付録 2.7.4- 19　　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 高発現）

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	133				288			
with one or more adverse events	126	(94.7)	75	(56.4)	278	(96.5)	145	(50.3)
with no adverse events	7	(5.3)	58	(43.6)	10	(3.5)	143	(49.7)
Blood and lymphatic system disorders	**47**	**(35.3)**	**28**	**(21.1)**	**54**	**(18.8)**	**15**	**(5.2)**
Anaemia	28	(21.1)	5	(3.8)	36	(12.5)	8	(2.8)
Febrile neutropenia	7	(5.3)	7	(5.3)	2	(0.7)	2	(0.7)
Leukaemoid reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Leukocytosis	4	(3.0)	1	(0.8)	3	(1.0)	0	(0.0)
Leukopenia	4	(3.0)	4	(3.0)	4	(1.4)	1	(0.3)
Lymphadenopathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lymphopenia	1	(0.8)	0	(0.0)	7	(2.4)	0	(0.0)
Microcytic anaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Neutropenia	20	(15.0)	18	(13.5)	1	(0.3)	0	(0.0)
Neutrophilia	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Normochromic normocytic anaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Thrombocytopenia	2	(1.5)	0	(0.0)	2	(0.7)	2	(0.7)
Thrombocytosis	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Cardiac disorders	**8**	**(6.0)**	**1**	**(0.8)**	**20**	**(6.9)**	**9**	**(3.1)**
Acute myocardial infarction	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Arrhythmia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Atrial fibrillation	3	(2.3)	1	(0.8)	2	(0.7)	0	(0.0)
Atrial flutter	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Atrioventricular block	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Bradycardia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**8**	**(6.0)**	**1**	**(0.8)**	**20**	**(6.9)**	**9**	**(3.1)**
Bundle branch block left	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Cardiac failure congestive	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Cardiac tamponade	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Cardiopulmonary failure	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Coronary artery disease	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Palpitations	1	(0.8)	0	(0.0)	1	(0.3)	1	(0.3)
Pericardial effusion	0	(0.0)	0	(0.0)	4	(1.4)	4	(1.4)
Sinus bradycardia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Sinus tachycardia	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Supraventricular tachycardia	1	(0.8)	0	(0.0)	2	(0.7)	1	(0.3)
Tachycardia	1	(0.8)	0	(0.0)	5	(1.7)	0	(0.0)
Ear and labyrinth disorders	**4**	**(3.0)**	**0**	**(0.0)**	**9**	**(3.1)**	**0**	**(0.0)**
Deafness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ear pruritus	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypoacusis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Otorrhoea	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tinnitus	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Vertigo	3	(2.3)	0	(0.0)	2	(0.7)	0	(0.0)
Vestibular disorder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Endocrine disorders	**5**	**(3.8)**	**0**	**(0.0)**	**43**	**(14.9)**	**3**	**(1.0)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	4	(1.4)	1	(0.3)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**5**	**(3.8)**	**0**	**(0.0)**	**43**	**(14.9)**	**3**	**(1.0)**
Goitre	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperthyroidism	3	(2.3)	0	(0.0)	18	(6.3)	1	(0.3)
Hypopituitarism	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hypothalamo-pituitary disorder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypothyroidism	1	(0.8)	0	(0.0)	29	(10.1)	0	(0.0)
Thyroiditis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Eye disorders	**14**	**(10.5)**	**0**	**(0.0)**	**33**	**(11.5)**	**3**	**(1.0)**
Blepharitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blepharospasm	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cataract	0	(0.0)	0	(0.0)	4	(1.4)	2	(0.7)
Cataract subcapsular	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctival haemorrhage	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Conjunctivitis allergic	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Dry eye	1	(0.8)	0	(0.0)	6	(2.1)	0	(0.0)
Eye haemorrhage	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Eye irritation	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Eye oedema	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Eye pain	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Eyelid irritation	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Glaucoma	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Lacrimation increased	8	(6.0)	0	(0.0)	3	(1.0)	0	(0.0)
Ocular discomfort	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ocular hyperaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Retinal detachment	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**14**	**(10.5)**	**0**	**(0.0)**	**33**	**(11.5)**	**3**	**(1.0)**
Vision blurred	2	(1.5)	0	(0.0)	8	(2.8)	0	(0.0)
Visual acuity reduced	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Visual impairment	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Vitreous floaters	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Gastrointestinal disorders	**86**	**(64.7)**	**8**	**(6.0)**	**162**	**(56.3)**	**20**	**(6.9)**
Abdominal discomfort	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Abdominal distension	2	(1.5)	0	(0.0)	5	(1.7)	0	(0.0)
Abdominal pain	7	(5.3)	0	(0.0)	21	(7.3)	0	(0.0)
Abdominal pain lower	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Abdominal pain upper	2	(1.5)	0	(0.0)	6	(2.1)	1	(0.3)
Aerophagia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ascites	2	(1.5)	1	(0.8)	4	(1.4)	2	(0.7)
Chronic gastritis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Colitis	0	(0.0)	0	(0.0)	2	(0.7)	1	(0.3)
Colitis ischaemic	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Constipation	16	(12.0)	0	(0.0)	48	(16.7)	3	(1.0)
Dental discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	43	(32.3)	3	(2.3)	46	(16.0)	0	(0.0)
Dry mouth	3	(2.3)	0	(0.0)	14	(4.9)	1	(0.3)
Duodenitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dyspepsia	9	(6.8)	0	(0.0)	5	(1.7)	0	(0.0)
Dysphagia	0	(0.0)	0	(0.0)	9	(3.1)	1	(0.3)
Eructation	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Faecaloma	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**86**	**(64.7)**	**8**	**(6.0)**	**162**	**(56.3)**	**20**	**(6.9)**
Flatulence	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Gastric haemorrhage	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Gastritis	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Gastritis erosive	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gastrointestinal disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal motility disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrooesophageal reflux disease	4	(3.0)	0	(0.0)	6	(2.1)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Haematemesis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Haemorrhoids	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hiatus hernia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperchlorhydria	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ileus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Inguinal hernia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Intra-abdominal haemorrhage	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Large intestinal obstruction	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Lip dry	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Lip pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nausea	26	(19.5)	1	(0.8)	68	(23.6)	5	(1.7)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Oesophageal stenosis	2	(1.5)	1	(0.8)	0	(0.0)	0	(0.0)
Oral disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oral dysaesthesia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	2	(1.5)	0	(0.0)	2	(0.7)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**86**	**(64.7)**	**8**	**(6.0)**	**162**	**(56.3)**	**20**	**(6.9)**
Pancreatitis acute	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Periodontal disease	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Proctitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Rectal haemorrhage	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Salivary hypersecretion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Stomatitis	25	(18.8)	0	(0.0)	17	(5.9)	1	(0.3)
Tongue discolouration	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Toothache	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Vomiting	17	(12.8)	1	(0.8)	47	(16.3)	2	(0.7)
General disorders and administration site conditions	**89**	**(66.9)**	**14**	**(10.5)**	**167**	**(58.0)**	**21**	**(7.3)**
Asthenia	21	(15.8)	2	(1.5)	34	(11.8)	2	(0.7)
Axillary pain	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Catheter site erythema	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Catheter site pain	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Catheter site rash	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Chest pain	12	(9.0)	1	(0.8)	19	(6.6)	3	(1.0)
Chills	3	(2.3)	0	(0.0)	4	(1.4)	0	(0.0)
Cyst	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Death	1	(0.8)	1	(0.8)	3	(1.0)	3	(1.0)
Device breakage	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Early satiety	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Enanthema	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**89**	**(66.9)**	**14**	**(10.5)**	**167**	**(58.0)**	**21**	**(7.3)**
Face oedema	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Fatigue	42	(31.6)	7	(5.3)	81	(28.1)	9	(3.1)
Feeling cold	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Gait disturbance	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	0	(0.0)	0	(0.0)	3	(1.0)	2	(0.7)
Generalised oedema	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Inflammation	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	11	(3.8)	0	(0.0)
Infusion site discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site extravasation	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Infusion site pruritus	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Infusion site vasculitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site bruising	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Injection site reaction	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Local swelling	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Malaise	5	(3.8)	0	(0.0)	12	(4.2)	0	(0.0)
Mucosal dryness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Mucosal inflammation	3	(2.3)	1	(0.8)	3	(1.0)	0	(0.0)
Nodule	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Non-cardiac chest pain	1	(0.8)	0	(0.0)	8	(2.8)	1	(0.3)
Oedema	3	(2.3)	0	(0.0)	5	(1.7)	0	(0.0)
Oedema peripheral	16	(12.0)	0	(0.0)	25	(8.7)	1	(0.3)
Pain	3	(2.3)	0	(0.0)	4	(1.4)	2	(0.7)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**89**	**(66.9)**	**14**	**(10.5)**	**167**	**(58.0)**	**21**	**(7.3)**
Performance status decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Peripheral swelling	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Pyrexia	22	(16.5)	2	(1.5)	33	(11.5)	1	(0.3)
Sensation of foreign body	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Serositis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**8**	**(2.8)**	**4**	**(1.4)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Bile duct obstruction	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Cholangitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cholestasis	0	(0.0)	0	(0.0)	2	(0.7)	1	(0.3)
Hepatic failure	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hepatic steatosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hepatotoxicity	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Jaundice cholestatic	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Portal hypertension	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Immune system disorders	**4**	**(3.0)**	**0**	**(0.0)**	**8**	**(2.8)**	**1**	**(0.3)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Contrast media allergy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Drug hypersensitivity	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Hypersensitivity	3	(2.3)	0	(0.0)	1	(0.3)	0	(0.0)
Seasonal allergy	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**44**	**(33.1)**	**18**	**(13.5)**	**112**	**(38.9)**	**28**	**(9.7)**
Acarodermatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Anal abscess	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Bacteraemia	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Bronchitis	1	(0.8)	1	(0.8)	6	(2.1)	0	(0.0)
Bronchopneumonia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Candida infection	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Cellulitis	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Clostridium difficile colitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Clostridium difficile infection	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Conjunctivitis	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Cystitis	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Device related infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Diverticulitis	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
External ear cellulitis	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Eye infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Folliculitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Fungal infection	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Fungal oesophagitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Fungal skin infection	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Gastroenteritis	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Gastroenteritis viral	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gastrointestinal infection	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Herpes simplex	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Herpes zoster	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**44**	**(33.1)**	**18**	**(13.5)**	**112**	**(38.9)**	**28**	**(9.7)**
Infected skin ulcer	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Infection	1	(0.8)	0	(0.0)	2	(0.7)	1	(0.3)
Infection masked	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Infection parasitic	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Infectious colitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Influenza	3	(2.3)	0	(0.0)	4	(1.4)	1	(0.3)
Laryngitis	1	(0.8)	1	(0.8)	2	(0.7)	0	(0.0)
Lobar pneumonia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	2	(1.5)	1	(0.8)	5	(1.7)	0	(0.0)
Lung abscess	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lung infection	4	(3.0)	1	(0.8)	8	(2.8)	2	(0.7)
Mucosal infection	1	(0.8)	1	(0.8)	2	(0.7)	0	(0.0)
Nail infection	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Nasopharyngitis	7	(5.3)	1	(0.8)	18	(6.3)	0	(0.0)
Onychomycosis	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	3	(2.3)	0	(0.0)	6	(2.1)	0	(0.0)
Oral fungal infection	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Oropharyngeal candidiasis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Osteomyelitis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Paronychia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Perichondritis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Periodontitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Pharyngitis	1	(0.8)	0	(0.0)	2	(0.7)	1	(0.3)
Phlebitis infective	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**44**	**(33.1)**	**18**	**(13.5)**	**112**	**(38.9)**	**28**	**(9.7)**
Pneumonia	8	(6.0)	6	(4.5)	20	(6.9)	14	(4.9)
Pneumonia bacterial	1	(0.8)	1	(0.8)	2	(0.7)	1	(0.3)
Pneumonia haemophilus	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pneumonia pneumococcal	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Pyuria	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rash pustular	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Respiratory tract infection	5	(3.8)	1	(0.8)	9	(3.1)	3	(1.0)
Rhinitis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Sepsis	1	(0.8)	1	(0.8)	2	(0.7)	0	(0.0)
Septic shock	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Sialoadenitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Sinusitis	1	(0.8)	0	(0.0)	7	(2.4)	0	(0.0)
Skin candida	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Skin infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Sputum purulent	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Staphylococcal infection	1	(0.8)	1	(0.8)	1	(0.3)	1	(0.3)
Tonsillitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tooth infection	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Tracheitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Upper respiratory tract infection	6	(4.5)	1	(0.8)	10	(3.5)	1	(0.3)
Urinary tract infection	3	(2.3)	0	(0.0)	11	(3.8)	0	(0.0)
Urinary tract infection viral	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Urosepsis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Vaginal infection	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Viral infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**44**	**(33.1)**	**18**	**(13.5)**	**112**	**(38.9)**	**28**	**(9.7)**
Vulvovaginal mycotic infection	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Injury, poisoning and procedural complications	**14**	**(10.5)**	**3**	**(2.3)**	**37**	**(12.8)**	**3**	**(1.0)**
Arthropod bite	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Clavicle fracture	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Contusion	3	(2.3)	1	(0.8)	6	(2.1)	1	(0.3)
Epicondylitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Eschar	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Facial bones fracture	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Fall	2	(1.5)	0	(0.0)	3	(1.0)	0	(0.0)
Foot fracture	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Heat stroke	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hip fracture	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Humerus fracture	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Infusion related reaction	4	(3.0)	0	(0.0)	3	(1.0)	0	(0.0)
Injection related reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Joint injury	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Limb injury	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Muscle rupture	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Muscle strain	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Procedural pain	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Radiation necrosis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Radiation pneumonitis	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**14**	**(10.5)**	**3**	**(2.3)**	**37**	**(12.8)**	**3**	**(1.0)**
Rib fracture	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Seroma	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Spinal compression fracture	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Sunburn	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Traumatic intracranial haemorrhage	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Wound	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	**28**	**(21.1)**	**14**	**(10.5)**	**88**	**(30.6)**	**18**	**(6.3)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Alanine aminotransferase increased	2	(1.5)	0	(0.0)	16	(5.6)	3	(1.0)
Aspartate aminotransferase	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Aspartate aminotransferase increased	1	(0.8)	0	(0.0)	14	(4.9)	4	(1.4)
Blood albumin decreased	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Blood albumin increased	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Blood alkaline phosphatase increased	1	(0.8)	0	(0.0)	13	(4.5)	4	(1.4)
Blood bilirubin increased	0	(0.0)	0	(0.0)	5	(1.7)	1	(0.3)
Blood chloride decreased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Blood creatine increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood creatine phosphokinase increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood creatinine increased	1	(0.8)	0	(0.0)	17	(5.9)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**28**	**(21.1)**	**14**	**(10.5)**	**88**	**(30.6)**	**18**	**(6.3)**
Blood follicle stimulating hormone increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood iron decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood lactate dehydrogenase increased	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Blood luteinising hormone increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood magnesium decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood phosphorus decreased	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Blood phosphorus increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood prolactin increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood sodium decreased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Blood triglycerides increased	0	(0.0)	0	(0.0)	3	(1.0)	1	(0.3)
Blood urea increased	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Breath sounds abnormal	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
C-reactive protein increased	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Electrocardiogram QT prolonged	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Electrocardiogram T wave inversion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gamma-glutamyltransferase increased	2	(1.5)	0	(0.0)	11	(3.8)	4	(1.4)
General physical condition abnormal	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Haematocrit decreased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Haemoglobin decreased	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
International normalised ratio increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**28**	**(21.1)**	**14**	**(10.5)**	**88**	**(30.6)**	**18**	**(6.3)**
Lymphocyte count decreased	2	(1.5)	1	(0.8)	3	(1.0)	2	(0.7)
Neutrophil count decreased	11	(8.3)	9	(6.8)	4	(1.4)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Platelet count decreased	1	(0.8)	1	(0.8)	3	(1.0)	1	(0.3)
Platelet count increased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Protein total decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Prothrombin time prolonged	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
QRS axis abnormal	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Red blood cell count decreased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Thyroxine decreased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Thyroxine increased	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Transaminases increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tri-iodothyronine decreased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Tri-iodothyronine free decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tri-iodothyronine free increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Waist circumference increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Weight decreased	4	(3.0)	0	(0.0)	24	(8.3)	2	(0.7)
Weight increased	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
White blood cell count decreased	8	(6.0)	5	(3.8)	2	(0.7)	0	(0.0)
White blood cell count increased	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Metabolism and nutrition disorders	**57**	**(42.9)**	**7**	**(5.3)**	**121**	**(42.0)**	**32**	**(11.1)**
Decreased appetite	35	(26.3)	3	(2.3)	75	(26.0)	5	(1.7)
Dehydration	4	(3.0)	1	(0.8)	8	(2.8)	2	(0.7)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**57**	**(42.9)**	7	**(5.3)**	**121**	**(42.0)**	**32**	**(11.1)**
Diabetes mellitus	1	(0.8)	0	(0.0)	2	(0.7)	1	(0.3)
Electrolyte imbalance	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Fluid retention	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperamylasaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hypercalcaemia	2	(1.5)	0	(0.0)	7	(2.4)	2	(0.7)
Hypercholesterolaemia	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Hyperglycaemia	7	(5.3)	1	(0.8)	16	(5.6)	6	(2.1)
Hyperkalaemia	2	(1.5)	0	(0.0)	5	(1.7)	0	(0.0)
Hypernatraemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypertriglyceridaemia	3	(2.3)	1	(0.8)	11	(3.8)	3	(1.0)
Hyperuricaemia	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Hypoalbuminaemia	2	(1.5)	0	(0.0)	10	(3.5)	1	(0.3)
Hypocalcaemia	1	(0.8)	0	(0.0)	8	(2.8)	1	(0.3)
Hypochloraemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypokalaemia	5	(3.8)	1	(0.8)	10	(3.5)	3	(1.0)
Hypomagnesaemia	2	(1.5)	0	(0.0)	11	(3.8)	0	(0.0)
Hyponatraemia	2	(1.5)	0	(0.0)	16	(5.6)	6	(2.1)
Hypophosphataemia	2	(1.5)	0	(0.0)	3	(1.0)	3	(1.0)
Iron deficiency	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Lactic acidosis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Musculoskeletal and connective tissue disorders	**42**	**(31.6)**	**3**	**(2.3)**	**138**	**(47.9)**	**15**	**(5.2)**

