(0.9)
Pneumothorax	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Pulmonary embolism	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Pulmonary oedema	0	(0.0)	2	(0.7)	0	(0.0)	2	(0.4)
Rhinorrhoea	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Throat tightness	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**4**	**(1.4)**	**2**	**(1.0)**	**6**	**(1.1)**
Dermatitis	0	(0.0)	1	(0.3)	1	(0.5)	2	(0.4)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Hyperkeratosis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Lichen planus	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Lichenoid keratosis	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Rash	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)
Vascular disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Hypertension	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.2)

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Subjects With Adverse Events Resulting in Treatment Interruption
(Incidence > 0% in One or More Treatment Groups)
All Subjects with NSCLC by Dose
(All Subjects as Treated)

	MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.5)**	**2**	**(0.4)**
Peripheral ischaemia	0	(0.0)	0	(0.0)	1	(0.5)	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 "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.
(Database Cutoff Date: [redacted])

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