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**42**	**(31.6)**	**3**	**(2.3)**	**138**	**(47.9)**	**15**	**(5.2)**
Arthralgia	12	(9.0)	1	(0.8)	41	(14.2)	3	(1.0)
Arthritis	0	(0.0)	0	(0.0)	8	(2.8)	1	(0.3)
Arthropathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Back pain	7	(5.3)	1	(0.8)	32	(11.1)	5	(1.7)
Bone pain	3	(2.3)	0	(0.0)	2	(0.7)	2	(0.7)
Bursitis	0	(0.0)	0	(0.0)	5	(1.7)	0	(0.0)
Dupuytren's contracture	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Flank pain	0	(0.0)	0	(0.0)	3	(1.0)	1	(0.3)
Groin pain	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Joint stiffness	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Joint swelling	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Limb discomfort	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Lower extremity mass	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Mastication disorder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Mobility decreased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Muscle atrophy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Muscle fatigue	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle haemorrhage	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Muscle spasms	3	(2.3)	0	(0.0)	8	(2.8)	0	(0.0)
Muscular weakness	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	11	(3.8)	1	(0.3)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	5	(1.7)	0	(0.0)
Musculoskeletal pain	4	(3.0)	0	(0.0)	24	(8.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**42**	**(31.6)**	**3**	**(2.3)**	**138**	**(47.9)**	**15**	**(5.2)**
Musculoskeletal stiffness	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Myalgia	15	(11.3)	0	(0.0)	23	(8.0)	1	(0.3)
Myopathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Neck pain	2	(1.5)	1	(0.8)	9	(3.1)	0	(0.0)
Osteoarthritis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Osteoporosis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Osteoporotic fracture	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Pain in extremity	4	(3.0)	0	(0.0)	18	(6.3)	2	(0.7)
Pain in jaw	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Pathological fracture	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Plantar fasciitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rhabdomyolysis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal column stenosis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Spinal pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Synovial cyst	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Tendonitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**2**	**(1.5)**	**0**	**(0.0)**	**21**	**(7.3)**	**8**	**(2.8)**
Basal cell carcinoma	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cancer pain	1	(0.8)	0	(0.0)	4	(1.4)	1	(0.3)
Lung neoplasm malignant	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Malignant pleural effusion	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Metastases to bone	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**2**	**(1.5)**	**0**	**(0.0)**	**21**	**(7.3)**	**8**	**(2.8)**
Metastases to central nervous system	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Metastatic pain	0	(0.0)	0	(0.0)	2	(0.7)	2	(0.7)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Skin papilloma	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tumour associated fever	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Tumour pain	0	(0.0)	0	(0.0)	5	(1.7)	2	(0.7)
Nervous system disorders	**55**	**(41.4)**	**5**	**(3.8)**	**93**	**(32.3)**	**11**	**(3.8)**
Amnesia	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Aphasia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Apraxia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ataxia	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Balance disorder	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Burning sensation	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Cerebellar syndrome	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Cerebral haematoma	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cerebral ischaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cerebrovascular accident	0	(0.0)	0	(0.0)	2	(0.7)	2	(0.7)
Cervical radiculopathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Clumsiness	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Cognitive disorder	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Coordination abnormal	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Disturbance in attention	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dizziness	6	(4.5)	0	(0.0)	24	(8.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**55**	**(41.4)**	**5**	**(3.8)**	**93**	**(32.3)**	**11**	**(3.8)**
Dysaesthesia	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Dysarthria	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	12	(9.0)	0	(0.0)	7	(2.4)	0	(0.0)
Encephalopathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Epilepsy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Haemorrhage intracranial	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Headache	10	(7.5)	1	(0.8)	24	(8.3)	3	(1.0)
Hemiparesis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Hypoaesthesia	5	(3.8)	0	(0.0)	10	(3.5)	0	(0.0)
Hypogeusia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Incoherent	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Intracranial aneurysm	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Ischaemic stroke	0	(0.0)	0	(0.0)	2	(0.7)	2	(0.7)
Lethargy	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Memory impairment	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Migraine	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Muscle spasticity	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Neuralgia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Neuropathy peripheral	14	(10.5)	0	(0.0)	8	(2.8)	0	(0.0)
Neurotoxicity	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	10	(7.5)	0	(0.0)	6	(2.1)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Peripheral sensory neuropathy	11	(8.3)	0	(0.0)	5	(1.7)	0	(0.0)
Peroneal nerve palsy	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**55**	**(41.4)**	**5**	**(3.8)**	**93**	**(32.3)**	**11**	**(3.8)**
Polyneuropathy	1	(0.8)	1	(0.8)	1	(0.3)	0	(0.0)
Radial nerve palsy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Sciatica	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Seizure	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Slow speech	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Somnolence	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Syncope	2	(1.5)	2	(1.5)	4	(1.4)	1	(0.3)
Toxic leukoencephalopathy	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Transient ischaemic attack	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tremor	2	(1.5)	0	(0.0)	2	(0.7)	0	(0.0)
VIIth nerve paralysis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vasogenic cerebral oedema	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Psychiatric disorders	**15**	**(11.3)**	**0**	**(0.0)**	**43**	**(14.9)**	**3**	**(1.0)**
Agitation	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Anxiety	4	(3.0)	0	(0.0)	12	(4.2)	1	(0.3)
Bradyphrenia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Confusional state	3	(2.3)	0	(0.0)	5	(1.7)	1	(0.3)
Delirium	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Depressed mood	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Depression	1	(0.8)	0	(0.0)	6	(2.1)	0	(0.0)
Disorientation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Hallucination	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Insomnia	8	(6.0)	0	(0.0)	19	(6.6)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric disorders	**15**	**(11.3)**	**0**	**(0.0)**	**43**	**(14.9)**	**3**	**(1.0)**
Irritability	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Mental status changes	0	(0.0)	0	(0.0)	4	(1.4)	1	(0.3)
Nervousness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Panic attack	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Restlessness	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Renal and urinary disorders	**7**	**(5.3)**	**0**	**(0.0)**	**31**	**(10.8)**	**5**	**(1.7)**
Acute kidney injury	0	(0.0)	0	(0.0)	3	(1.0)	3	(1.0)
Chromaturia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Chronic kidney disease	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dysuria	1	(0.8)	0	(0.0)	7	(2.4)	0	(0.0)
Haematuria	1	(0.8)	0	(0.0)	3	(1.0)	1	(0.3)
Hypertonic bladder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Micturition urgency	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nocturia	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Pelvi-ureteric obstruction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pollakiuria	1	(0.8)	0	(0.0)	5	(1.7)	0	(0.0)
Polyuria	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Renal pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Strangury	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Urinary incontinence	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**7**	**(5.3)**	**0**	**(0.0)**	**31**	**(10.8)**	**5**	**(1.7)**
Urinary tract obstruction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**2**	**(1.5)**	**0**	**(0.0)**	**8**	**(2.8)**	**1**	**(0.3)**
Erectile dysfunction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pelvic pain	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Testicular pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vaginal haemorrhage	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Vulvovaginal burning sensation	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vulvovaginal dryness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vulvovaginal pruritus	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**64**	**(48.1)**	**11**	**(8.3)**	**148**	**(51.4)**	**35**	**(12.2)**
Acute respiratory failure	0	(0.0)	0	(0.0)	2	(0.7)	2	(0.7)
Asthma	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Bronchitis chronic	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Bronchospasm	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Chronic obstructive pulmonary disease	2	(1.5)	1	(0.8)	11	(3.8)	7	(2.4)
Chronic respiratory failure	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cough	18	(13.5)	0	(0.0)	58	(20.1)	3	(1.0)
Dysphonia	2	(1.5)	0	(0.0)	9	(3.1)	0	(0.0)
Dyspnoea	25	(18.8)	5	(3.8)	58	(20.1)	8	(2.8)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**64**	**(48.1)**	**11**	**(8.3)**	**148**	**(51.4)**	**35**	**(12.2)**
Dyspnoea exertional	0	(0.0)	0	(0.0)	5	(1.7)	0	(0.0)
Epistaxis	5	(3.8)	0	(0.0)	8	(2.8)	0	(0.0)
Haemoptysis	12	(9.0)	0	(0.0)	15	(5.2)	1	(0.3)
Hiccups	4	(3.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypoxia	1	(0.8)	0	(0.0)	4	(1.4)	1	(0.3)
Interstitial lung disease	1	(0.8)	1	(0.8)	1	(0.3)	0	(0.0)
Lung infiltration	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nasal congestion	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Nasal discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal dryness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nasal inflammation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal discomfort	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Oropharyngeal pain	4	(3.0)	0	(0.0)	9	(3.1)	0	(0.0)
Painful respiration	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Paranasal sinus discomfort	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pharyngeal inflammation	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Pleural effusion	5	(3.8)	2	(1.5)	10	(3.5)	3	(1.0)
Pleuritic pain	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Pneumonia aspiration	1	(0.8)	1	(0.8)	2	(0.7)	1	(0.3)
Pneumonitis	2	(1.5)	0	(0.0)	17	(5.9)	7	(2.4)
Pneumothorax	3	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)
Productive cough	1	(0.8)	0	(0.0)	16	(5.6)	0	(0.0)
Pulmonary embolism	2	(1.5)	2	(1.5)	8	(2.8)	8	(2.8)
Pulmonary haemorrhage	2	(1.5)	1	(0.8)	1	(0.3)	1	(0.3)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**64**	**(48.1)**	**11**	**(8.3)**	**148**	**(51.4)**	**35**	**(12.2)**
Pulmonary hypertension	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Pulmonary oedema	0	(0.0)	0	(0.0)	2	(0.7)	2	(0.7)
Pulmonary pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pulmonary vascular disorder	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Rales	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Respiratory acidosis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Respiratory failure	2	(1.5)	2	(1.5)	3	(1.0)	3	(1.0)
Respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rhinitis allergic	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Rhinorrhoea	5	(3.8)	0	(0.0)	9	(3.1)	0	(0.0)
Sinus congestion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Sneezing	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Stridor	0	(0.0)	0	(0.0)	2	(0.7)	1	(0.3)
Tachypnoea	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Tracheal inflammation	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Upper respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Upper-airway cough syndrome	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Wheezing	1	(0.8)	0	(0.0)	8	(2.8)	1	(0.3)
Skin and subcutaneous tissue disorders	**65**	**(48.9)**	**4**	**(3.0)**	**106**	**(36.8)**	**2**	**(0.7)**
Acne	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Alopecia	49	(36.8)	2	(1.5)	8	(2.8)	0	(0.0)
Decubitus ulcer	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**65**	**(48.9)**	**4**	**(3.0)**	**106**	**(36.8)**	**2**	**(0.7)**
Dermal cyst	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis allergic	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dry skin	3	(2.3)	0	(0.0)	17	(5.9)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Erythema	1	(0.8)	0	(0.0)	5	(1.7)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperhidrosis	2	(1.5)	0	(0.0)	3	(1.0)	0	(0.0)
Hyperkeratosis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Ingrowing nail	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Macule	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nail discolouration	4	(3.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nail disorder	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nail dystrophy	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	1	(0.8)	0	(0.0)	5	(1.7)	0	(0.0)
Onycholysis	7	(5.3)	1	(0.8)	0	(0.0)	0	(0.0)
Onychomadesis	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Photosensitivity reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**65**	**(48.9)**	**4**	**(3.0)**	**106**	**(36.8)**	**2**	**(0.7)**
Pruritus	5	(3.8)	1	(0.8)	37	(12.8)	0	(0.0)
Pruritus generalised	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Psoriasis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Rash	9	(6.8)	0	(0.0)	49	(17.0)	1	(0.3)
Rash macular	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rash maculo-papular	0	(0.0)	0	(0.0)	6	(2.1)	0	(0.0)
Rash papular	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rash pruritic	2	(1.5)	0	(0.0)	5	(1.7)	0	(0.0)
Scar pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Seborrhoeic dermatitis	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Skin discolouration	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Skin fissures	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Skin lesion	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Skin ulcer	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Telangiectasia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vitiligo	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Xeroderma	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders	**23**	**(17.3)**	**2**	**(1.5)**	**42**	**(14.6)**	**14**	**(4.9)**
Deep vein thrombosis	2	(1.5)	1	(0.8)	4	(1.4)	0	(0.0)
Embolism	0	(0.0)	0	(0.0)	3	(1.0)	1	(0.3)
Flushing	2	(1.5)	0	(0.0)	2	(0.7)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**23**	**(17.3)**	**2**	**(1.5)**	**42**	**(14.6)**	**14**	**(4.9)**
Haematoma	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Hot flush	3	(2.3)	0	(0.0)	8	(2.8)	1	(0.3)
Hypertension	4	(3.0)	1	(0.8)	11	(3.8)	7	(2.4)
Hypotension	2	(1.5)	0	(0.0)	8	(2.8)	1	(0.3)
Intermittent claudication	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Ischaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lymphoedema	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Orthostatic hypotension	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral arterial occlusive disease	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Peripheral ischaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Phlebitis	6	(4.5)	0	(0.0)	0	(0.0)	0	(0.0)
Superior vena cava syndrome	1	(0.8)	1	(0.8)	3	(1.0)	3	(1.0)
Thrombophlebitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Thrombophlebitis superficial	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Thrombosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vena cava thrombosis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Venous thrombosis limb	1	(0.8)	0	(0.0)	0	(0.0)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 20　　有害事象（いずれかの投与群で発現割合 0%超）

010 試験（安全性解析対象集団）（PD-L1 低発現）

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	176				202				192			
with one or more adverse events	171	(97.2)	98	(55.7)	198	(98.0)	89	(44.1)	185	(96.4)	80	(41.7)
with no adverse events	5	(2.8)	78	(44.3)	4	(2.0)	113	(55.9)	7	(3.6)	112	(58.3)
Blood and lymphatic system disorders	**67**	**(38.1)**	**36**	**(20.5)**	**27**	**(13.4)**	**6**	**(3.0)**	**24**	**(12.5)**	**5**	**(2.6)**
Anaemia	32	(18.2)	2	(1.1)	17	(8.4)	5	(2.5)	13	(6.8)	3	(1.6)
Bone marrow failure	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Disseminated intravascular coagulation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Eosinophilia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Febrile neutropenia	10	(5.7)	10	(5.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Granulocytopenia	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypercoagulation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Iron deficiency anaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Leukocytosis	3	(1.7)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Leukopenia	5	(2.8)	4	(2.3)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymph node pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Lymphadenopathy	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Lymphopenia	5	(2.8)	0	(0.0)	2	(1.0)	1	(0.5)	5	(2.6)	0	(0.0)
Neutropenia	30	(17.0)	24	(13.6)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Neutrophilia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia	5	(2.8)	1	(0.6)	2	(1.0)	0	(0.0)	3	(1.6)	1	(0.5)
Thrombocytosis	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**10**	**(5.7)**	**6**	**(3.4)**	**18**	**(8.9)**	**9**	**(4.5)**	**17**	**(8.9)**	**5**	**(2.6)**
Acute coronary syndrome	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Acute myocardial infarction	1	(0.6)	1	(0.6)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Arrhythmia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Arteriosclerosis coronary artery	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrial fibrillation	1	(0.6)	1	(0.6)	4	(2.0)	1	(0.5)	1	(0.5)	0	(0.0)
Atrial flutter	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Atrial thrombosis	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)	0	(0.0)	0	(0.0)
Atrioventricular block complete	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Bradycardia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cardiac arrest	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Cardiac failure	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Cardiac failure acute	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cardio-respiratory arrest	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cardiomyopathy	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Cyanosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Myocardial infarction	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Myocardial ischaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Palpitations	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	0	(0.0)
Pericardial effusion	2	(1.1)	1	(0.6)	3	(1.5)	2	(1.0)	1	(0.5)	1	(0.5)
Pericarditis	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Sinus tachycardia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**10**	**(5.7)**	**6**	**(3.4)**	**18**	**(8.9)**	**9**	**(4.5)**	**17**	**(8.9)**	**5**	**(2.6)**
Supraventricular tachycardia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tachycardia	2	(1.1)	0	(0.0)	2	(1.0)	0	(0.0)	3	(1.6)	0	(0.0)
Ventricular fibrillation	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.5)**	**1**	**(0.5)**	**2**	**(1.0)**	**2**	**(1.0)**
Pyloric stenosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Tracheo-oesophageal fistula	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Ear and labyrinth disorders	**9**	**(5.1)**	**0**	**(0.0)**	**1**	**(0.5)**	**0**	**(0.0)**	**5**	**(2.6)**	**1**	**(0.5)**
Deafness neurosensory	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Ear discomfort	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Ear pain	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ear pruritus	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tinnitus	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Vertigo	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	1	(0.5)
Endocrine disorders	**1**	**(0.6)**	**0**	**(0.0)**	**20**	**(9.9)**	**0**	**(0.0)**	**20**	**(10.4)**	**1**	**(0.5)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Goitre	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperthyroidism	0	(0.0)	0	(0.0)	6	(3.0)	0	(0.0)	8	(4.2)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**1**	**(0.6)**	**0**	**(0.0)**	**20**	**(9.9)**	**0**	**(0.0)**	**20**	**(10.4)**	**1**	**(0.5)**
Hypopituitarism	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Hypothyroidism	0	(0.0)	0	(0.0)	14	(6.9)	0	(0.0)	13	(6.8)	0	(0.0)
Eye disorders	**14**	**(8.0)**	**0**	**(0.0)**	**16**	**(7.9)**	**0**	**(0.0)**	**14**	**(7.3)**	**0**	**(0.0)**
Blindness	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cataract	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctival haemorrhage	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Diplopia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Dry eye	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	3	(1.6)	0	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Eyelid oedema	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eyelid ptosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Halo vision	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Keratitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lacrimation increased	9	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Ocular discomfort	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Photopsia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Scintillating scotoma	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vision blurred	1	(0.6)	0	(0.0)	3	(1.5)	0	(0.0)	4	(2.1)	0	(0.0)
Visual impairment	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Vitreous floaters	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrointestinal disorders	**102**	**(58.0)**	**16**	**(9.1)**	**102**	**(50.5)**	**11**	**(5.4)**	**90**	**(46.9)**	**11**	**(5.7)**
Abdominal discomfort	2	(1.1)	0	(0.0)	4	(2.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**102**	**(58.0)**	**16**	**(9.1)**	**102**	**(50.5)**	**11**	**(5.4)**	**90**	**(46.9)**	**11**	**(5.7)**
Abdominal distension	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Abdominal pain	7	(4.0)	1	(0.6)	8	(4.0)	1	(0.5)	9	(4.7)	2	(1.0)
Abdominal pain lower	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)	0	(0.0)	0	(0.0)
Abdominal pain upper	5	(2.8)	1	(0.6)	8	(4.0)	0	(0.0)	7	(3.6)	0	(0.0)
Anal fissure	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Aptyalism	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ascites	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Breath odour	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Colitis	0	(0.0)	0	(0.0)	3	(1.5)	3	(1.5)	1	(0.5)	0	(0.0)
Constipation	22	(12.5)	2	(1.1)	31	(15.3)	0	(0.0)	26	(13.5)	1	(0.5)
Dental caries	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Diarrhoea	37	(21.0)	5	(2.8)	27	(13.4)	3	(1.5)	22	(11.5)	0	(0.0)
Dry mouth	5	(2.8)	0	(0.0)	4	(2.0)	0	(0.0)	4	(2.1)	0	(0.0)
Dyspepsia	4	(2.3)	0	(0.0)	4	(2.0)	0	(0.0)	2	(1.0)	0	(0.0)
Dysphagia	3	(1.7)	2	(1.1)	7	(3.5)	1	(0.5)	6	(3.1)	3	(1.6)
Faecaloma	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Flatulence	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastritis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal inflammation	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrooesophageal reflux disease	1	(0.6)	0	(0.0)	3	(1.5)	0	(0.0)	4	(2.1)	0	(0.0)
Gingival pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**102**	**(58.0)**	**16**	**(9.1)**	**102**	**(50.5)**	**11**	**(5.4)**	**90**	**(46.9)**	**11**	**(5.7)**
Glossitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Haematochezia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Haemorrhoids	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperchlorhydria	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Large intestinal obstruction	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Lip dry	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Lip ulceration	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Melaena	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Mouth ulceration	3	(1.7)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	31	(17.6)	1	(0.6)	42	(20.8)	2	(1.0)	29	(15.1)	2	(1.0)
Odynophagia	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oesophageal obstruction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Oesophageal pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oesophageal stenosis	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oesophagitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral discomfort	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	4	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia oral	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Periodontal disease	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Proctalgia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Rectal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**102**	**(58.0)**	**16**	**(9.1)**	**102**	**(50.5)**	**11**	**(5.4)**	**90**	**(46.9)**	**11**	**(5.7)**
Regurgitation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Stomatitis	21	(11.9)	3	(1.7)	7	(3.5)	0	(0.0)	6	(3.1)	0	(0.0)
Swollen tongue	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue coated	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue ulceration	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Toothache	3	(1.7)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Umbilical hernia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Upper gastrointestinal haemorrhage	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	15	(8.5)	1	(0.6)	21	(10.4)	1	(0.5)	20	(10.4)	3	(1.6)
General disorders and administration site conditions	**119**	**(67.6)**	**21**	**(11.9)**	**107**	**(53.0)**	**20**	**(9.9)**	**108**	**(56.3)**	**14**	**(7.3)**
Adverse drug reaction	1	(0.6)	1	(0.6)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Asthenia	26	(14.8)	6	(3.4)	23	(11.4)	3	(1.5)	19	(9.9)	4	(2.1)
Axillary pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Catheter site bruise	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Catheter site pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort	2	(1.1)	0	(0.0)	3	(1.5)	0	(0.0)	2	(1.0)	0	(0.0)
Chest pain	8	(4.5)	0	(0.0)	16	(7.9)	2	(1.0)	20	(10.4)	1	(0.5)
Chills	1	(0.6)	0	(0.0)	5	(2.5)	0	(0.0)	7	(3.6)	0	(0.0)
Crepitations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Death	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)	1	(0.5)	1	(0.5)
Device dislocation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**119**	**(67.6)**	**21**	**(11.9)**	**107**	**(53.0)**	**20**	**(9.9)**	**108**	**(56.3)**	**14**	**(7.3)**
Face oedema	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Fatigue	57	(32.4)	10	(5.7)	47	(23.3)	7	(3.5)	43	(22.4)	5	(2.6)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gait disturbance	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	5	(2.8)	2	(1.1)	3	(1.5)	3	(1.5)	2	(1.0)	1	(0.5)
Generalised oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Implant site inflammation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Inflammation	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Influenza like illness	2	(1.1)	0	(0.0)	4	(2.0)	0	(0.0)	4	(2.1)	0	(0.0)
Infusion site extravasation	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site phlebitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site reaction	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site vasculitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Malaise	8	(4.5)	0	(0.0)	5	(2.5)	0	(0.0)	7	(3.6)	0	(0.0)
Medical device pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Mucosal inflammation	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Multi-organ failure	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	3	(1.6)	0	(0.0)
Oedema	4	(2.3)	2	(1.1)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**119**	**(67.6)**	**21**	**(11.9)**	**107**	**(53.0)**	**20**	**(9.9)**	**108**	**(56.3)**	**14**	**(7.3)**
Oedema peripheral	17	(9.7)	0	(0.0)	12	(5.9)	0	(0.0)	16	(8.3)	0	(0.0)
Pain	5	(2.8)	1	(0.6)	4	(2.0)	2	(1.0)	4	(2.1)	0	(0.0)
Peripheral swelling	3	(1.7)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.6)	0	(0.0)
Pyrexia	22	(12.5)	1	(0.6)	23	(11.4)	3	(1.5)	21	(10.9)	1	(0.5)
Sensitivity to weather change	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Temperature intolerance	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Thrombosis in device	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Xerosis	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**1**	**(0.6)**	**0**	**(0.0)**	**2**	**(1.0)**	**1**	**(0.5)**	**7**	**(3.6)**	**2**	**(1.0)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Cholestasis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Hepatic function abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hepatic pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hepatocellular injury	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	1	(0.5)
Hepatomegaly	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumobilia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Immune system disorders	**5**	**(2.8)**	**0**	**(0.0)**	**2**	**(1.0)**	**1**	**(0.5)**	**2**	**(1.0)**	**0**	**(0.0)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Drug hypersensitivity	3	(1.7)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Hypersensitivity	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Immune system disorders	**5**	**(2.8)**	**0**	**(0.0)**	**2**	**(1.0)**	**1**	**(0.5)**	**2**	**(1.0)**	**0**	**(0.0)**
Seasonal allergy	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Infections and infestations	**62**	**(35.2)**	**24**	**(13.6)**	**69**	**(34.2)**	**21**	**(10.4)**	**64**	**(33.3)**	**22**	**(11.5)**
Abscess oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Arthritis infective	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Aspergillus infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Atypical pneumonia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bronchitis	8	(4.5)	3	(1.7)	6	(3.0)	1	(0.5)	6	(3.1)	0	(0.0)
Bronchopneumonia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Candida infection	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Clostridium difficile infection	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Conjunctivitis viral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cystitis	0	(0.0)	0	(0.0)	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Device related infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Device related sepsis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Endocarditis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)
Enterococcal infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Escherichia infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Escherichia urinary tract infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eye infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Folliculitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fungal infection	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**62**	**(35.2)**	**24**	**(13.6)**	**69**	**(34.2)**	**21**	**(10.4)**	**64**	**(33.3)**	**22**	**(11.5)**
Furuncle	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Gastroenteritis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Genital candidiasis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Genital herpes	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Herpes simplex	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Herpes zoster	3	(1.7)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Infected dermal cyst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Infection	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Infectious pleural effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Influenza	0	(0.0)	0	(0.0)	7	(3.5)	1	(0.5)	1	(0.5)	0	(0.0)
Lip infection	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Localised infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	3	(1.7)	1	(0.6)	1	(0.5)	0	(0.0)	3	(1.6)	1	(0.5)
Lung infection	3	(1.7)	1	(0.6)	5	(2.5)	2	(1.0)	1	(0.5)	0	(0.0)
Moraxella infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nail infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nasopharyngitis	10	(5.7)	0	(0.0)	1	(0.5)	0	(0.0)	10	(5.2)	0	(0.0)
Nosocomial infection	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Oesophageal candidiasis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Onychomycosis	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	1	(0.6)	0	(0.0)	4	(2.0)	0	(0.0)	5	(2.6)	0	(0.0)
Oral fungal infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Oral herpes	1	(0.6)	0	(0.0)	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal candidiasis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**62**	**(35.2)**	**24**	**(13.6)**	**69**	**(34.2)**	**21**	**(10.4)**	**64**	**(33.3)**	**22**	**(11.5)**
Osteomyelitis	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Otitis media acute	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Paronychia	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Periodontitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pharyngitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	0	(0.0)
Pharyngitis streptococcal	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural infection	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumocystis jirovecii pneumonia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Pneumonia	13	(7.4)	11	(6.3)	15	(7.4)	10	(5.0)	15	(7.8)	12	(6.3)
Pneumonia influenzal	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Proteus infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pseudomonas infection	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Pyelonephritis acute	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Pyopneumothorax	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Rash pustular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Respiratory tract infection	7	(4.0)	3	(1.7)	9	(4.5)	1	(0.5)	3	(1.6)	1	(0.5)
Respiratory tract infection viral	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Rhinitis	2	(1.1)	0	(0.0)	3	(1.5)	0	(0.0)	4	(2.1)	0	(0.0)
Sepsis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Septic shock	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Sinusitis	1	(0.6)	0	(0.0)	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal cord infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sputum purulent	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**62**	**(35.2)**	**24**	**(13.6)**	**69**	**(34.2)**	**21**	**(10.4)**	**64**	**(33.3)**	**22**	**(11.5)**
Streptococcal urinary tract infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tinea pedis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tooth abscess	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Tooth infection	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tracheitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Trichophytosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tuberculosis gastrointestinal	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract infection	7	(4.0)	1	(0.6)	4	(2.0)	0	(0.0)	8	(4.2)	0	(0.0)
Urinary tract infection	6	(3.4)	2	(1.1)	7	(3.5)	0	(0.0)	7	(3.6)	1	(0.5)
Urosepsis	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaginal infection	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Viral infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vulvitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vulvovaginal candidiasis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Wound sepsis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Injury, poisoning and procedural complications	**15**	**(8.5)**	**3**	**(1.7)**	**14**	**(6.9)**	**4**	**(2.0)**	**14**	**(7.3)**	**3**	**(1.6)**
Ankle fracture	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Arthropod bite	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Contusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**15**	**(8.5)**	**3**	**(1.7)**	**14**	**(6.9)**	**4**	**(2.0)**	**14**	**(7.3)**	**3**	**(1.6)**
Eyelid contusion	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Fall	1	(0.6)	0	(0.0)	2	(1.0)	1	(0.5)	1	(0.5)	1	(0.5)
Femur fracture	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Humerus fracture	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Incisional hernia, obstructive	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Infusion related reaction	4	(2.3)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Ligament sprain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Limb injury	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle injury	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle strain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Post procedural complication	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Post procedural inflammation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Post procedural urine leak	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Procedural pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Radiation pneumonitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Radius fracture	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Rib fracture	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin abrasion	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Skin wound	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**15**	**(8.5)**	**3**	**(1.7)**	**14**	**(6.9)**	**4**	**(2.0)**	**14**	**(7.3)**	**3**	**(1.6)**
Spinal compression fracture	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Thoracic vertebral fracture	1	(0.6)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Toxicity to various agents	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper limb fracture	0	(0.0)	0	(0.0)	3	(1.5)	1	(0.5)	0	(0.0)	0	(0.0)
Investigations	**36**	**(20.5)**	**14**	**(8.0)**	**59**	**(29.2)**	**6**	**(3.0)**	**54**	**(28.1)**	**8**	**(4.2)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Activated partial thromboplastin time shortened	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Alanine aminotransferase increased	2	(1.1)	0	(0.0)	17	(8.4)	1	(0.5)	7	(3.6)	1	(0.5)
Amylase increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Aspartate aminotransferase increased	3	(1.7)	0	(0.0)	11	(5.4)	1	(0.5)	6	(3.1)	0	(0.0)
Aspiration bronchial	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Bilirubin conjugated increased	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood albumin decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**36**	**(20.5)**	**14**	**(8.0)**	**59**	**(29.2)**	**6**	**(3.0)**	**54**	**(28.1)**	**8**	**(4.2)**
Blood alkaline phosphatase increased	2	(1.1)	0	(0.0)	6	(3.0)	0	(0.0)	8	(4.2)	2	(1.0)
Blood bicarbonate decreased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Blood bicarbonate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood bilirubin increased	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood chloride decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood cholesterol decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Blood creatine phosphokinase increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatinine decreased	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatinine increased	3	(1.7)	0	(0.0)	9	(4.5)	0	(0.0)	7	(3.6)	0	(0.0)
Blood iron decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood lactate dehydrogenase increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood magnesium decreased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood magnesium increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**36**	**(20.5)**	**14**	**(8.0)**	**59**	**(29.2)**	**6**	**(3.0)**	**54**	**(28.1)**	**8**	**(4.2)**
Blood phosphorus decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood phosphorus increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood potassium increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood sodium decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Blood triglycerides increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Blood urea increased	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	5	(2.5)	0	(0.0)	1	(0.5)	0	(0.0)
Body temperature increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Breath sounds abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
C-reactive protein increased	1	(0.6)	0	(0.0)	3	(1.5)	0	(0.0)	4	(2.1)	0	(0.0)
Computerised tomogram thorax abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Creatinine renal clearance decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eosinophil count increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Fibrin D dimer increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**36**	**(20.5)**	**14**	**(8.0)**	**59**	**(29.2)**	**6**	**(3.0)**	**54**	**(28.1)**	**8**	**(4.2)**
Forced expiratory volume	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Free thyroxine index increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	1	(0.6)	1	(0.6)	7	(3.5)	2	(1.0)	0	(0.0)	0	(0.0)
Haemoglobin decreased	3	(1.7)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	4	(2.3)	2	(1.1)	1	(0.5)	1	(0.5)	2	(1.0)	0	(0.0)
N-terminal prohormone brain natriuretic peptide increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Neutrophil count decreased	15	(8.5)	11	(6.3)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Oxygen saturation decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Platelet count decreased	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Platelet count increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Protein total increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Protein urine present	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Prothrombin time prolonged	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Transaminases increased	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**36**	**(20.5)**	**14**	**(8.0)**	**59**	**(29.2)**	**6**	**(3.0)**	**54**	**(28.1)**	**8**	**(4.2)**
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Tri-iodothyronine increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Troponin I increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Urine output decreased	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Weight decreased	5	(2.8)	0	(0.0)	19	(9.4)	0	(0.0)	15	(7.8)	1	(0.5)
Weight increased	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
White blood cell count decreased	8	(4.5)	5	(2.8)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
White blood cell count increased	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**55**	**(31.3)**	**11**	**(6.3)**	**82**	**(40.6)**	**13**	**(6.4)**	**63**	**(32.8)**	**13**	**(6.8)**
Cachexia	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Decreased appetite	37	(21.0)	5	(2.8)	52	(25.7)	3	(1.5)	41	(21.4)	2	(1.0)
Dehydration	6	(3.4)	3	(1.7)	3	(1.5)	2	(1.0)	4	(2.1)	1	(0.5)
Diabetes mellitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Diabetic ketoacidosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Failure to thrive	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Hyperalbuminaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hypercalcaemia	3	(1.7)	0	(0.0)	6	(3.0)	2	(1.0)	6	(3.1)	3	(1.6)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	3	(1.5)	0	(0.0)	2	(1.0)	0	(0.0)
Hyperglycaemia	3	(1.7)	1	(0.6)	8	(4.0)	3	(1.5)	4	(2.1)	1	(0.5)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**55**	**(31.3)**	**11**	**(6.3)**	**82**	**(40.6)**	**13**	**(6.4)**	**63**	**(32.8)**	**13**	**(6.8)**
Hyperkalaemia	3	(1.7)	0	(0.0)	4	(2.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperlipidaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypermagnesaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypernatraemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertriglyceridaemia	0	(0.0)	0	(0.0)	4	(2.0)	0	(0.0)	2	(1.0)	1	(0.5)
Hyperuricaemia	1	(0.6)	0	(0.0)	3	(1.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hypoalbuminaemia	5	(2.8)	0	(0.0)	4	(2.0)	0	(0.0)	3	(1.6)	0	(0.0)
Hypocalcaemia	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Hypochloraemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoglycaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypokalaemia	5	(2.8)	1	(0.6)	9	(4.5)	3	(1.5)	2	(1.0)	1	(0.5)
Hypomagnesaemia	6	(3.4)	0	(0.0)	3	(1.5)	0	(0.0)	6	(3.1)	0	(0.0)
Hyponatraemia	1	(0.6)	0	(0.0)	6	(3.0)	3	(1.5)	5	(2.6)	4	(2.1)
Hypophosphataemia	4	(2.3)	1	(0.6)	2	(1.0)	0	(0.0)	3	(1.6)	1	(0.5)
Hypoproteinaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Iron deficiency	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lactose intolerance	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Polydipsia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vitamin D deficiency	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**70**	**(39.8)**	**2**	**(1.1)**	**74**	**(36.6)**	**5**	**(2.5)**	**83**	**(43.2)**	**12**	**(6.3)**
Arthralgia	16	(9.1)	0	(0.0)	19	(9.4)	1	(0.5)	15	(7.8)	3	(1.6)
Arthritis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Back pain	17	(9.7)	0	(0.0)	19	(9.4)	0	(0.0)	22	(11.5)	5	(2.6)
Bone lesion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Bone pain	3	(1.7)	0	(0.0)	4	(2.0)	0	(0.0)	6	(3.1)	2	(1.0)
Bursitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Clubbing	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Flank pain	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Groin pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Joint instability	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Joint swelling	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Muscle necrosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	1	(0.6)	0	(0.0)	4	(2.0)	0	(0.0)	4	(2.1)	0	(0.0)
Muscular weakness	8	(4.5)	0	(0.0)	4	(2.0)	0	(0.0)	7	(3.6)	0	(0.0)
Musculoskeletal chest pain	2	(1.1)	0	(0.0)	6	(3.0)	0	(0.0)	4	(2.1)	0	(0.0)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Musculoskeletal pain	6	(3.4)	0	(0.0)	22	(10.9)	4	(2.0)	19	(9.9)	1	(0.5)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	0	(0.0)
Myalgia	19	(10.8)	0	(0.0)	8	(4.0)	0	(0.0)	4	(2.1)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Myositis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neck mass	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**70**	**(39.8)**	**2**	**(1.1)**	**74**	**(36.6)**	**5**	**(2.5)**	**83**	**(43.2)**	**12**	**(6.3)**
Neck pain	2	(1.1)	1	(0.6)	6	(3.0)	0	(0.0)	7	(3.6)	1	(0.5)
Osteoarthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Pain in extremity	9	(5.1)	0	(0.0)	10	(5.0)	1	(0.5)	14	(7.3)	1	(0.5)
Pain in jaw	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pathological fracture	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Periarthritis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Polyarthritis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal osteoarthritis	1	(0.6)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Synovial cyst	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Synovitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**9**	**(5.1)**	**0**	**(0.0)**	**7**	**(3.5)**	**5**	**(2.5)**	**8**	**(4.2)**	**4**	**(2.1)**
Cancer pain	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	1	(0.5)
Gastric cancer	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Lymphangiosis carcinomatosa	1	(0.6)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Malignant neoplasm progression	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Malignant pleural effusion	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**9**	**(5.1)**	**0**	**(0.0)**	**7**	**(3.5)**	**5**	**(2.5)**	**8**	**(4.2)**	**4**	**(2.1)**
Metastases to central nervous system	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Metastatic pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Paraneoplastic syndrome	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Seborrhoeic keratosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin papilloma	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tumour exudation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tumour pain	3	(1.7)	0	(0.0)	1	(0.5)	1	(0.5)	4	(2.1)	2	(1.0)
Nervous system disorders	**65**	**(36.9)**	**5**	**(2.8)**	**55**	**(27.2)**	**3**	**(1.5)**	**59**	**(30.7)**	**9**	**(4.7)**
Aphonia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Brain oedema	1	(0.6)	1	(0.6)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Cerebrovascular accident	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Diabetic neuropathy	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Disturbance in attention	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dizziness	6	(3.4)	1	(0.6)	11	(5.4)	0	(0.0)	13	(6.8)	1	(0.5)
Dysaesthesia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dysarthria	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dysgeusia	6	(3.4)	0	(0.0)	4	(2.0)	0	(0.0)	3	(1.6)	0	(0.0)
Encephalopathy	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**65**	**(36.9)**	**5**	**(2.8)**	**55**	**(27.2)**	**3**	**(1.5)**	**59**	**(30.7)**	**9**	**(4.7)**
Epilepsy	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Extensor plantar response	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Facial neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Headache	9	(5.1)	0	(0.0)	23	(11.4)	0	(0.0)	17	(8.9)	0	(0.0)
Hypersomnia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Hypoaesthesia	3	(1.7)	0	(0.0)	3	(1.5)	0	(0.0)	5	(2.6)	0	(0.0)
Hypogeusia	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ischaemic stroke	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Migraine with aura	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Myelitis transverse	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Myoclonus	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nervous system disorder	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neurological decompensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Neuropathy peripheral	22	(12.5)	1	(0.6)	2	(1.0)	0	(0.0)	4	(2.1)	0	(0.0)
Neurotoxicity	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	10	(5.7)	0	(0.0)	5	(2.5)	0	(0.0)	4	(2.1)	1	(0.5)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Peripheral motor neuropathy	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Peripheral sensory neuropathy	6	(3.4)	0	(0.0)	2	(1.0)	0	(0.0)	4	(2.1)	0	(0.0)
Polyneuropathy	2	(1.1)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Post herpetic neuralgia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**65**	**(36.9)**	**5**	**(2.8)**	**55**	**(27.2)**	**3**	**(1.5)**	**59**	**(30.7)**	**9**	**(4.7)**
Psychomotor hyperactivity	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Seizure	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Somnolence	2	(1.1)	0	(0.0)	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal cord compression	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)
Syncope	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	4	(2.1)	3	(1.6)
Toxic neuropathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Transient ischaemic attack	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tremor	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vocal cord paralysis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Psychiatric disorders	**21**	**(11.9)**	**1**	**(0.6)**	**34**	**(16.8)**	**5**	**(2.5)**	**29**	**(15.1)**	**3**	**(1.6)**
Affect lability	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Agitation	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Anxiety	3	(1.7)	0	(0.0)	11	(5.4)	1	(0.5)	9	(4.7)	1	(0.5)
Binge eating	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bradyphrenia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Completed suicide	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Confusional state	2	(1.1)	0	(0.0)	3	(1.5)	2	(1.0)	0	(0.0)	0	(0.0)
Delirium	1	(0.6)	1	(0.6)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Depressed mood	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Depression	1	(0.6)	0	(0.0)	11	(5.4)	0	(0.0)	6	(3.1)	0	(0.0)
Disorientation	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	1	(0.5)
Hallucination	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Insomnia	12	(6.8)	0	(0.0)	13	(6.4)	0	(0.0)	10	(5.2)	0	(0.0)
Irritability	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric disorders	**21**	**(11.9)**	**1**	**(0.6)**	**34**	**(16.8)**	**5**	**(2.5)**	**29**	**(15.1)**	**3**	**(1.6)**
Libido decreased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Mental status changes	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Nervousness	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Panic attack	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Psychomotor retardation	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Sleep disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Substance-induced psychotic disorder	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Tension	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Renal and urinary disorders	**6**	**(3.4)**	**1**	**(0.6)**	**8**	**(4.0)**	**3**	**(1.5)**	**13**	**(6.8)**	**2**	**(1.0)**
Acute kidney injury	2	(1.1)	1	(0.6)	4	(2.0)	2	(1.0)	0	(0.0)	0	(0.0)
Bladder hypertrophy	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bladder obstruction	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bladder spasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Haematuria	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.6)	0	(0.0)
Haemoglobinuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nocturia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Pollakiuria	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	0	(0.0)
Polyuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Renal impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**6**	**(3.4)**	**1**	**(0.6)**	**8**	**(4.0)**	**3**	**(1.5)**	**13**	**(6.8)**	**2**	**(1.0)**
Urinary bladder polyp	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Urinary retention	1	(0.6)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Urinary tract pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**6**	**(3.4)**	**0**	**(0.0)**	**4**	**(2.0)**	**0**	**(0.0)**	**7**	**(3.6)**	**0**	**(0.0)**
Balanoposthitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Benign prostatic hyperplasia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Breast pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Cervix oedema	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dysfunctional uterine bleeding	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Erectile dysfunction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Haematospermia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pelvic pain	4	(2.3)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Scrotal swelling	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaginal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**80**	**(45.5)**	**11**	**(6.3)**	**109**	**(54.0)**	**23**	**(11.4)**	**93**	**(48.4)**	**25**	**(13.0)**
Allergic respiratory disease	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**80**	**(45.5)**	**11**	**(6.3)**	**109**	**(54.0)**	**23**	**(11.4)**	**93**	**(48.4)**	**25**	**(13.0)**
Allergic sinusitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Asthma	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bronchial obstruction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Bronchial oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bronchospasm	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bronchostenosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Catarrh	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)	2	(1.0)	0	(0.0)
Cough	24	(13.6)	0	(0.0)	40	(19.8)	1	(0.5)	32	(16.7)	0	(0.0)
Diffuse panbronchiolitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dysphonia	7	(4.0)	0	(0.0)	7	(3.5)	0	(0.0)	5	(2.6)	0	(0.0)
Dyspnoea	37	(21.0)	3	(1.7)	55	(27.2)	8	(4.0)	43	(22.4)	9	(4.7)
Dyspnoea exertional	3	(1.7)	0	(0.0)	3	(1.5)	0	(0.0)	2	(1.0)	1	(0.5)
Epistaxis	5	(2.8)	0	(0.0)	2	(1.0)	0	(0.0)	3	(1.6)	0	(0.0)
Haemoptysis	8	(4.5)	0	(0.0)	19	(9.4)	3	(1.5)	15	(7.8)	0	(0.0)
Hiccups	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypercapnia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)
Hypoxia	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)	6	(3.1)	2	(1.0)
Increased upper airway secretion	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Interstitial lung disease	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Laryngeal haemorrhage	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**80**	**(45.5)**	**11**	**(6.3)**	**109**	**(54.0)**	**23**	**(11.4)**	**93**	**(48.4)**	**25**	**(13.0)**
Lower respiratory tract congestion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Lung disorder	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal congestion	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Obstructive airways disorder	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Oesophagobronchial fistula	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Oropharyngeal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Oropharyngeal pain	3	(1.7)	0	(0.0)	5	(2.5)	0	(0.0)	3	(1.6)	0	(0.0)
Orthopnoea	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Painful respiration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Paranasal sinus discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pharyngeal erythema	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pharyngeal inflammation	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	3	(1.7)	1	(0.6)	10	(5.0)	3	(1.5)	5	(2.6)	4	(2.1)
Pleurisy	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleuritic pain	1	(0.6)	1	(0.6)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia aspiration	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Pneumonitis	2	(1.1)	1	(0.6)	7	(3.5)	4	(2.0)	4	(2.1)	3	(1.6)
Pneumothorax	2	(1.1)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Productive cough	7	(4.0)	0	(0.0)	13	(6.4)	1	(0.5)	14	(7.3)	1	(0.5)
Pulmonary artery thrombosis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**80**	**(45.5)**	**11**	**(6.3)**	**109**	**(54.0)**	**23**	**(11.4)**	**93**	**(48.4)**	**25**	**(13.0)**
Pulmonary embolism	3	(1.7)	3	(1.7)	6	(3.0)	5	(2.5)	6	(3.1)	5	(2.6)
Pulmonary haemorrhage	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Pulmonary hypertension	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary venous thrombosis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Rales	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Respiratory acidosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Respiratory distress	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Respiratory failure	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Respiratory tract congestion	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rhinitis allergic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Rhinorrhoea	6	(3.4)	0	(0.0)	4	(2.0)	0	(0.0)	3	(1.6)	0	(0.0)
Sneezing	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sputum discoloured	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sputum increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Stridor	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tachypnoea	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	1	(0.5)
Upper respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract inflammation	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**80**	**(45.5)**	**11**	**(6.3)**	**109**	**(54.0)**	**23**	**(11.4)**	**93**	**(48.4)**	**25**	**(13.0)**
Upper-airway cough syndrome	2	(1.1)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Wheezing	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	4	(2.1)	0	(0.0)
Skin and subcutaneous tissue disorders	**83**	**(47.2)**	**1**	**(0.6)**	**57**	**(28.2)**	**3**	**(1.5)**	**59**	**(30.7)**	**2**	**(1.0)**
Acne	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Actinic keratosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Alopecia	56	(31.8)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Anhidrosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood blister	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dandruff	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Decubitus ulcer	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis bullous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis contact	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Drug eruption	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Dry skin	5	(2.8)	0	(0.0)	5	(2.5)	0	(0.0)	6	(3.1)	0	(0.0)
Eczema	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Erythema	4	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	5	(2.6)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Granuloma annulare	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperhidrosis	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**83**	**(47.2)**	**1**	**(0.6)**	**57**	**(28.2)**	**3**	**(1.5)**	**59**	**(30.7)**	**2**	**(1.0)**
Ingrowing nail	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Macule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nail bed disorder	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail discolouration	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail disorder	9	(5.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nail ridging	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	3	(1.7)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	3	(1.5)	0	(0.0)	2	(1.0)	0	(0.0)
Onychalgia	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Onychoclasis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Onycholysis	2	(1.1)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Palmar erythema	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	5	(2.8)	0	(0.0)	16	(7.9)	0	(0.0)	20	(10.4)	0	(0.0)
Pruritus generalised	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Psoriasis	0	(0.0)	0	(0.0)	3	(1.5)	1	(0.5)	0	(0.0)	0	(0.0)
Rash	13	(7.4)	0	(0.0)	19	(9.4)	1	(0.5)	26	(13.5)	0	(0.0)
Rash erythematous	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash macular	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**83**	**(47.2)**	**1**	**(0.6)**	**57**	**(28.2)**	**3**	**(1.5)**	**59**	**(30.7)**	**2**	**(1.0)**
Rash maculo-papular	0	(0.0)	0	(0.0)	4	(2.0)	1	(0.5)	1	(0.5)	0	(0.0)
Rash pruritic	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Seborrhoeic dermatitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin discolouration	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin exfoliation	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin fissures	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hypopigmentation	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin induration	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin irritation	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin lesion	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Skin mass	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin ulcer	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Vascular disorders	**18**	**(10.2)**	**6**	**(3.4)**	**19**	**(9.4)**	**8**	**(4.0)**	**25**	**(13.0)**	**4**	**(2.1)**
Aortic thrombosis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Arterial thrombosis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Axillary vein thrombosis	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Deep vein thrombosis	2	(1.1)	1	(0.6)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Embolism	1	(0.6)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Embolism venous	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Extravasation blood	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Femoral artery occlusion	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**18**	**(10.2)**	**6**	**(3.4)**	**19**	**(9.4)**	**8**	**(4.0)**	**25**	**(13.0)**	**4**	**(2.1)**
Flushing	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Haematoma	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hot flush	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertension	2	(1.1)	1	(0.6)	7	(3.5)	2	(1.0)	7	(3.6)	1	(0.5)
Hypotension	7	(4.0)	3	(1.7)	4	(2.0)	1	(0.5)	5	(2.6)	0	(0.0)
Orthostatic hypotension	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pelvic venous thrombosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral coldness	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Peripheral vascular disorder	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Phlebitis	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Phlebitis superficial	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Subclavian vein thrombosis	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Superior vena cava occlusion	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Superior vena cava syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Thrombosis	2	(1.1)	0	(0.0)	1	(0.5)	1	(0.5)	2	(1.0)	2	(1.0)

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Subjects With Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**18**	**(10.2)**	**6**	**(3.4)**	**19**	**(9.4)**	**8**	**(4.0)**	**25**	**(13.0)**	**4**	**(2.1)**
Venous thrombosis limb	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 21　　副作用（いずれかの投与群で発現割合 0%超）

010 試験（安全性解析対象集団）（PD-L1 発現陽性）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	309				339				343			
with one or more adverse events	251	(81.2)	109	(35.3)	215	(63.4)	43	(12.7)	226	(65.9)	55	(16.0)
with no adverse events	58	(18.8)	200	(64.7)	124	(36.6)	296	(87.3)	117	(34.1)	288	(84.0)
Blood and lymphatic system disorders	**87**	**(28.2)**	**55**	**(17.8)**	**19**	**(5.6)**	**3**	**(0.9)**	**22**	**(6.4)**	**4**	**(1.2)**
Anaemia	40	(12.9)	5	(1.6)	10	(2.9)	3	(0.9)	14	(4.1)	1	(0.3)
Bone marrow failure	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eosinophilia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Febrile neutropenia	15	(4.9)	15	(4.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Granulocytopenia	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Leukaemoid reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Leukocytosis	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Leukopenia	9	(2.9)	8	(2.6)	3	(0.9)	0	(0.0)	1	(0.3)	1	(0.3)
Lymph node pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lymphadenopathy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphopenia	5	(1.6)	0	(0.0)	4	(1.2)	0	(0.0)	2	(0.6)	0	(0.0)
Microcytic anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Neutropenia	44	(14.2)	38	(12.3)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Neutrophilia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia	7	(2.3)	1	(0.3)	2	(0.6)	0	(0.0)	2	(0.6)	1	(0.3)
Cardiac disorders	**6**	**(1.9)**	**3**	**(1.0)**	**3**	**(0.9)**	**0**	**(0.0)**	**5**	**(1.5)**	**3**	**(0.9)**
Arrhythmia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**6**	**(1.9)**	**3**	**(1.0)**	**3**	**(0.9)**	**0**	**(0.0)**	**5**	**(1.5)**	**3**	**(0.9)**
Arteriosclerosis coronary artery	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrial fibrillation	3	(1.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrioventricular block	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrioventricular block complete	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Cardiac failure acute	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cyanosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Myocardial infarction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pericardial effusion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	1	(0.3)
Tachycardia	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders	**3**	**(1.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(0.9)**	**1**	**(0.3)**
Ear pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tinnitus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Vertigo	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)
Endocrine disorders	**1**	**(0.3)**	**0**	**(0.0)**	**35**	**(10.3)**	**1**	**(0.3)**	**36**	**(10.5)**	**3**	**(0.9)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	1	(0.3)	1	(0.3)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperthyroidism	0	(0.0)	0	(0.0)	10	(2.9)	0	(0.0)	15	(4.4)	1	(0.3)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**1**	**(0.3)**	**0**	**(0.0)**	**35**	**(10.3)**	**1**	**(0.3)**	**36**	**(10.5)**	**3**	**(0.9)**
Hypopituitarism	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	1	(0.3)
Hypothalamo-pituitary disorder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hypothyroidism	1	(0.3)	0	(0.0)	25	(7.4)	0	(0.0)	23	(6.7)	0	(0.0)
Thyroiditis	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Eye disorders	**13**	**(4.2)**	**0**	**(0.0)**	**8**	**(2.4)**	**0**	**(0.0)**	**10**	**(2.9)**	**0**	**(0.0)**
Cataract	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dry eye	1	(0.3)	0	(0.0)	4	(1.2)	0	(0.0)	6	(1.7)	0	(0.0)
Eye irritation	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Eyelid oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Keratitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lacrimation increased	8	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Photopsia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vision blurred	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Visual impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gastrointestinal disorders	**132**	**(42.7)**	**14**	**(4.5)**	**87**	**(25.7)**	**6**	**(1.8)**	**66**	**(19.2)**	**5**	**(1.5)**
Abdominal discomfort	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal distension	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)
Abdominal pain	4	(1.3)	0	(0.0)	5	(1.5)	0	(0.0)	2	(0.6)	0	(0.0)
Abdominal pain lower	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Abdominal pain upper	2	(0.6)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**132**	**(42.7)**	**14**	**(4.5)**	**87**	**(25.7)**	**6**	**(1.8)**	**66**	**(19.2)**	**5**	**(1.5)**
Colitis	0	(0.0)	0	(0.0)	3	(0.9)	3	(0.9)	2	(0.6)	1	(0.3)
Colitis ischaemic	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	14	(4.5)	0	(0.0)	13	(3.8)	0	(0.0)	10	(2.9)	0	(0.0)
Dental discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	56	(18.1)	7	(2.3)	24	(7.1)	2	(0.6)	22	(6.4)	0	(0.0)
Dry mouth	3	(1.0)	0	(0.0)	5	(1.5)	0	(0.0)	3	(0.9)	0	(0.0)
Dyspepsia	4	(1.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Dysphagia	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)	1	(0.3)	0	(0.0)
Faecaloma	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Flatulence	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0		0	(0.0)
Gastritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal inflammation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal motility disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gastrooesophageal reflux disease	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Mouth ulceration	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	45	(14.6)	1	(0.3)	37	(10.9)	1	(0.3)	31	(9.0)	2	(0.6)
Odynophagia	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oesophageal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**132**	**(42.7)**	**14**	**(4.5)**	**87**	**(25.7)**	**6**	**(1.8)**	**66**	**(19.2)**	**5**	**(1.5)**
Oral discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral dysaesthesia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	4	(1.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia oral	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Stomatitis	43	(13.9)	3	(1.0)	13	(3.8)	0	(0.0)	7	(2.0)	1	(0.3)
Tongue ulceration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	24	(7.8)	2	(0.6)	12	(3.5)	0	(0.0)	13	(3.8)	1	(0.3)
General disorders and administration site conditions	**149**	**(48.2)**	**23**	**(7.4)**	**79**	**(23.3)**	**6**	**(1.8)**	**101**	**(29.4)**	**7**	**(2.0)**
Adverse drug reaction	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Asthenia	35	(11.3)	6	(1.9)	20	(5.9)	1	(0.3)	19	(5.5)	2	(0.6)
Catheter site pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Chest pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Chills	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)	4	(1.2)	0	(0.0)
Enanthema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Face oedema	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	76	(24.6)	11	(3.6)	46	(13.6)	4	(1.2)	49	(14.3)	6	(1.7)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**149**	**(48.2)**	**23**	**(7.4)**	**79**	**(23.3)**	**6**	**(1.8)**	**101**	**(29.4)**	**7**	**(2.0)**
Gait disturbance	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Generalised oedema	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	6	(1.7)	0	(0.0)
Infusion site extravasation	3	(1.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site phlebitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site reaction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site vasculitis	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site reaction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Local swelling	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Malaise	11	(3.6)	0	(0.0)	4	(1.2)	0	(0.0)	10	(2.9)	0	(0.0)
Mucosal dryness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Mucosal inflammation	3	(1.0)	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Nodule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Oedema	5	(1.6)	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	21	(6.8)	0	(0.0)	5	(1.5)	0	(0.0)	4	(1.2)	0	(0.0)
Pain	3	(1.0)	0	(0.0)	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)
Peripheral swelling	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pyrexia	17	(5.5)	1	(0.3)	10	(2.9)	1	(0.3)	14	(4.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**149**	**(48.2)**	**23**	**(7.4)**	**79**	**(23.3)**	**6**	**(1.8)**	**101**	**(29.4)**	**7**	**(2.0)**
Serositis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.6)**	**1**	**(0.3)**	**5**	**(1.5)**	**1**	**(0.3)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	2	(0.6)	0	(0.0)
Cholestasis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)
Hepatic function abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hepatotoxicity	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Immune system disorders	**7**	**(2.3)**	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**	**2**	**(0.6)**	**0**	**(0.0)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Drug hypersensitivity	4	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypersensitivity	3	(1.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Infections and infestations	**34**	**(11.0)**	**13**	**(4.2)**	**17**	**(5.0)**	**3**	**(0.9)**	**13**	**(3.8)**	**4**	**(1.2)**
Anal abscess	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Bronchitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Candida infection	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Cystitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Eye infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups) APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**34**	**(11.0)**	**13**	**(4.2)**	**17**	**(5.0)**	**3**	**(0.9)**	**13**	**(3.8)**	**4**	**(1.2)**
Fungal infection	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Furuncle	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Genital candidiasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Herpes zoster	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infection	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Laryngitis	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lobar pneumonia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lung infection	4	(1.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Mucosal infection	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nail infection	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nasopharyngitis	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Onychomycosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	3	(1.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Otitis media acute	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Paronychia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Perichondritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pharyngitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Phlebitis infective	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia	5	(1.6)	4	(1.3)	5	(1.5)	3	(0.9)	5	(1.5)	3	(0.9)
Pneumonia bacterial	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash pustular	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**34**	**(11.0)**	**13**	**(4.2)**	**17**	**(5.0)**	**3**	**(0.9)**	**13**	**(3.8)**	**4**	**(1.2)**
Respiratory tract infection	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Sepsis	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Septic shock	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract infection	6	(1.9)	2	(0.6)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Urinary tract infection	4	(1.3)	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications	**11**	**(3.6)**	**1**	**(0.3)**	**2**	**(0.6)**	**1**	**(0.3)**	**7**	**(2.0)**	**1**	**(0.3)**
Contusion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Femur fracture	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion related reaction	8	(2.6)	0	(0.0)	1	(0.3)	0	(0.0)	4	(1.2)	0	(0.0)
Injection related reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ligament sprain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	1	(0.3)
Skin abrasion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Toxicity to various agents	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	**42**	**(13.6)**	**25**	**(8.1)**	**41**	**(12.1)**	**2**	**(0.6)**	**47**	**(13.7)**	**9**	**(2.6)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**42**	**(13.6)**	**25**	**(8.1)**	**41**	**(12.1)**	**2**	**(0.6)**	**47**	**(13.7)**	**9**	**(2.6)**
Alanine aminotransferase increased	4	(1.3)	0	(0.0)	16	(4.7)	2	(0.6)	8	(2.3)	1	(0.3)
Amylase increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Aspartate aminotransferase	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Aspartate aminotransferase increased	3	(1.0)	0	(0.0)	10	(2.9)	2	(0.6)	7	(2.0)	0	(0.0)
Blood albumin increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Blood alkaline phosphatase increased	2	(0.6)	0	(0.0)	3	(0.9)	0	(0.0)	8	(2.3)	2	(0.6)
Blood bilirubin increased	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	3	(0.9)	0	(0.0)
Blood chloride decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)
Blood creatinine decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatinine increased	0	(0.0)	0	(0.0)	6	(1.8)	0	(0.0)	7	(2.0)	0	(0.0)
Blood magnesium decreased	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Blood phosphorus decreased	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**42**	**(13.6)**	**25**	**(8.1)**	**41**	**(12.1)**	**2**	**(0.6)**	**47**	**(13.7)**	**9**	**(2.6)**
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	3	(0.9)	0	(0.0)	4	(1.2)	0	(0.0)
Blood triglycerides increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood urea increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	3	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Eosinophil count increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Free thyroxine index increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	1	(0.3)	1	(0.3)	4	(1.2)	0	(0.0)	1	(0.3)	1	(0.3)
Haematocrit decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Haemoglobin decreased	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	4	(1.3)	1	(0.3)	1	(0.3)	0	(0.0)	3	(0.9)	2	(0.6)
Neutrophil count decreased	24	(7.8)	19	(6.1)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Platelet count decreased	2	(0.6)	1	(0.3)	1	(0.3)	0	(0.0)	3	(0.9)	1	(0.3)
Platelet count increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Protein total decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**42**	**(13.6)**	**25**	**(8.1)**	**41**	**(12.1)**	**2**	**(0.6)**	**47**	**(13.7)**	**9**	**(2.6)**
Protein urine present	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Thyroxine decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	4	(1.2)	0	(0.0)
Thyroxine increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Transaminases increased	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Tri-iodothyronine free decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tri-iodothyronine free increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Tri-iodothyronine increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Weight decreased	2	(0.6)	0	(0.0)	5	(1.5)	0	(0.0)	10	(2.9)	1	(0.3)
Weight increased	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)
White blood cell count decreased	16	(5.2)	10	(3.2)	0	(0.0)	0	(0.0)	3	(0.9)	0	(0.0)
White blood cell count increased	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**63**	**(20.4)**	**8**	**(2.6)**	**63**	**(18.6)**	**8**	**(2.4)**	**56**	**(16.3)**	**13**	**(3.8)**
Decreased appetite	49	(15.9)	3	(1.0)	46	(13.6)	3	(0.9)	33	(9.6)	1	(0.3)
Dehydration	4	(1.3)	3	(1.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**63**	**(20.4)**	**8**	**(2.6)**	**63**	**(18.6)**	**8**	**(2.4)**	**56**	**(16.3)**	**13**	**(3.8)**
Diabetes mellitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Diabetic ketoacidosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hyperamylasaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hypercalcaemia	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	3	(0.9)	0	(0.0)
Hyperglycaemia	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)	1	(0.3)	1	(0.3)
Hyperkalaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertriglyceridaemia	0	(0.0)	0	(0.0)	3	(0.9)	1	(0.3)	7	(2.0)	3	(0.9)
Hyperuricaemia	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Hypoalbuminaemia	5	(1.6)	0	(0.0)	4	(1.2)	0	(0.0)	2	(0.6)	0	(0.0)
Hypocalcaemia	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)
Hypokalaemia	1	(0.3)	1	(0.3)	2	(0.6)	1	(0.3)	2	(0.6)	0	(0.0)
Hypomagnesaemia	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	5	(1.5)	0	(0.0)
Hyponatraemia	1	(0.3)	0	(0.0)	1	(0.3)	1	(0.3)	3	(0.9)	3	(0.9)
Hypophosphataemia	3	(1.0)	1	(0.3)	0	(0.0)	0	(0.0)	3	(0.9)	2	(0.6)
Hypoproteinaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Iron deficiency	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lactic acidosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	2	(0.6)	1	(0.3)
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**57**	**(18.4)**	**0**	**(0.0)**	**39**	**(11.5)**	**1**	**(0.3)**	**38**	**(11.1)**	**3**	**(0.9)**
Arthralgia	18	(5.8)	0	(0.0)	13	(3.8)	0	(0.0)	19	(5.5)	2	(0.6)
Arthritis	0	(0.0)	0	(0.0)	5	(1.5)	1	(0.3)	1	(0.3)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	5	(1.5)	1	(0.3)	4	(1.2)	0	(0.0)
Bone pain	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Bursitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Joint stiffness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Joint swelling	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Limb discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle necrosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	1	(0.3)	0	(0.0)	3	(0.9)	0	(0.0)	2	(0.6)	0	(0.0)
Muscular weakness	5	(1.6)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Musculoskeletal pain	4	(1.3)	0	(0.0)	4	(1.2)	0	(0.0)	4	(1.2)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Myalgia	29	(9.4)	0	(0.0)	9	(2.7)	0	(0.0)	10	(2.9)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Pain in extremity	5	(1.6)	0	(0.0)	2	(0.6)	0	(0.0)	4	(1.2)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**57**	**(18.4)**	**0**	**(0.0)**	**39**	**(11.5)**	**1**	**(0.3)**	**38**	**(11.1)**	**3**	**(0.9)**
Pain in jaw	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Periarthritis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Polyarthritis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Synovitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(0.3)**	**0**	**(0.0)**	**1**	**(0.3)**	**1**	**(0.3)**	**3**	**(0.9)**	**1**	**(0.3)**
Cancer pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Malignant neoplasm progression	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Oncologic complication	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Paraneoplastic syndrome	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Nervous system disorders	**80**	**(25.9)**	**4**	**(1.3)**	**28**	**(8.3)**	**2**	**(0.6)**	**32**	**(9.3)**	**1**	**(0.3)**
Ataxia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Burning sensation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cerebrovascular accident	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Cognitive disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dizziness	5	(1.6)	1	(0.3)	5	(1.5)	0	(0.0)	6	(1.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups) APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**80**	**(25.9)**	**4**	**(1.3)**	**28**	**(8.3)**	**2**	**(0.6)**	**32**	**(9.3)**	**1**	**(0.3)**
Dysaesthesia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	16	(5.2)	0	(0.0)	4	(1.2)	0	(0.0)	7	(2.0)	0	(0.0)
Headache	2	(0.6)	0	(0.0)	8	(2.4)	0	(0.0)	6	(1.7)	0	(0.0)
Hypersomnia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Hypoaesthesia	5	(1.6)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)
Hypogeusia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	3	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Myelitis transverse	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Neuropathy peripheral	28	(9.1)	1	(0.3)	2	(0.6)	0	(0.0)	3	(0.9)	0	(0.0)
Neurotoxicity	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	17	(5.5)	0	(0.0)	3	(0.9)	0	(0.0)	3	(0.9)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral motor neuropathy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Peripheral sensory neuropathy	14	(4.5)	0	(0.0)	3	(0.9)	0	(0.0)	3	(0.9)	0	(0.0)
Peroneal nerve palsy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Polyneuropathy	2	(0.6)	2	(0.6)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Somnolence	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Toxic leukoencephalopathy	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Toxic neuropathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric disorders	**7**	**(2.3)**	**0**	**(0.0)**	**3**	**(0.9)**	**1**	**(0.3)**	**8**	**(2.3)**	**1**	**(0.3)**
Anxiety	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Confusional state	1	(0.3)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Disorientation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Insomnia	6	(1.9)	0	(0.0)	1	(0.3)	0	(0.0)	5	(1.5)	0	(0.0)
Libido decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Restlessness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Renal and urinary disorders	**3**	**(1.0)**	**1**	**(0.3)**	**6**	**(1.8)**	**2**	**(0.6)**	**5**	**(1.5)**	**0**	**(0.0)**
Acute kidney injury	1	(0.3)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Chronic kidney disease	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Micturition urgency	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pollakiuria	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Renal impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Urinary tract obstruction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**1**	**(0.3)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**4**	**(1.2)**	**1**	**(0.3)**
Erectile dysfunction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive system and breast disorders	**1**	**(0.3)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**4**	**(1.2)**	**1**	**(0.3)**
Pruritus genital	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Respiratory, thoracic and mediastinal disorders	**44**	**(14.2)**	**8**	**(2.6)**	**44**	**(13.0)**	**10**	**(2.9)**	**30**	**(8.7)**	**7**	**(2.0)**
Bronchospasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)
Cough	3	(1.0)	0	(0.0)	9	(2.7)	0	(0.0)	2	(0.6)	0	(0.0)
Dysphonia	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Dyspnoea	13	(4.2)	4	(1.3)	7	(2.1)	2	(0.6)	14	(4.1)	2	(0.6)
Dyspnoea exertional	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Epistaxis	5	(1.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoptysis	2	(0.6)	0	(0.0)	3	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Hiccups	3	(1.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.9)	1	(0.3)
Interstitial lung disease	2	(0.6)	1	(0.3)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)
Nasal congestion	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal inflammation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal pain	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pharyngeal inflammation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	3	(1.0)	2	(0.6)	4	(1.2)	1	(0.3)	1	(0.3)	0	(0.0)
Pneumonia aspiration	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**44**	**(14.2)**	**8**	**(2.6)**	**44**	**(13.0)**	**10**	**(2.9)**	**30**	**(8.7)**	7	**(2.0)**
Pneumonitis	3	(1.0)	1	(0.3)	14	(4.1)	6	(1.8)	12	(3.5)	6	(1.7)
Productive cough	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary artery thrombosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary embolism	0	(0.0)	0	(0.0)	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)
Rhinitis allergic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Rhinorrhoea	3	(1.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Tachypnoea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Upper respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Upper-airway cough syndrome	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	**127**	**(41.1)**	**4**	**(1.3)**	**64**	**(18.9)**	**3**	**(0.9)**	**84**	**(24.5)**	**3**	**(0.9)**
Acne	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Alopecia	101	(32.7)	2	(0.6)	3	(0.9)	0	(0.0)	2	(0.6)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Dermatitis bullous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Drug eruption	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Dry skin	4	(1.3)	0	(0.0)	4	(1.2)	0	(0.0)	14	(4.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**127**	**(41.1)**	**4**	**(1.3)**	**64**	**(18.9)**	**3**	**(0.9)**	**84**	**(24.5)**	**3**	**(0.9)**
Eczema	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)
Erythema	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.9)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperhidrosis	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Macule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Nail discolouration	7	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nail disorder	11	(3.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nail dystrophy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail ridging	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	5	(1.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)
Onychalgia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Onychoclasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Onycholysis	8	(2.6)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Onychomadesis	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	4	(1.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	5	(1.6)	1	(0.3)	25	(7.4)	0	(0.0)	32	(9.3)	0	(0.0)
Pruritus generalised	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**127**	**(41.1)**	**4**	**(1.3)**	**64**	**(18.9)**	**3**	**(0.9)**	**84**	**(24.5)**	**3**	**(0.9)**
Psoriasis	0	(0.0)	0	(0.0)	3	(0.9)	1	(0.3)	1	(0.3)	0	(0.0)
Rash	14	(4.5)	0	(0.0)	29	(8.6)	1	(0.3)	44	(12.8)	1	(0.3)
Rash macular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.6)	0	(0.0)
Rash maculo-papular	0	(0.0)	0	(0.0)	6	(1.8)	1	(0.3)	3	(0.9)	0	(0.0)
Rash pruritic	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	4	(1.2)	0	(0.0)
Seborrhoeic dermatitis	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Skin exfoliation	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin fissures	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin induration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin irritation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin lesion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Skin oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin ulcer	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)
Urticaria	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vitiligo	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders	**16**	**(5.2)**	**1**	**(0.3)**	**6**	**(1.8)**	**0**	**(0.0)**	**10**	**(2.9)**	**4**	**(1.2)**
Deep vein thrombosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Embolism	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Flushing	2	(0.6)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)
Hot flush	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**16**	**(5.2)**	**1**	**(0.3)**	**6**	**(1.8)**	**0**	**(0.0)**	**10**	**(2.9)**	**4**	**(1.2)**
Hypertension	2	(0.6)	0	(0.0)	2	(0.6)	0	(0.0)	3	(0.9)	2	(0.6)
Hypotension	3	(1.0)	1	(0.3)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)
Lymphoedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral ischaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Phlebitis	6	(1.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombophlebitis superficial	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Venous thrombosis limb	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(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.

Grades are based on NCI CTCAE version 4.0.

Adverse event terms are from MedDRA Version 18.0.

(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 22　　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			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	309				682			
with one or more adverse events	251	(81.2)	109	(35.3)	441	(64.7)	98	(14.4)
with no adverse events	58	(18.8)	200	(64.7)	241	(35.3)	584	(85.6)
Blood and lymphatic system disorders	**87**	**(28.2)**	**55**	**(17.8)**	**41**	**(6.0)**	7	**(1.0)**
Anaemia	40	(12.9)	5	(1.6)	24	(3.5)	4	(0.6)
Bone marrow failure	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Eosinophilia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Febrile neutropenia	15	(4.9)	15	(4.9)	0	(0.0)	0	(0.0)
Granulocytopenia	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Leukaemoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Leukocytosis	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Leukopenia	9	(2.9)	8	(2.6)	4	(0.6)	1	(0.1)
Lymph node pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphadenopathy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphopenia	5	(1.6)	0	(0.0)	6	(0.9)	0	(0.0)
Microcytic anaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Neutropenia	44	(14.2)	38	(12.3)	2	(0.3)	0	(0.0)
Neutrophilia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thrombocytopenia	7	(2.3)	1	(0.3)	4	(0.6)	1	(0.1)
Cardiac disorders	**6**	**(1.9)**	**3**	**(1.0)**	**8**	**(1.2)**	**3**	**(0.4)**
Arrhythmia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Arteriosclerosis coronary artery	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Atrial fibrillation	3	(1.0)	2	(0.6)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**6**	**(1.9)**	**3**	**(1.0)**	**8**	**(1.2)**	**3**	**(0.4)**
Atrioventricular block	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Atrioventricular block complete	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cardiac failure acute	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Cyanosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Myocardial infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Palpitations	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pericardial effusion	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Tachycardia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Ear and labyrinth disorders	**3**	**(1.0)**	**0**	**(0.0)**	**3**	**(0.4)**	**1**	**(0.1)**
Ear pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tinnitus	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)
Vertigo	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)
Endocrine disorders	**1**	**(0.3)**	**0**	**(0.0)**	**71**	**(10.4)**	**4**	**(0.6)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperthyroidism	0	(0.0)	0	(0.0)	25	(3.7)	1	(0.1)
Hypopituitarism	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.3)
Hypothalamo-pituitary disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypothyroidism	1	(0.3)	0	(0.0)	48	(7.0)	0	(0.0)
Thyroiditis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**13**	**(4.2)**	**0**	**(0.0)**	**18**	**(2.6)**	**0**	**(0.0)**
Cataract	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dry eye	1	(0.3)	0	(0.0)	10	(1.5)	0	(0.0)
Eye irritation	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Keratitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lacrimation increased	8	(2.6)	0	(0.0)	1	(0.1)	0	(0.0)
Photopsia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vision blurred	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Visual impairment	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrointestinal disorders	**132**	**(42.7)**	**14**	**(4.5)**	**153**	**(22.4)**	**11**	**(1.6)**
Abdominal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Abdominal distension	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
Abdominal pain	4	(1.3)	0	(0.0)	7	(1.0)	0	(0.0)
Abdominal pain lower	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Abdominal pain upper	2	(0.6)	1	(0.3)	1	(0.1)	0	(0.0)
Colitis	0	(0.0)	0	(0.0)	5	(0.7)	4	(0.6)
Colitis ischaemic	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Constipation	14	(4.5)	0	(0.0)	23	(3.4)	0	(0.0)
Dental discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	56	(18.1)	7	(2.3)	46	(6.7)	2	(0.3)
Dry mouth	3	(1.0)	0	(0.0)	8	(1.2)	0	(0.0)
Dyspepsia	4	(1.3)	0	(0.0)	2	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**132**	**(42.7)**	**14**	**(4.5)**	**153**	**(22.4)**	**11**	**(1.6)**
Dysphagia	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)
Faecaloma	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Flatulence	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Gastritis	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrointestinal inflammation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Gastrointestinal motility disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrooesophageal reflux disease	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mouth ulceration	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	45	(14.6)	1	(0.3)	68	(10.0)	3	(0.4)
Odynophagia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Oesophageal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oral discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oral disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oral dysaesthesia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	4	(1.3)	0	(0.0)	1	(0.1)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paraesthesia oral	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Stomatitis	43	(13.9)	3	(1.0)	20	(2.9)	1	(0.1)
Tongue ulceration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	24	(7.8)	2	(0.6)	25	(3.7)	1	(0.1)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**149**	**(48.2)**	**23**	**(7.4)**	**180**	**(26.4)**	**13**	**(1.9)**
Adverse drug reaction	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Asthenia	35	(11.3)	6	(1.9)	39	(5.7)	3	(0.4)
Catheter site pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Chest pain	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Chills	1	(0.3)	0	(0.0)	6	(0.9)	0	(0.0)
Enanthema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Face oedema	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	76	(24.6)	11	(3.6)	95	(13.9)	10	(1.5)
Feeling cold	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gait disturbance	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	2	(0.6)	1	(0.3)	1	(0.1)	0	(0.0)
Generalised oedema	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	7	(1.0)	0	(0.0)
Infusion site extravasation	3	(1.0)	1	(0.3)	0	(0.0)	0	(0.0)
Infusion site phlebitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site reaction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site vasculitis	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site reaction	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Local swelling	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Malaise	11	(3.6)	0	(0.0)	14	(2.1)	0	(0.0)
Mucosal dryness	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**149**	**(48.2)**	**23**	**(7.4)**	**180**	**(26.4)**	**13**	**(1.9)**
Mucosal inflammation	3	(1.0)	1	(0.3)	2	(0.3)	0	(0.0)
Nodule	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oedema	5	(1.6)	2	(0.6)	1	(0.1)	0	(0.0)
Oedema peripheral	21	(6.8)	0	(0.0)	9	(1.3)	0	(0.0)
Pain	3	(1.0)	0	(0.0)	4	(0.6)	0	(0.0)
Peripheral swelling	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Pyrexia	17	(5.5)	1	(0.3)	24	(3.5)	1	(0.1)
Serositis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**7**	**(1.0)**	**2**	**(0.3)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)
Cholestasis	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Hepatic function abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hepatotoxicity	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Immune system disorders	**7**	**(2.3)**	**0**	**(0.0)**	**3**	**(0.4)**	**0**	**(0.0)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Drug hypersensitivity	4	(1.3)	0	(0.0)	1	(0.1)	0	(0.0)
Hypersensitivity	3	(1.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infections and infestations	**34**	**(11.0)**	**13**	**(4.2)**	**30**	**(4.4)**	7	**(1.0)**

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**34**	**(11.0)**	**13**	**(4.2)**	**30**	**(4.4)**	**7**	**(1.0)**
Anal abscess	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bronchitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Candida infection	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Conjunctivitis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Cystitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eye infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fungal infection	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Furuncle	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Genital candidiasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Herpes zoster	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Infection	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Laryngitis	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)
Lobar pneumonia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Lung infection	4	(1.3)	1	(0.3)	1	(0.1)	0	(0.0)
Mucosal infection	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)
Nail infection	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Nasopharyngitis	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Onychomycosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	3	(1.0)	0	(0.0)	2	(0.3)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Otitis media acute	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paronychia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**34**	**(11.0)**	**13**	**(4.2)**	**30**	**(4.4)**	**7**	**(1.0)**
Perichondritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pharyngitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Phlebitis infective	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Pneumonia	5	(1.6)	4	(1.3)	10	(1.5)	6	(0.9)
Pneumonia bacterial	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Rash pustular	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Respiratory tract infection	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Sepsis	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)
Septic shock	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Upper respiratory tract infection	6	(1.9)	2	(0.6)	1	(0.1)	0	(0.0)
Urinary tract infection	4	(1.3)	2	(0.6)	1	(0.1)	0	(0.0)
Injury, poisoning and procedural complications	**11**	**(3.6)**	**1**	**(0.3)**	**9**	**(1.3)**	**2**	**(0.3)**
Contusion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Femur fracture	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Infusion related reaction	8	(2.6)	0	(0.0)	5	(0.7)	0	(0.0)
Injection related reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ligament sprain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.3)
Skin abrasion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Toxicity to various agents	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**42**	**(13.6)**	**25**	**(8.1)**	**88**	**(12.9)**	**11**	**(1.6)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Alanine aminotransferase increased	4	(1.3)	0	(0.0)	24	(3.5)	3	(0.4)
Amylase increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Aspartate aminotransferase	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aspartate aminotransferase increased	3	(1.0)	0	(0.0)	17	(2.5)	2	(0.3)
Blood albumin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Blood alkaline phosphatase increased	2	(0.6)	0	(0.0)	11	(1.6)	2	(0.3)
Blood bilirubin increased	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)
Blood chloride decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
Blood creatinine decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatinine increased	0	(0.0)	0	(0.0)	13	(1.9)	0	(0.0)
Blood magnesium decreased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Blood phosphorus decreased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Blood thyroid stimulating hormone decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	7	(1.0)	0	(0.0)
Blood triglycerides increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood urea increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
C-reactive protein increased	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Eosinophil count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**42**	**(13.6)**	**25**	**(8.1)**	**88**	**(12.9)**	**11**	**(1.6)**
Free thyroxine index increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gamma-glutamyltransferase increased	1	(0.3)	1	(0.3)	5	(0.7)	1	(0.1)
Haematocrit decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haemoglobin decreased	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphocyte count decreased	4	(1.3)	1	(0.3)	4	(0.6)	2	(0.3)
Neutrophil count decreased	24	(7.8)	19	(6.1)	2	(0.3)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Platelet count decreased	2	(0.6)	1	(0.3)	4	(0.6)	1	(0.1)
Platelet count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Protein total decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Protein urine present	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroxine decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)
Thyroxine increased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Transaminases increased	2	(0.6)	0	(0.0)	1	(0.1)	1	(0.1)
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Tri-iodothyronine free decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tri-iodothyronine free increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tri-iodothyronine increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Weight decreased	2	(0.6)	0	(0.0)	15	(2.2)	1	(0.1)
Weight increased	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
White blood cell count decreased	16	(5.2)	10	(3.2)	3	(0.4)	0	(0.0)
White blood cell count increased	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**63**	**(20.4)**	**8**	**(2.6)**	**119**	**(17.4)**	**21**	**(3.1)**
Decreased appetite	49	(15.9)	3	(1.0)	79	(11.6)	4	(0.6)
Dehydration	4	(1.3)	3	(1.0)	2	(0.3)	0	(0.0)
Diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Diabetic ketoacidosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Hyperamylasaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Hypercalcaemia	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	4	(0.6)	0	(0.0)
Hyperglycaemia	1	(0.3)	0	(0.0)	3	(0.4)	1	(0.1)
Hyperkalaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertriglyceridaemia	0	(0.0)	0	(0.0)	10	(1.5)	4	(0.6)
Hyperuricaemia	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Hypoalbuminaemia	5	(1.6)	0	(0.0)	6	(0.9)	0	(0.0)
Hypocalcaemia	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Hypokalaemia	1	(0.3)	1	(0.3)	4	(0.6)	1	(0.1)
Hypomagnesaemia	2	(0.6)	0	(0.0)	6	(0.9)	0	(0.0)
Hyponatraemia	1	(0.3)	0	(0.0)	4	(0.6)	4	(0.6)
Hypophosphataemia	3	(1.0)	1	(0.3)	3	(0.4)	2	(0.3)
Hypoproteinaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Iron deficiency	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Lactic acidosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	3	(0.4)	2	(0.3)
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**57**	**(18.4)**	**0**	**(0.0)**	77	**(11.3)**	**4**	**(0.6)**
Arthralgia	18	(5.8)	0	(0.0)	32	(4.7)	2	(0.3)
Arthritis	0	(0.0)	0	(0.0)	6	(0.9)	1	(0.1)
Back pain	0	(0.0)	0	(0.0)	9	(1.3)	1	(0.1)
Bone pain	3	(1.0)	0	(0.0)	1	(0.1)	1	(0.1)
Bursitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Joint stiffness	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Joint swelling	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Limb discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle necrosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle spasms	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)
Muscular weakness	5	(1.6)	0	(0.0)	2	(0.3)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Musculoskeletal pain	4	(1.3)	0	(0.0)	8	(1.2)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Myalgia	29	(9.4)	0	(0.0)	19	(2.8)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Pain in extremity	5	(1.6)	0	(0.0)	6	(0.9)	0	(0.0)
Pain in jaw	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Periarthritis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Polyarthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**57**	**(18.4)**	**0**	**(0.0)**	77	**(11.3)**	**4**	**(0.6)**
Spinal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Synovitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(0.3)**	**0**	**(0.0)**	**4**	**(0.6)**	**2**	**(0.3)**
Cancer pain	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Malignant neoplasm progression	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paraneoplastic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Nervous system disorders	**80**	**(25.9)**	**4**	**(1.3)**	**60**	**(8.8)**	**3**	**(0.4)**
Ataxia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Burning sensation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Cerebrovascular accident	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cognitive disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dizziness	5	(1.6)	1	(0.3)	11	(1.6)	0	(0.0)
Dysaesthesia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	16	(5.2)	0	(0.0)	11	(1.6)	0	(0.0)
Headache	2	(0.6)	0	(0.0)	14	(2.1)	0	(0.0)
Hypersomnia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Hypoaesthesia	5	(1.6)	0	(0.0)	3	(0.4)	0	(0.0)
Hypogeusia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**80**	**(25.9)**	**4**	**(1.3)**	**60**	**(8.8)**	**3**	**(0.4)**
Myelitis transverse	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Neuropathy peripheral	28	(9.1)	1	(0.3)	5	(0.7)	0	(0.0)
Neurotoxicity	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	17	(5.5)	0	(0.0)	6	(0.9)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral motor neuropathy	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Peripheral sensory neuropathy	14	(4.5)	0	(0.0)	6	(0.9)	0	(0.0)
Peroneal nerve palsy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Polyneuropathy	2	(0.6)	2	(0.6)	1	(0.1)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Somnolence	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Toxic leukoencephalopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Toxic neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Psychiatric disorders	**7**	**(2.3)**	**0**	**(0.0)**	**11**	**(1.6)**	**2**	**(0.3)**
Anxiety	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Confusional state	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)
Disorientation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Insomnia	6	(1.9)	0	(0.0)	6	(0.9)	0	(0.0)
Libido decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Restlessness	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Renal and urinary disorders	**3**	**(1.0)**	**1**	**(0.3)**	**11**	**(1.6)**	**2**	**(0.3)**
Acute kidney injury	1	(0.3)	1	(0.3)	1	(0.1)	1	(0.1)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**3**	**(1.0)**	**1**	**(0.3)**	**11**	**(1.6)**	**2**	**(0.3)**
Chronic kidney disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Micturition urgency	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pollakiuria	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Renal impairment	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Urinary tract obstruction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**1**	**(0.3)**	**0**	**(0.0)**	**4**	**(0.6)**	**1**	**(0.1)**
Erectile dysfunction	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Respiratory, thoracic and mediastinal disorders	**44**	**(14.2)**	**8**	**(2.6)**	**74**	**(10.9)**	**17**	**(2.5)**
Bronchospasm	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Cough	3	(1.0)	0	(0.0)	11	(1.6)	0	(0.0)
Dysphonia	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Dyspnoea	13	(4.2)	4	(1.3)	21	(3.1)	4	(0.6)
Dyspnoea exertional	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**44**	**(14.2)**	**8**	**(2.6)**	**74**	**(10.9)**	**17**	**(2.5)**
Epistaxis	5	(1.6)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoptysis	2	(0.6)	0	(0.0)	3	(0.4)	0	(0.0)
Hiccups	3	(1.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)
Interstitial lung disease	2	(0.6)	1	(0.3)	3	(0.4)	0	(0.0)
Nasal congestion	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Nasal discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal inflammation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal pain	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Pharyngeal inflammation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	3	(1.0)	2	(0.6)	5	(0.7)	1	(0.1)
Pneumonia aspiration	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Pneumonitis	3	(1.0)	1	(0.3)	26	(3.8)	12	(1.8)
Productive cough	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary artery thrombosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary embolism	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Rhinitis allergic	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Rhinorrhoea	3	(1.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tachypnoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper-airway cough syndrome	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**127**	**(41.1)**	**4**	**(1.3)**	**148**	**(21.7)**	**6**	**(0.9)**
Acne	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Alopecia	101	(32.7)	2	(0.6)	5	(0.7)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Dermatitis bullous	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Drug eruption	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Dry skin	4	(1.3)	0	(0.0)	18	(2.6)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	4	(0.6)	0	(0.0)
Erythema	2	(0.6)	0	(0.0)	3	(0.4)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperhidrosis	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Macule	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Nail discolouration	7	(2.3)	0	(0.0)	1	(0.1)	0	(0.0)
Nail disorder	11	(3.6)	0	(0.0)	1	(0.1)	0	(0.0)
Nail dystrophy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nail ridging	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	5	(1.6)	0	(0.0)	1	(0.1)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	4	(0.6)	0	(0.0)
Onychalgia	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Onychoclasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Onycholysis	8	(2.6)	1	(0.3)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**127**	**(41.1)**	**4**	**(1.3)**	**148**	**(21.7)**	**6**	**(0.9)**
Onychomadesis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	4	(1.3)	0	(0.0)	1	(0.1)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Photosensitivity reaction	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Pruritus	5	(1.6)	1	(0.3)	57	(8.4)	0	(0.0)
Pruritus generalised	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Psoriasis	0	(0.0)	0	(0.0)	4	(0.6)	1	(0.1)
Rash	14	(4.5)	0	(0.0)	73	(10.7)	2	(0.3)
Rash macular	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Rash maculo-papular	0	(0.0)	0	(0.0)	9	(1.3)	1	(0.1)
Rash pruritic	2	(0.6)	0	(0.0)	5	(0.7)	0	(0.0)
Seborrhoeic dermatitis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Skin exfoliation	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Skin fissures	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Skin induration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Skin irritation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Skin lesion	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Skin oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Skin ulcer	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Urticaria	3	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vitiligo	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups) APaT Population (TPS ≥1%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**16**	**(5.2)**	**1**	**(0.3)**	**16**	**(2.3)**	**4**	**(0.6)**
Deep vein thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Embolism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Flushing	2	(0.6)	0	(0.0)	3	(0.4)	0	(0.0)
Hot flush	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertension	2	(0.6)	0	(0.0)	5	(0.7)	2	(0.3)
Hypotension	3	(1.0)	1	(0.3)	3	(0.4)	0	(0.0)
Lymphoedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral ischaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Phlebitis	6	(1.9)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombophlebitis superficial	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Venous thrombosis limb	1	(0.3)	0	(0.0)	0	(0.0)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

Confidential

付録 2.7.4- 23　　副作用（いずれかの投与群で発現割合 5%以上）

010 試験（安全性解析対象集団）（PD-L1 高発現）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	133				137				151			
with one or more adverse events	105	(78.9)	45	(33.8)	93	(67.9)	18	(13.1)	109	(72.2)	33	(21.9)
with no adverse events	28	(21.1)	88	(66.2)	44	(32.1)	119	(86.9)	42	(27.8)	118	(78.1)
Blood and lymphatic system disorders	**35**	**(26.3)**	**25**	**(18.8)**	**13**	**(9.5)**	**2**	**(1.5)**	**13**	**(8.6)**	**4**	**(2.6)**
Anaemia	18	(13.5)	5	(3.8)	9	(6.6)	2	(1.5)	9	(6.0)	1	(0.7)
Neutropenia	18	(13.5)	17	(12.8)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Endocrine disorders	**1**	**(0.8)**	**0**	**(0.0)**	**18**	**(13.1)**	**1**	**(0.7)**	**19**	**(12.6)**	**2**	**(1.3)**
Hyperthyroidism	0	(0.0)	0	(0.0)	5	(3.6)	0	(0.0)	8	(5.3)	1	(0.7)
Hypothyroidism	1	(0.8)	0	(0.0)	13	(9.5)	0	(0.0)	12	(7.9)	0	(0.0)
Eye disorders	**7**	**(5.3)**	**0**	**(0.0)**	**3**	**(2.2)**	**0**	**(0.0)**	**5**	**(3.3)**	**0**	**(0.0)**
Gastrointestinal disorders	**64**	**(48.1)**	**4**	**(3.0)**	**42**	**(30.7)**	**0**	**(0.0)**	**34**	**(22.5)**	**3**	**(2.0)**
Constipation	7	(5.3)	0	(0.0)	6	(4.4)	0	(0.0)	5	(3.3)	0	(0.0)
Diarrhoea	31	(23.3)	2	(1.5)	13	(9.5)	0	(0.0)	12	(7.9)	0	(0.0)
Nausea	21	(15.8)	0	(0.0)	18	(13.1)	0	(0.0)	18	(11.9)	1	(0.7)
Stomatitis	23	(17.3)	0	(0.0)	7	(5.1)	0	(0.0)	3	(2.0)	1	(0.7)
Vomiting	14	(10.5)	1	(0.8)	8	(5.8)	0	(0.0)	10	(6.6)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**64**	**(48.1)**	**7**	**(5.3)**	**38**	**(27.7)**	**2**	**(1.5)**	**50**	**(33.1)**	**2**	**(1.3)**
Asthenia	13	(9.8)	1	(0.8)	8	(5.8)	0	(0.0)	9	(6.0)	0	(0.0)
Fatigue	33	(24.8)	4	(3.0)	25	(18.2)	2	(1.5)	23	(15.2)	2	(1.3)
Oedema peripheral	10	(7.5)	0	(0.0)	4	(2.9)	0	(0.0)	1	(0.7)	0	(0.0)
Pyrexia	8	(6.0)	1	(0.8)	6	(4.4)	0	(0.0)	8	(5.3)	0	(0.0)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**10**	**(7.3)**	**1**	**(0.7)**	**6**	**(4.0)**	**1**	**(0.7)**
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**18**	**(13.1)**	**2**	**(1.5)**	**28**	**(18.5)**	**5**	**(3.3)**
Neutrophil count decreased	9	(6.8)	8	(6.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
White blood cell count decreased	8	(6.0)	5	(3.8)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Metabolism and nutrition disorders	**30**	**(22.6)**	**2**	**(1.5)**	**30**	**(21.9)**	**3**	**(2.2)**	**28**	**(18.5)**	**9**	**(6.0)**
Decreased appetite	25	(18.8)	1	(0.8)	21	(15.3)	1	(0.7)	14	(9.3)	1	(0.7)
Musculoskeletal and connective tissue disorders	**20**	**(15.0)**	**0**	**(0.0)**	**17**	**(12.4)**	**1**	**(0.7)**	**23**	**(15.2)**	**0**	**(0.0)**
Arthralgia	7	(5.3)	0	(0.0)	4	(2.9)	0	(0.0)	12	(7.9)	0	(0.0)
Myalgia	11	(8.3)	0	(0.0)	5	(3.6)	0	(0.0)	8	(5.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**38**	**(28.6)**	**1**	**(0.8)**	**14**	**(10.2)**	**2**	**(1.5)**	**16**	**(10.6)**	**0**	**(0.0)**
Dysgeusia	10	(7.5)	0	(0.0)	2	(1.5)	0	(0.0)	4	(2.6)	0	(0.0)
Neuropathy peripheral	10	(7.5)	0	(0.0)	1	(0.7)	0	(0.0)	3	(2.0)	0	(0.0)
Paraesthesia	8	(6.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Peripheral sensory neuropathy	10	(7.5)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**25**	**(18.8)**	**6**	**(4.5)**	**23**	**(16.8)**	**6**	**(4.4)**	**19**	**(12.6)**	**5**	**(3.3)**
Pneumonitis	1	(0.8)	0	(0.0)	7	(5.1)	2	(1.5)	9	(6.0)	4	(2.6)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**32**	**(23.4)**	**0**	**(0.0)**	**43**	**(28.5)**	**2**	**(1.3)**
Alopecia	46	(34.6)	2	(1.5)	3	(2.2)	0	(0.0)	2	(1.3)	0	(0.0)
Dry skin	3	(2.3)	0	(0.0)	2	(1.5)	0	(0.0)	9	(6.0)	0	(0.0)
Onycholysis	7	(5.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	4	(3.0)	1	(0.8)	14	(10.2)	0	(0.0)	15	(9.9)	0	(0.0)
Rash	4	(3.0)	0	(0.0)	16	(11.7)	0	(0.0)	23	(15.2)	1	(0.7)
Vascular disorders	**13**	**(9.8)**	**0**	**(0.0)**	**3**	**(2.2)**	**0**	**(0.0)**	**6**	**(4.0)**	**3**	**(2.0)**

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.

Grades are based on NCI CTCAE version 4.0.

Adverse event terms are from MedDRA Version 18.0.

(Database Cutoff Date: 30SEP2015).

Confidential

付録 2.7.4- 24　　副作用（いずれかの投与群で発現割合 5%以上）

010 試験（MK-3475 併合、安全性解析対象集団）（PD-L1 高発現）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	133				288			
with one or more adverse events	105	(78.9)	45	(33.8)	202	(70.1)	51	(17.7)
with no adverse events	28	(21.1)	88	(66.2)	86	(29.9)	237	(82.3)
Blood and lymphatic system disorders	**35**	**(26.3)**	**25**	**(18.8)**	**26**	**(9.0)**	**6**	**(2.1)**
Anaemia	18	(13.5)	5	(3.8)	18	(6.3)	3	(1.0)
Neutropenia	18	(13.5)	17	(12.8)	1	(0.3)	0	(0.0)
Endocrine disorders	**1**	**(0.8)**	**0**	**(0.0)**	**37**	**(12.8)**	**3**	**(1.0)**
Hypothyroidism	1	(0.8)	0	(0.0)	25	(8.7)	0	(0.0)
Eye disorders	**7**	**(5.3)**	**0**	**(0.0)**	**8**	**(2.8)**	**0**	**(0.0)**
Gastrointestinal disorders	**64**	**(48.1)**	**4**	**(3.0)**	**76**	**(26.4)**	**3**	**(1.0)**
Constipation	7	(5.3)	0	(0.0)	11	(3.8)	0	(0.0)
Diarrhoea	31	(23.3)	2	(1.5)	25	(8.7)	0	(0.0)
Nausea	21	(15.8)	0	(0.0)	36	(12.5)	1	(0.3)
Stomatitis	23	(17.3)	0	(0.0)	10	(3.5)	1	(0.3)
Vomiting	14	(10.5)	1	(0.8)	18	(6.3)	0	(0.0)
General disorders and administration site conditions	**64**	**(48.1)**	**7**	**(5.3)**	**88**	**(30.6)**	**4**	**(1.4)**
Asthenia	13	(9.8)	1	(0.8)	17	(5.9)	0	(0.0)
Fatigue	33	(24.8)	4	(3.0)	48	(16.7)	4	(1.4)
Oedema peripheral	10	(7.5)	0	(0.0)	5	(1.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**64**	**(48.1)**	**7**	**(5.3)**	**88**	**(30.6)**	**4**	**(1.4)**
Pyrexia	8	(6.0)	1	(0.8)	14	(4.9)	0	(0.0)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**16**	**(5.6)**	**2**	**(0.7)**
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**46**	**(16.0)**	**7**	**(2.4)**
Neutrophil count decreased	9	(6.8)	8	(6.0)	2	(0.7)	0	(0.0)
White blood cell count decreased	8	(6.0)	5	(3.8)	2	(0.7)	0	(0.0)
Metabolism and nutrition disorders	**30**	**(22.6)**	**2**	**(1.5)**	**58**	**(20.1)**	**12**	**(4.2)**
Decreased appetite	25	(18.8)	1	(0.8)	35	(12.2)	2	(0.7)
Musculoskeletal and connective tissue disorders	**20**	**(15.0)**	**0**	**(0.0)**	**40**	**(13.9)**	**1**	**(0.3)**
Arthralgia	7	(5.3)	0	(0.0)	16	(5.6)	0	(0.0)
Myalgia	11	(8.3)	0	(0.0)	13	(4.5)	0	(0.0)
Nervous system disorders	**38**	**(28.6)**	**1**	**(0.8)**	**30**	**(10.4)**	**2**	**(0.7)**
Dysgeusia	10	(7.5)	0	(0.0)	6	(2.1)	0	(0.0)
Neuropathy peripheral	10	(7.5)	0	(0.0)	4	(1.4)	0	(0.0)
Paraesthesia	8	(6.0)	0	(0.0)	2	(0.7)	0	(0.0)
Peripheral sensory neuropathy	10	(7.5)	0	(0.0)	2	(0.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**25**	**(18.8)**	**6**	**(4.5)**	**42**	**(14.6)**	**11**	**(3.8)**
Pneumonitis	1	(0.8)	0	(0.0)	16	(5.6)	6	(2.1)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**75**	**(26.0)**	**2**	**(0.7)**
Alopecia	46	(34.6)	2	(1.5)	5	(1.7)	0	(0.0)
Onycholysis	7	(5.3)	1	(0.8)	0	(0.0)	0	(0.0)
Pruritus	4	(3.0)	1	(0.8)	29	(10.1)	0	(0.0)
Rash	4	(3.0)	0	(0.0)	39	(13.5)	1	(0.3)
Vascular disorders	**13**	**(9.8)**	**0**	**(0.0)**	**9**	**(3.1)**	**3**	**(1.0)**

Every subject is counted a single time for each applicable row and column.
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Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

Confidential

付録 2.7.4- 25　　副作用（いずれかの投与群で発現割合 5%以上）

010 試験（安全性解析対象集団）（PD-L1 低発現）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	176				202				192			
with one or more adverse events	146	(83.0)	64	(36.4)	122	(60.4)	25	(12.4)	117	(60.9)	22	(11.5)
with no adverse events	30	(17.0)	112	(63.6)	80	(39.6)	177	(87.6)	75	(39.1)	170	(88.5)
Blood and lymphatic system disorders	**52**	**(29.5)**	**30**	**(17.0)**	**6**	**(3.0)**	**1**	**(0.5)**	**9**	**(4.7)**	**0**	**(0.0)**
Anaemia	22	(12.5)	0	(0.0)	1	(0.5)	1	(0.5)	5	(2.6)	0	(0.0)
Febrile neutropenia	9	(5.1)	9	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Neutropenia	26	(14.8)	21	(11.9)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Endocrine disorders	**0**	**(0.0)**	**0**	**(0.0)**	**17**	**(8.4)**	**0**	**(0.0)**	**17**	**(8.9)**	**1**	**(0.5)**
Hypothyroidism	0	(0.0)	0	(0.0)	12	(5.9)	0	(0.0)	11	(5.7)	0	(0.0)
Gastrointestinal disorders	**68**	**(38.6)**	**10**	**(5.7)**	**45**	**(22.3)**	**6**	**(3.0)**	**32**	**(16.7)**	**2**	**(1.0)**
Diarrhoea	25	(14.2)	5	(2.8)	11	(5.4)	2	(1.0)	10	(5.2)	0	(0.0)
Nausea	24	(13.6)	1	(0.6)	19	(9.4)	1	(0.5)	13	(6.8)	1	(0.5)
Stomatitis	20	(11.4)	3	(1.7)	6	(3.0)	0	(0.0)	4	(2.1)	0	(0.0)
Vomiting	10	(5.7)	1	(0.6)	4	(2.0)	0	(0.0)	3	(1.6)	1	(0.5)
General disorders and administration site conditions	**85**	**(48.3)**	**16**	**(9.1)**	**41**	**(20.3)**	**4**	**(2.0)**	**51**	**(26.6)**	**5**	**(2.6)**
Asthenia	22	(12.5)	5	(2.8)	12	(5.9)	1	(0.5)	10	(5.2)	2	(1.0)
Fatigue	43	(24.4)	7	(4.0)	21	(10.4)	2	(1.0)	26	(13.5)	4	(2.1)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**85**	**(48.3)**	**16**	**(9.1)**	**41**	**(20.3)**	**4**	**(2.0)**	**51**	**(26.6)**	**5**	**(2.6)**
Oedema peripheral	11	(6.3)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.6)	0	(0.0)
Pyrexia	9	(5.1)	0	(0.0)	4	(2.0)	1	(0.5)	6	(3.1)	0	(0.0)
Infections and infestations	**18**	**(10.2)**	**5**	**(2.8)**	**7**	**(3.5)**	**2**	**(1.0)**	**7**	**(3.6)**	**3**	**(1.6)**
Investigations	**24**	**(13.6)**	**13**	**(7.4)**	**23**	**(11.4)**	**0**	**(0.0)**	**19**	**(9.9)**	**4**	**(2.1)**
Alanine aminotransferase increased	2	(1.1)	0	(0.0)	10	(5.0)	0	(0.0)	3	(1.6)	1	(0.5)
Neutrophil count decreased	15	(8.5)	11	(6.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**33**	**(18.8)**	**6**	**(3.4)**	**33**	**(16.3)**	**5**	**(2.5)**	**28**	**(14.6)**	**4**	**(2.1)**
Decreased appetite	24	(13.6)	2	(1.1)	25	(12.4)	2	(1.0)	19	(9.9)	0	(0.0)
Musculoskeletal and connective tissue disorders	**37**	**(21.0)**	**0**	**(0.0)**	**22**	**(10.9)**	**0**	**(0.0)**	**15**	**(7.8)**	**3**	**(1.6)**
Arthralgia	11	(6.3)	0	(0.0)	9	(4.5)	0	(0.0)	7	(3.6)	2	(1.0)
Myalgia	18	(10.2)	0	(0.0)	4	(2.0)	0	(0.0)	2	(1.0)	0	(0.0)
Nervous system disorders	**42**	**(23.9)**	**3**	**(1.7)**	**14**	**(6.9)**	**0**	**(0.0)**	**16**	**(8.3)**	**1**	**(0.5)**

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence ≥ 5% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**42**	**(23.9)**	**3**	**(1.7)**	**14**	**(6.9)**	**0**	**(0.0)**	**16**	**(8.3)**	**1**	**(0.5)**
Neuropathy peripheral	18	(10.2)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	9	(5.1)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**19**	**(10.8)**	**2**	**(1.1)**	**21**	**(10.4)**	**4**	**(2.0)**	**11**	**(5.7)**	**2**	**(1.0)**
Skin and subcutaneous tissue disorders	**73**	**(41.5)**	**0**	**(0.0)**	**32**	**(15.8)**	**3**	**(1.5)**	**41**	**(21.4)**	**1**	**(0.5)**
Alopecia	55	(31.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail disorder	9	(5.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	1	(0.6)	0	(0.0)	11	(5.4)	0	(0.0)	17	(8.9)	0	(0.0)
Rash	10	(5.7)	0	(0.0)	13	(6.4)	1	(0.5)	21	(10.9)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 26　　副作用（いずれかの投与群で発現割合 0%超）

010 試験（安全性解析対象集団）（PD-L1 高発現）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	133				137				151			
with one or more adverse events	105	(78.9)	45	(33.8)	93	(67.9)	18	(13.1)	109	(72.2)	33	(21.9)
with no adverse events	28	(21.1)	88	(66.2)	44	(32.1)	119	(86.9)	42	(27.8)	118	(78.1)
Blood and lymphatic system disorders	**35**	**(26.3)**	**25**	**(18.8)**	**13**	**(9.5)**	**2**	**(1.5)**	**13**	**(8.6)**	**4**	**(2.6)**
Anaemia	18	(13.5)	5	(3.8)	9	(6.6)	2	(1.5)	9	(6.0)	1	(0.7)
Febrile neutropenia	6	(4.5)	6	(4.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Leukaemoid reaction	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Leukopenia	4	(3.0)	4	(3.0)	1	(0.7)	0	(0.0)	1	(0.7)	1	(0.7)
Lymphopenia	1	(0.8)	0	(0.0)	3	(2.2)	0	(0.0)	1	(0.7)	0	(0.0)
Microcytic anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Neutropenia	18	(13.5)	17	(12.8)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Cardiac disorders	**3**	**(2.3)**	**1**	**(0.8)**	**3**	**(2.2)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Arrhythmia	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Atrial fibrillation	2	(1.5)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrioventricular block	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pericardial effusion	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Tachycardia	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders	**2**	**(1.5)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Ear and labyrinth disorders	**2**	**(1.5)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Tinnitus	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vertigo	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Endocrine disorders	**1**	**(0.8)**	**0**	**(0.0)**	**18**	**(13.1)**	**1**	**(0.7)**	**19**	**(12.6)**	**2**	**(1.3)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	1	(0.7)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Hyperthyroidism	0	(0.0)	0	(0.0)	5	(3.6)	0	(0.0)	8	(5.3)	1	(0.7)
Hypopituitarism	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)	0	(0.0)	0	(0.0)
Hypothalamo-pituitary disorder	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Hypothyroidism	1	(0.8)	0	(0.0)	13	(9.5)	0	(0.0)	12	(7.9)	0	(0.0)
Thyroiditis	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eye disorders	**7**	**(5.3)**	**0**	**(0.0)**	**3**	**(2.2)**	**0**	**(0.0)**	**5**	**(3.3)**	**0**	**(0.0)**
Dry eye	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	3	(2.0)	0	(0.0)
Eye irritation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Lacrimation increased	4	(3.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Vision blurred	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal disorders	**64**	**(48.1)**	**4**	**(3.0)**	**42**	**(30.7)**	**0**	**(0.0)**	**34**	**(22.5)**	**3**	**(2.0)**
Abdominal distension	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Abdominal pain	4	(3.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)
Abdominal pain lower	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**64**	**(48.1)**	**4**	**(3.0)**	**42**	**(30.7)**	**0**	**(0.0)**	**34**	**(22.5)**	**3**	**(2.0)**
Colitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Colitis ischaemic	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	7	(5.3)	0	(0.0)	6	(4.4)	0	(0.0)	5	(3.3)	0	(0.0)
Dental discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	31	(23.3)	2	(1.5)	13	(9.5)	0	(0.0)	12	(7.9)	0	(0.0)
Dry mouth	2	(1.5)	0	(0.0)	4	(2.9)	0	(0.0)	1	(0.7)	0	(0.0)
Dyspepsia	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysphagia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Gastritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Gastrointestinal motility disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrooesophageal reflux disease	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	21	(15.8)	0	(0.0)	18	(13.1)	0	(0.0)	18	(11.9)	1	(0.7)
Oral disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral dysaesthesia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Stomatitis	23	(17.3)	0	(0.0)	7	(5.1)	0	(0.0)	3	(2.0)	1	(0.7)
Vomiting	14	(10.5)	1	(0.8)	8	(5.8)	0	(0.0)	10	(6.6)	0	(0.0)
General disorders and administration site conditions	**64**	**(48.1)**	**7**	**(5.3)**	**38**	**(27.7)**	**2**	**(1.5)**	**50**	**(33.1)**	**2**	**(1.3)**
Asthenia	13	(9.8)	1	(0.8)	8	(5.8)	0	(0.0)	9	(6.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**64**	**(48.1)**	7	**(5.3)**	**38**	**(27.7)**	**2**	**(1.5)**	**50**	**(33.1)**	**2**	**(1.3)**
Catheter site pain	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Chills	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Enanthema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Face oedema	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	33	(24.8)	4	(3.0)	25	(18.2)	2	(1.5)	23	(15.2)	2	(1.3)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Gait disturbance	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Generalised oedema	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(2.6)	0	(0.0)
Infusion site extravasation	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site vasculitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site reaction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Local swelling	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Malaise	4	(3.0)	0	(0.0)	3	(2.2)	0	(0.0)	5	(3.3)	0	(0.0)
Mucosal dryness	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Mucosal inflammation	2	(1.5)	1	(0.8)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Nodule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**64**	**(48.1)**	**7**	**(5.3)**	**38**	**(27.7)**	**2**	**(1.5)**	**50**	**(33.1)**	**2**	**(1.3)**
Oedema	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	10	(7.5)	0	(0.0)	4	(2.9)	0	(0.0)	1	(0.7)	0	(0.0)
Pain	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Pyrexia	8	(6.0)	1	(0.8)	6	(4.4)	0	(0.0)	8	(5.3)	0	(0.0)
Serositis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.7)**	**0**	**(0.0)**	**2**	**(1.3)**	**0**	**(0.0)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Cholestasis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Hepatotoxicity	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Immune system disorders	**3**	**(2.3)**	**0**	**(0.0)**	**1**	**(0.7)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Drug hypersensitivity	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypersensitivity	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**10**	**(7.3)**	**1**	**(0.7)**	**6**	**(4.0)**	**1**	**(0.7)**
Anal abscess	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Candida infection	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Cystitis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**10**	**(7.3)**	**1**	**(0.7)**	**6**	**(4.0)**	**1**	**(0.7)**
Dermatophytosis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Eye infection	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Laryngitis	1	(0.8)	1	(0.8)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Lobar pneumonia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Lung infection	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Mucosal infection	1	(0.8)	1	(0.8)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Nail infection	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nasopharyngitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Onychomycosis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Perichondritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Pharyngitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Phlebitis infective	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia	2	(1.5)	2	(1.5)	1	(0.7)	1	(0.7)	2	(1.3)	1	(0.7)
Pneumonia bacterial	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash pustular	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Sepsis	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Septic shock	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract infection	3	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**10**	**(7.3)**	**1**	**(0.7)**	**6**	**(4.0)**	**1**	**(0.7)**
Urinary tract infection	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications	**5**	**(3.8)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**5**	**(3.3)**	**1**	**(0.7)**
Contusion	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion related reaction	4	(3.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.0)	0	(0.0)
Injection related reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**18**	**(13.1)**	**2**	**(1.5)**	**28**	**(18.5)**	**5**	**(3.3)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Alanine aminotransferase increased	2	(1.5)	0	(0.0)	6	(4.4)	2	(1.5)	5	(3.3)	0	(0.0)
Aspartate aminotransferase	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Aspartate aminotransferase increased	1	(0.8)	0	(0.0)	5	(3.6)	2	(1.5)	4	(2.6)	0	(0.0)
Blood albumin increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Blood alkaline phosphatase increased	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	3	(2.0)	1	(0.7)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**18**	**(13.1)**	**2**	**(1.5)**	**28**	**(18.5)**	**5**	**(3.3)**
Blood bilirubin increased	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	2	(1.3)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Blood creatinine increased	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	4	(2.6)	0	(0.0)
Blood phosphorus decreased	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	2	(1.3)	0	(0.0)
Blood triglycerides increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Blood urea increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	0	(0.0)	0	(0.0)	3	(2.2)	0	(0.0)	1	(0.7)	1	(0.7)
Haematocrit decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Haemoglobin decreased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	2	(1.3)	2	(1.3)
Neutrophil count decreased	9	(6.8)	8	(6.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**18**	**(13.1)**	**2**	**(1.5)**	**28**	**(18.5)**	**5**	**(3.3)**
Platelet count decreased	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	3	(2.0)	1	(0.7)
Protein total decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Thyroxine decreased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	2	(1.3)	0	(0.0)
Thyroxine increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Tri-iodothyronine free decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Tri-iodothyronine free increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Weight decreased	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	6	(4.0)	0	(0.0)
Weight increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
White blood cell count decreased	8	(6.0)	5	(3.8)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
White blood cell count increased	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**30**	**(22.6)**	**2**	**(1.5)**	**30**	**(21.9)**	**3**	**(2.2)**	**28**	**(18.5)**	**9**	**(6.0)**
Decreased appetite	25	(18.8)	1	(0.8)	21	(15.3)	1	(0.7)	14	(9.3)	1	(0.7)
Dehydration	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diabetes mellitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Hyperamylasaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Hypercalcaemia	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	2	(1.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**30**	**(22.6)**	**2**	**(1.5)**	**30**	**(21.9)**	**3**	**(2.2)**	**28**	**(18.5)**	**9**	**(6.0)**
Hyperglycaemia	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.7)	1	(0.7)
Hypertriglyceridaemia	0	(0.0)	0	(0.0)	2	(1.5)	1	(0.7)	5	(3.3)	2	(1.3)
Hyperuricaemia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoalbuminaemia	1	(0.8)	0	(0.0)	3	(2.2)	0	(0.0)	2	(1.3)	0	(0.0)
Hypocalcaemia	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	2	(1.3)	0	(0.0)
Hypokalaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Hypomagnesaemia	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	3	(2.0)	0	(0.0)
Hyponatraemia	1	(0.8)	0	(0.0)	1	(0.7)	1	(0.7)	1	(0.7)	1	(0.7)
Hypophosphataemia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Lactic acidosis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	**20**	**(15.0)**	**0**	**(0.0)**	**17**	**(12.4)**	**1**	**(0.7)**	**23**	**(15.2)**	**0**	**(0.0)**
Arthralgia	7	(5.3)	0	(0.0)	4	(2.9)	0	(0.0)	12	(7.9)	0	(0.0)
Arthritis	0	(0.0)	0	(0.0)	4	(2.9)	1	(0.7)	1	(0.7)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	2	(1.5)	1	(0.7)	2	(1.3)	0	(0.0)
Bone pain	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bursitis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**20**	**(15.0)**	**0**	**(0.0)**	**17**	**(12.4)**	**1**	**(0.7)**	**23**	**(15.2)**	**0**	**(0.0)**
Joint stiffness	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Joint swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Limb discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Muscular weakness	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Myalgia	11	(8.3)	0	(0.0)	5	(3.6)	0	(0.0)	8	(5.3)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Pain in extremity	2	(1.5)	0	(0.0)	2	(1.5)	0	(0.0)	2	(1.3)	0	(0.0)
Pain in jaw	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.3)**	**0**	**(0.0)**
Cancer pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Oncologic complication	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Nervous system disorders	**38**	**(28.6)**	**1**	**(0.8)**	**14**	**(10.2)**	**2**	**(1.5)**	**16**	**(10.6)**	**0**	**(0.0)**

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**38**	**(28.6)**	**1**	**(0.8)**	**14**	**(10.2)**	**2**	**(1.5)**	**16**	**(10.6)**	**0**	**(0.0)**
Ataxia	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Burning sensation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cerebrovascular accident	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)	0	(0.0)	0	(0.0)
Cognitive disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dizziness	2	(1.5)	0	(0.0)	4	(2.9)	0	(0.0)	3	(2.0)	0	(0.0)
Dysaesthesia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	10	(7.5)	0	(0.0)	2	(1.5)	0	(0.0)	4	(2.6)	0	(0.0)
Headache	2	(1.5)	0	(0.0)	3	(2.2)	0	(0.0)	3	(2.0)	0	(0.0)
Hypoaesthesia	4	(3.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Hypogeusia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neuropathy peripheral	10	(7.5)	0	(0.0)	1	(0.7)	0	(0.0)	3	(2.0)	0	(0.0)
Neurotoxicity	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	8	(6.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Peripheral sensory neuropathy	10	(7.5)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Peroneal nerve palsy	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Polyneuropathy	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Toxic leukoencephalopathy	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric disorders	**3**	**(2.3)**	**0**	**(0.0)**	**1**	**(0.7)**	**0**	**(0.0)**	**5**	**(3.3)**	**0**	**(0.0)**
Insomnia	3	(2.3)	0	(0.0)	1	(0.7)	0	(0.0)	3	(2.0)	0	(0.0)
Restlessness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Renal and urinary disorders	**2**	**(1.5)**	**0**	**(0.0)**	**5**	**(3.6)**	**1**	**(0.7)**	**1**	**(0.7)**	**0**	**(0.0)**
Chronic kidney disease	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Micturition urgency	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Pollakiuria	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)	0	(0.0)	0	(0.0)
Urinary tract obstruction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**1**	**(0.8)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.3)**	**1**	**(0.7)**
Erectile dysfunction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Respiratory, thoracic and mediastinal disorders	**25**	**(18.8)**	**6**	**(4.5)**	**23**	**(16.8)**	**6**	**(4.4)**	**19**	**(12.6)**	**5**	**(3.3)**
Bronchospasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	2	(1.5)	1	(0.7)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**25**	**(18.8)**	**6**	**(4.5)**	**23**	**(16.8)**	**6**	**(4.4)**	**19**	**(12.6)**	**5**	**(3.3)**
Cough	1	(0.8)	0	(0.0)	4	(2.9)	0	(0.0)	2	(1.3)	0	(0.0)
Dysphonia	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Dyspnoea	6	(4.5)	3	(2.3)	4	(2.9)	2	(1.5)	5	(3.3)	1	(0.7)
Dyspnoea exertional	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Epistaxis	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoptysis	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Hiccups	3	(2.3)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Interstitial lung disease	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Nasal congestion	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal inflammation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal pain	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	3	(2.3)	2	(1.5)	3	(2.2)	1	(0.7)	1	(0.7)	0	(0.0)
Pneumonia aspiration	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonitis	1	(0.8)	0	(0.0)	7	(5.1)	2	(1.5)	9	(6.0)	4	(2.6)
Pulmonary embolism	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)	0	(0.0)	0	(0.0)
Rhinitis allergic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.3)	0	(0.0)
Rhinorrhoea	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**32**	**(23.4)**	**0**	**(0.0)**	**43**	**(28.5)**	**2**	**(1.3)**
Acne	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups) APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**32**	**(23.4)**	**0**	**(0.0)**	**43**	**(28.5)**	**2**	**(1.3)**
Alopecia	46	(34.6)	2	(1.5)	3	(2.2)	0	(0.0)	2	(1.3)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Dry skin	3	(2.3)	0	(0.0)	2	(1.5)	0	(0.0)	9	(6.0)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.7)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Hyperhidrosis	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Macule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Nail discolouration	4	(3.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Nail disorder	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail dystrophy	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	2	(1.3)	0	(0.0)
Onycholysis	7	(5.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Onychomadesis	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	4	(3.0)	1	(0.8)	14	(10.2)	0	(0.0)	15	(9.9)	0	(0.0)
Pruritus generalised	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**32**	**(23.4)**	**0**	**(0.0)**	**43**	**(28.5)**	**2**	**(1.3)**
Psoriasis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Rash	4	(3.0)	0	(0.0)	16	(11.7)	0	(0.0)	23	(15.2)	1	(0.7)
Rash macular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Rash maculo-papular	0	(0.0)	0	(0.0)	3	(2.2)	0	(0.0)	3	(2.0)	0	(0.0)
Rash pruritic	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	3	(2.0)	0	(0.0)
Seborrhoeic dermatitis	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Skin fissures	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin lesion	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Skin ulcer	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Urticaria	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vitiligo	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders	**13**	**(9.8)**	**0**	**(0.0)**	**3**	**(2.2)**	**0**	**(0.0)**	**6**	**(4.0)**	**3**	**(2.0)**
Deep vein thrombosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Embolism	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Flushing	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	0	(0.0)
Hot flush	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertension	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.7)	1	(0.7)
Hypotension	1	(0.8)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.7)	0	(0.0)
Lymphoedema	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral ischaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.7)
Phlebitis	6	(4.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**13**	**(9.8)**	**0**	**(0.0)**	**3**	**(2.2)**	**0**	**(0.0)**	**6**	**(4.0)**	**3**	**(2.0)**
Thrombophlebitis superficial	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Venous thrombosis limb	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 27　　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 高発現）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	133				288			
with one or more adverse events	105	(78.9)	45	(33.8)	202	(70.1)	51	(17.7)
with no adverse events	28	(21.1)	88	(66.2)	86	(29.9)	237	(82.3)
Blood and lymphatic system disorders	**35**	**(26.3)**	**25**	**(18.8)**	**26**	**(9.0)**	**6**	**(2.1)**
Anaemia	18	(13.5)	5	(3.8)	18	(6.3)	3	(1.0)
Febrile neutropenia	6	(4.5)	6	(4.5)	0	(0.0)	0	(0.0)
Leukaemoid reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Leukopenia	4	(3.0)	4	(3.0)	2	(0.7)	1	(0.3)
Lymphopenia	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Microcytic anaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Neutropenia	18	(13.5)	17	(12.8)	1	(0.3)	0	(0.0)
Thrombocytopenia	2	(1.5)	0	(0.0)	1	(0.3)	1	(0.3)
Cardiac disorders	**3**	**(2.3)**	**1**	**(0.8)**	**3**	**(1.0)**	**0**	**(0.0)**
Arrhythmia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Atrial fibrillation	2	(1.5)	1	(0.8)	0	(0.0)	0	(0.0)
Atrioventricular block	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Pericardial effusion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Tachycardia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Ear and labyrinth disorders	**2**	**(1.5)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Tinnitus	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Vertigo	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**1**	**(0.8)**	**0**	**(0.0)**	**37**	**(12.8)**	**3**	**(1.0)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	2	(0.7)	1	(0.3)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperthyroidism	0	(0.0)	0	(0.0)	13	(4.5)	1	(0.3)
Hypopituitarism	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hypothalamo-pituitary disorder	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypothyroidism	1	(0.8)	0	(0.0)	25	(8.7)	0	(0.0)
Thyroiditis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Eye disorders	**7**	**(5.3)**	**0**	**(0.0)**	**8**	**(2.8)**	**0**	**(0.0)**
Dry eye	1	(0.8)	0	(0.0)	5	(1.7)	0	(0.0)
Eye irritation	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Lacrimation increased	4	(3.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vision blurred	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Gastrointestinal disorders	**64**	**(48.1)**	**4**	**(3.0)**	**76**	**(26.4)**	**3**	**(1.0)**
Abdominal distension	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Abdominal pain	4	(3.0)	0	(0.0)	3	(1.0)	0	(0.0)
Abdominal pain lower	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Colitis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Colitis ischaemic	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Constipation	7	(5.3)	0	(0.0)	11	(3.8)	0	(0.0)
Dental discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	31	(23.3)	2	(1.5)	25	(8.7)	0	(0.0)
Dry mouth	2	(1.5)	0	(0.0)	5	(1.7)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**64**	**(48.1)**	**4**	**(3.0)**	**76**	**(26.4)**	**3**	**(1.0)**
Dyspepsia	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dysphagia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gastritis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gastrointestinal motility disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrooesophageal reflux disease	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Nausea	21	(15.8)	0	(0.0)	36	(12.5)	1	(0.3)
Oral disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oral dysaesthesia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Stomatitis	23	(17.3)	0	(0.0)	10	(3.5)	1	(0.3)
Vomiting	14	(10.5)	1	(0.8)	18	(6.3)	0	(0.0)
General disorders and administration site conditions	**64**	**(48.1)**	**7**	**(5.3)**	**88**	**(30.6)**	**4**	**(1.4)**
Asthenia	13	(9.8)	1	(0.8)	17	(5.9)	0	(0.0)
Catheter site pain	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Chills	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Enanthema	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Face oedema	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	33	(24.8)	4	(3.0)	48	(16.7)	4	(1.4)
Feeling cold	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Gait disturbance	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**64**	**(48.1)**	7	**(5.3)**	**88**	**(30.6)**	**4**	**(1.4)**
Generalised oedema	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Infusion site extravasation	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Infusion site vasculitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site reaction	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Local swelling	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Malaise	4	(3.0)	0	(0.0)	8	(2.8)	0	(0.0)
Mucosal dryness	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Mucosal inflammation	2	(1.5)	1	(0.8)	2	(0.7)	0	(0.0)
Nodule	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Oedema	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	10	(7.5)	0	(0.0)	5	(1.7)	0	(0.0)
Pain	2	(1.5)	0	(0.0)	2	(0.7)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pyrexia	8	(6.0)	1	(0.8)	14	(4.9)	0	(0.0)
Serositis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(1.0)**	**0**	**(0.0)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cholestasis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(1.0)**	**0**	**(0.0)**
Hepatotoxicity	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Immune system disorders	**3**	**(2.3)**	**0**	**(0.0)**	**1**	**(0.3)**	**0**	**(0.0)**
Drug hypersensitivity	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Hypersensitivity	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**16**	**(5.6)**	**2**	**(0.7)**
Anal abscess	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Candida infection	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Cystitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Eye infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Laryngitis	1	(0.8)	1	(0.8)	1	(0.3)	0	(0.0)
Lobar pneumonia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Lung infection	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)
Mucosal infection	1	(0.8)	1	(0.8)	1	(0.3)	0	(0.0)
Nail infection	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Nasopharyngitis	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Onychomycosis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Perichondritis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**16**	**(12.0)**	**8**	**(6.0)**	**16**	**(5.6)**	**2**	**(0.7)**
Pharyngitis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Phlebitis infective	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Pneumonia	2	(1.5)	2	(1.5)	3	(1.0)	2	(0.7)
Pneumonia bacterial	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Rash pustular	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Sepsis	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Septic shock	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Upper respiratory tract infection	3	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)
Urinary tract infection	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Injury, poisoning and procedural complications	**5**	**(3.8)**	**0**	**(0.0)**	**5**	**(1.7)**	**1**	**(0.3)**
Contusion	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion related reaction	4	(3.0)	0	(0.0)	3	(1.0)	0	(0.0)
Injection related reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**46**	**(16.0)**	**7**	**(2.4)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Alanine aminotransferase increased	2	(1.5)	0	(0.0)	11	(3.8)	2	(0.7)
Aspartate aminotransferase	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Aspartate aminotransferase increased	1	(0.8)	0	(0.0)	9	(3.1)	2	(0.7)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**46**	**(16.0)**	**7**	**(2.4)**
Blood albumin increased	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Blood alkaline phosphatase increased	1	(0.8)	0	(0.0)	4	(1.4)	1	(0.3)
Blood bilirubin increased	0	(0.0)	0	(0.0)	4	(1.4)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Blood creatinine increased	0	(0.0)	0	(0.0)	6	(2.1)	0	(0.0)
Blood phosphorus decreased	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Blood triglycerides increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood urea increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
C-reactive protein increased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	0	(0.0)	0	(0.0)	4	(1.4)	1	(0.3)
Haematocrit decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Haemoglobin decreased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	1	(0.8)	0	(0.0)	3	(1.0)	2	(0.7)
Neutrophil count decreased	9	(6.8)	8	(6.0)	2	(0.7)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Platelet count decreased	1	(0.8)	1	(0.8)	3	(1.0)	1	(0.3)
Protein total decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Thyroxine decreased	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Thyroxine increased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Tri-iodothyronine free decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**18**	**(13.5)**	**12**	**(9.0)**	**46**	**(16.0)**	**7**	**(2.4)**
Tri-iodothyronine free increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Weight decreased	0	(0.0)	0	(0.0)	8	(2.8)	0	(0.0)
Weight increased	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
White blood cell count decreased	8	(6.0)	5	(3.8)	2	(0.7)	0	(0.0)
White blood cell count increased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Metabolism and nutrition disorders	**30**	**(22.6)**	**2**	**(1.5)**	**58**	**(20.1)**	**12**	**(4.2)**
Decreased appetite	25	(18.8)	1	(0.8)	35	(12.2)	2	(0.7)
Dehydration	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hyperamylasaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Hypercalcaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Hyperglycaemia	1	(0.8)	0	(0.0)	3	(1.0)	1	(0.3)
Hypertriglyceridaemia	0	(0.0)	0	(0.0)	7	(2.4)	3	(1.0)
Hyperuricaemia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoalbuminaemia	1	(0.8)	0	(0.0)	5	(1.7)	0	(0.0)
Hypocalcaemia	1	(0.8)	0	(0.0)	3	(1.0)	0	(0.0)
Hypokalaemia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hypomagnesaemia	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Hyponatraemia	1	(0.8)	0	(0.0)	2	(0.7)	2	(0.7)
Hypophosphataemia	1	(0.8)	0	(0.0)	1	(0.3)	1	(0.3)
Lactic acidosis	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**30**	**(22.6)**	**2**	**(1.5)**	**58**	**(20.1)**	**12**	**(4.2)**
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Musculoskeletal and connective tissue disorders	**20**	**(15.0)**	**0**	**(0.0)**	**40**	**(13.9)**	**1**	**(0.3)**
Arthralgia	7	(5.3)	0	(0.0)	16	(5.6)	0	(0.0)
Arthritis	0	(0.0)	0	(0.0)	5	(1.7)	1	(0.3)
Back pain	0	(0.0)	0	(0.0)	4	(1.4)	1	(0.3)
Bone pain	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bursitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Joint stiffness	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Joint swelling	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Limb discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Muscular weakness	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Myalgia	11	(8.3)	0	(0.0)	13	(4.5)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pain in extremity	2	(1.5)	0	(0.0)	4	(1.4)	0	(0.0)
Pain in jaw	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.7)**	**0**	**(0.0)**
Cancer pain	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nervous system disorders	**38**	**(28.6)**	**1**	**(0.8)**	**30**	**(10.4)**	**2**	**(0.7)**
Ataxia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Burning sensation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Cerebrovascular accident	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Cognitive disorder	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Dizziness	2	(1.5)	0	(0.0)	7	(2.4)	0	(0.0)
Dysaesthesia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	10	(7.5)	0	(0.0)	6	(2.1)	0	(0.0)
Headache	2	(1.5)	0	(0.0)	6	(2.1)	0	(0.0)
Hypoaesthesia	4	(3.0)	0	(0.0)	2	(0.7)	0	(0.0)
Hypogeusia	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Neuropathy peripheral	10	(7.5)	0	(0.0)	4	(1.4)	0	(0.0)
Neurotoxicity	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	8	(6.0)	0	(0.0)	2	(0.7)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Peripheral sensory neuropathy	10	(7.5)	0	(0.0)	2	(0.7)	0	(0.0)
Peroneal nerve palsy	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Polyneuropathy	1	(0.8)	1	(0.8)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**38**	**(28.6)**	**1**	**(0.8)**	**30**	**(10.4)**	**2**	**(0.7)**
Restless legs syndrome	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Toxic leukoencephalopathy	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Psychiatric disorders	**3**	**(2.3)**	**0**	**(0.0)**	**6**	**(2.1)**	**0**	**(0.0)**
Insomnia	3	(2.3)	0	(0.0)	4	(1.4)	0	(0.0)
Restlessness	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Renal and urinary disorders	**2**	**(1.5)**	**0**	**(0.0)**	**6**	**(2.1)**	**1**	**(0.3)**
Chronic kidney disease	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Micturition urgency	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pollakiuria	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Urinary tract obstruction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**1**	**(0.8)**	**0**	**(0.0)**	**2**	**(0.7)**	**1**	**(0.3)**
Erectile dysfunction	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Respiratory, thoracic and mediastinal disorders	**25**	**(18.8)**	**6**	**(4.5)**	**42**	**(14.6)**	**11**	**(3.8)**

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**25**	**(18.8)**	**6**	**(4.5)**	**42**	**(14.6)**	**11**	**(3.8)**
Bronchospasm	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Chronic obstructive pulmonary disease	0	(0.0)	0	(0.0)	2	(0.7)	1	(0.3)
Cough	1	(0.8)	0	(0.0)	6	(2.1)	0	(0.0)
Dysphonia	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Dyspnoea	6	(4.5)	3	(2.3)	9	(3.1)	3	(1.0)
Dyspnoea exertional	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Epistaxis	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoptysis	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Hiccups	3	(2.3)	0	(0.0)	1	(0.3)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Interstitial lung disease	1	(0.8)	1	(0.8)	1	(0.3)	0	(0.0)
Nasal congestion	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nasal discomfort	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal inflammation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal pain	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	3	(2.3)	2	(1.5)	4	(1.4)	1	(0.3)
Pneumonia aspiration	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)
Pneumonitis	1	(0.8)	0	(0.0)	16	(5.6)	6	(2.1)
Pulmonary embolism	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Rhinitis allergic	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Rhinorrhoea	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**75**	**(26.0)**	**2**	**(0.7)**
Acne	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Alopecia	46	(34.6)	2	(1.5)	5	(1.7)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Dry skin	3	(2.3)	0	(0.0)	11	(3.8)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Hyperhidrosis	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Macule	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nail discolouration	4	(3.0)	0	(0.0)	1	(0.3)	0	(0.0)
Nail disorder	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nail dystrophy	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	3	(1.0)	0	(0.0)
Onycholysis	7	(5.3)	1	(0.8)	0	(0.0)	0	(0.0)
Onychomadesis	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	1	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)
Photosensitivity reaction	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Pruritus	4	(3.0)	1	(0.8)	29	(10.1)	0	(0.0)
Pruritus generalised	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**54**	**(40.6)**	**4**	**(3.0)**	**75**	**(26.0)**	**2**	**(0.7)**
Psoriasis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rash	4	(3.0)	0	(0.0)	39	(13.5)	1	(0.3)
Rash macular	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Rash maculo-papular	0	(0.0)	0	(0.0)	6	(2.1)	0	(0.0)
Rash pruritic	1	(0.8)	0	(0.0)	4	(1.4)	0	(0.0)
Seborrhoeic dermatitis	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Skin fissures	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Skin lesion	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Skin ulcer	0	(0.0)	0	(0.0)	2	(0.7)	0	(0.0)
Urticaria	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vitiligo	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Vascular disorders	**13**	**(9.8)**	**0**	**(0.0)**	**9**	**(3.1)**	**3**	**(1.0)**
Deep vein thrombosis	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
Embolism	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Flushing	2	(1.5)	0	(0.0)	1	(0.3)	0	(0.0)
Hot flush	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertension	1	(0.8)	0	(0.0)	3	(1.0)	1	(0.3)
Hypotension	1	(0.8)	0	(0.0)	2	(0.7)	0	(0.0)
Lymphoedema	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral ischaemia	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)
Phlebitis	6	(4.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (TPS ≥50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 Pooled			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**13**	**(9.8)**	**0**	**(0.0)**	**9**	**(3.1)**	**3**	**(1.0)**
Thrombophlebitis superficial	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
Venous thrombosis limb	1	(0.8)	0	(0.0)	0	(0.0)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 28　　副作用（いずれかの投与群で発現割合 0%超）

010 試験（安全性解析対象集団）（PD-L1 低発現）

Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	176				202				192			
with one or more adverse events	146	(83.0)	64	(36.4)	122	(60.4)	25	(12.4)	117	(60.9)	22	(11.5)
with no adverse events	30	(17.0)	112	(63.6)	80	(39.6)	177	(87.6)	75	(39.1)	170	(88.5)
Blood and lymphatic system disorders	**52**	**(29.5)**	**30**	**(17.0)**	**6**	**(3.0)**	**1**	**(0.5)**	**9**	**(4.7)**	**0**	**(0.0)**
Anaemia	22	(12.5)	0	(0.0)	1	(0.5)	1	(0.5)	5	(2.6)	0	(0.0)
Bone marrow failure	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eosinophilia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Febrile neutropenia	9	(5.1)	9	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Granulocytopenia	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Leukocytosis	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Leukopenia	5	(2.8)	4	(2.3)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymph node pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lymphadenopathy	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphopenia	4	(2.3)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Neutropenia	26	(14.8)	21	(11.9)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Neutrophilia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia	5	(2.8)	1	(0.6)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cardiac disorders	**3**	**(1.7)**	**2**	**(1.1)**	**0**	**(0.0)**	**0**	**(0.0)**	**5**	**(2.6)**	**3**	**(1.6)**
Arteriosclerosis coronary artery	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrial fibrillation	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**3**	**(1.7)**	**2**	**(1.1)**	**0**	**(0.0)**	**0**	**(0.0)**	**5**	**(2.6)**	**3**	**(1.6)**
Atrioventricular block complete	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Cardiac failure acute	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cyanosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Myocardial infarction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pericardial effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Tachycardia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders	**1**	**(0.6)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**3**	**(1.6)**	**1**	**(0.5)**
Ear pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Vertigo	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Endocrine disorders	**0**	**(0.0)**	**0**	**(0.0)**	**17**	**(8.4)**	**0**	**(0.0)**	**17**	**(8.9)**	**1**	**(0.5)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperthyroidism	0	(0.0)	0	(0.0)	5	(2.5)	0	(0.0)	7	(3.6)	0	(0.0)
Hypopituitarism	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Hypothyroidism	0	(0.0)	0	(0.0)	12	(5.9)	0	(0.0)	11	(5.7)	0	(0.0)
Eye disorders	**6**	**(3.4)**	**0**	**(0.0)**	**5**	**(2.5)**	**0**	**(0.0)**	**5**	**(2.6)**	**0**	**(0.0)**
Cataract	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**6**	**(3.4)**	**0**	**(0.0)**	**5**	**(2.5)**	**0**	**(0.0)**	**5**	**(2.6)**	**0**	**(0.0)**
Dry eye	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	3	(1.6)	0	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eyelid oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Keratitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lacrimation increased	4	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Photopsia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vision blurred	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Visual impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrointestinal disorders	**68**	**(38.6)**	**10**	**(5.7)**	**45**	**(22.3)**	**6**	**(3.0)**	**32**	**(16.7)**	**2**	**(1.0)**
Abdominal discomfort	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal distension	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain	0	(0.0)	0	(0.0)	3	(1.5)	0	(0.0)	1	(0.5)	0	(0.0)
Abdominal pain upper	2	(1.1)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Colitis	0	(0.0)	0	(0.0)	3	(1.5)	3	(1.5)	1	(0.5)	0	(0.0)
Constipation	7	(4.0)	0	(0.0)	7	(3.5)	0	(0.0)	5	(2.6)	0	(0.0)
Diarrhoea	25	(14.2)	5	(2.8)	11	(5.4)	2	(1.0)	10	(5.2)	0	(0.0)
Dry mouth	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Dyspepsia	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Dysphagia	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)	0	(0.0)	0	(0.0)
Faecaloma	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Flatulence	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**68**	**(38.6)**	**10**	**(5.7)**	**45**	**(22.3)**	**6**	**(3.0)**	**32**	**(16.7)**	**2**	**(1.0)**
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal inflammation	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrooesophageal reflux disease	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Mouth ulceration	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	24	(13.6)	1	(0.6)	19	(9.4)	1	(0.5)	13	(6.8)	1	(0.5)
Odynophagia	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oesophageal pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral discomfort	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia oral	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Stomatitis	20	(11.4)	3	(1.7)	6	(3.0)	0	(0.0)	4	(2.1)	0	(0.0)
Tongue ulceration	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	10	(5.7)	1	(0.6)	4	(2.0)	0	(0.0)	3	(1.6)	1	(0.5)
General disorders and administration site conditions	**85**	**(48.3)**	**16**	**(9.1)**	**41**	**(20.3)**	**4**	**(2.0)**	**51**	**(26.6)**	**5**	**(2.6)**
Adverse drug reaction	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**85**	**(48.3)**	**16**	**(9.1)**	**41**	**(20.3)**	**4**	**(2.0)**	**51**	**(26.6)**	**5**	**(2.6)**
Asthenia	22	(12.5)	5	(2.8)	12	(5.9)	1	(0.5)	10	(5.2)	2	(1.0)
Chest discomfort	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Chills	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	4	(2.1)	0	(0.0)
Face oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	43	(24.4)	7	(4.0)	21	(10.4)	2	(1.0)	26	(13.5)	4	(2.1)
General physical health deterioration	2	(1.1)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Generalised oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Influenza like illness	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	0	(0.0)
Infusion site extravasation	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site phlebitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site reaction	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion site vasculitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malaise	7	(4.0)	0	(0.0)	1	(0.5)	0	(0.0)	5	(2.6)	0	(0.0)
Mucosal inflammation	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema	3	(1.7)	2	(1.1)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	11	(6.3)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.6)	0	(0.0)
Pain	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Peripheral swelling	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pyrexia	9	(5.1)	0	(0.0)	4	(2.0)	1	(0.5)	6	(3.1)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.5)**	**1**	**(0.5)**	**3**	**(1.6)**	**1**	**(0.5)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Cholestasis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Hepatic function abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Immune system disorders	**4**	**(2.3)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**0**	**(0.0)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Drug hypersensitivity	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hypersensitivity	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infections and infestations	**18**	**(10.2)**	**5**	**(2.8)**	**7**	**(3.5)**	**2**	**(1.0)**	**7**	**(3.6)**	**3**	**(1.6)**
Bronchitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Candida infection	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Fungal infection	2	(1.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Furuncle	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Genital candidiasis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Herpes zoster	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lung infection	1	(0.6)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nail infection	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nasopharyngitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral candidiasis	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**18**	**(10.2)**	**5**	**(2.8)**	**7**	**(3.5)**	**2**	**(1.0)**	**7**	**(3.6)**	**3**	**(1.6)**
Otitis media acute	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Paronychia	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia	3	(1.7)	2	(1.1)	4	(2.0)	2	(1.0)	3	(1.6)	2	(1.0)
Rash pustular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Respiratory tract infection	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Sepsis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract infection	3	(1.7)	1	(0.6)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Urinary tract infection	2	(1.1)	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications	**6**	**(3.4)**	**1**	**(0.6)**	**2**	**(1.0)**	**1**	**(0.5)**	**2**	**(1.0)**	**0**	**(0.0)**
Femur fracture	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion related reaction	4	(2.3)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Ligament sprain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonitis chemical	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Skin abrasion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Toxicity to various agents	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	**24**	**(13.6)**	**13**	**(7.4)**	**23**	**(11.4)**	**0**	**(0.0)**	**19**	**(9.9)**	**4**	**(2.1)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**24**	**(13.6)**	**13**	**(7.4)**	**23**	**(11.4)**	**0**	**(0.0)**	**19**	**(9.9)**	**4**	**(2.1)**
Alanine aminotransferase increased	2	(1.1)	0	(0.0)	10	(5.0)	0	(0.0)	3	(1.6)	1	(0.5)
Amylase increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Aspartate aminotransferase increased	2	(1.1)	0	(0.0)	5	(2.5)	0	(0.0)	3	(1.6)	0	(0.0)
Blood alkaline phosphatase increased	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	5	(2.6)	1	(0.5)
Blood bilirubin increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood chloride decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood cholesterol increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatinine decreased	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatinine increased	0	(0.0)	0	(0.0)	4	(2.0)	0	(0.0)	3	(1.6)	0	(0.0)
Blood magnesium decreased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone increased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Blood urea increased	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**24**	**(13.6)**	**13**	**(7.4)**	**23**	**(11.4)**	**0**	**(0.0)**	**19**	**(9.9)**	**4**	**(2.1)**
Eosinophil count increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Free thyroxine index increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	1	(0.6)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoglobin decreased	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	3	(1.7)	1	(0.6)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Neutrophil count decreased	15	(8.5)	11	(6.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Platelet count decreased	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Platelet count increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Protein urine present	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Thyroxine free increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Transaminases increased	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Tri-iodothyronine increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Weight decreased	2	(1.1)	0	(0.0)	3	(1.5)	0	(0.0)	4	(2.1)	1	(0.5)
Weight increased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
White blood cell count decreased	8	(4.5)	5	(2.8)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**24**	**(13.6)**	**13**	**(7.4)**	**23**	**(11.4)**	**0**	**(0.0)**	**19**	**(9.9)**	**4**	**(2.1)**
White blood cell count increased	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**33**	**(18.8)**	**6**	**(3.4)**	**33**	**(16.3)**	**5**	**(2.5)**	**28**	**(14.6)**	**4**	**(2.1)**
Decreased appetite	24	(13.6)	2	(1.1)	25	(12.4)	2	(1.0)	19	(9.9)	0	(0.0)
Dehydration	3	(1.7)	2	(1.1)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Diabetic ketoacidosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Hypercalcaemia	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperkalaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertriglyceridaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	2	(1.0)	1	(0.5)
Hyperuricaemia	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hypoalbuminaemia	4	(2.3)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypokalaemia	1	(0.6)	1	(0.6)	2	(1.0)	1	(0.5)	1	(0.5)	0	(0.0)
Hypomagnesaemia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Hyponatraemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	2	(1.0)
Hypophosphataemia	2	(1.1)	1	(0.6)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Hypoproteinaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Iron deficiency	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Type 2 diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**37**	**(21.0)**	**0**	**(0.0)**	**22**	**(10.9)**	**0**	**(0.0)**	**15**	**(7.8)**	**3**	**(1.6)**
Arthralgia	11	(6.3)	0	(0.0)	9	(4.5)	0	(0.0)	7	(3.6)	2	(1.0)
Arthritis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	3	(1.5)	0	(0.0)	2	(1.0)	0	(0.0)
Bone pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Joint swelling	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle necrosis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	1	(0.5)	0	(0.0)
Muscular weakness	4	(2.3)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal pain	4	(2.3)	0	(0.0)	4	(2.0)	0	(0.0)	2	(1.0)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Myalgia	18	(10.2)	0	(0.0)	4	(2.0)	0	(0.0)	2	(1.0)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pain in extremity	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Periarthritis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Polyarthritis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Synovitis	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(0.6)**	**0**	**(0.0)**	**1**	**(0.5)**	**1**	**(0.5)**	**1**	**(0.5)**	**1**	**(0.5)**
Cancer pain	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malignant neoplasm progression	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Paraneoplastic syndrome	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Nervous system disorders	**42**	**(23.9)**	**3**	**(1.7)**	**14**	**(6.9)**	**0**	**(0.0)**	**16**	**(8.3)**	**1**	**(0.5)**
Dizziness	3	(1.7)	1	(0.6)	1	(0.5)	0	(0.0)	3	(1.6)	0	(0.0)
Dysaesthesia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	6	(3.4)	0	(0.0)	2	(1.0)	0	(0.0)	3	(1.6)	0	(0.0)
Headache	0	(0.0)	0	(0.0)	5	(2.5)	0	(0.0)	3	(1.6)	0	(0.0)
Hypersomnia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Hypoaesthesia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hypogeusia	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Myelitis transverse	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Neuropathy peripheral	18	(10.2)	1	(0.6)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neurotoxicity	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia	9	(5.1)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Peripheral motor neuropathy	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**42**	**(23.9)**	**3**	**(1.7)**	**14**	**(6.9)**	**0**	**(0.0)**	**16**	**(8.3)**	**1**	**(0.5)**
Peripheral sensory neuropathy	4	(2.3)	0	(0.0)	2	(1.0)	0	(0.0)	2	(1.0)	0	(0.0)
Polyneuropathy	1	(0.6)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Somnolence	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Toxic neuropathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Psychiatric disorders	**4**	**(2.3)**	**0**	**(0.0)**	**2**	**(1.0)**	**1**	**(0.5)**	**3**	**(1.6)**	**1**	**(0.5)**
Anxiety	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Confusional state	1	(0.6)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Disorientation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Insomnia	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Libido decreased	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Renal and urinary disorders	**1**	**(0.6)**	**1**	**(0.6)**	**1**	**(0.5)**	**1**	**(0.5)**	**4**	**(2.1)**	**0**	**(0.0)**
Acute kidney injury	1	(0.6)	1	(0.6)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Renal impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)
Reproductive system and breast disorders	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.0)**	**0**	**(0.0)**
Erectile dysfunction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gynaecomastia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**19**	**(10.8)**	**2**	**(1.1)**	**21**	**(10.4)**	**4**	**(2.0)**	**11**	**(5.7)**	**2**	**(1.0)**
Cough	2	(1.1)	0	(0.0)	5	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dysphonia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dyspnoea	7	(4.0)	1	(0.6)	3	(1.5)	0	(0.0)	9	(4.7)	1	(0.5)
Dyspnoea exertional	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Epistaxis	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoptysis	0	(0.0)	0	(0.0)	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)
Interstitial lung disease	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Nasal congestion	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal pain	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pharyngeal inflammation	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonitis	2	(1.1)	1	(0.6)	7	(3.5)	4	(2.0)	3	(1.6)	2	(1.0)
Productive cough	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary artery thrombosis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary embolism	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Rhinorrhoea	1	(0.6)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tachypnoea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Upper respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper-airway cough syndrome	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**73**	**(41.5)**	**0**	**(0.0)**	**32**	**(15.8)**	**3**	**(1.5)**	**41**	**(21.4)**	**1**	**(0.5)**
Alopecia	55	(31.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis bullous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Drug eruption	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Dry skin	1	(0.6)	0	(0.0)	2	(1.0)	0	(0.0)	5	(2.6)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Erythema	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.6)	0	(0.0)
Hyperhidrosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Macule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nail discolouration	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail disorder	9	(5.1)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nail ridging	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nail toxicity	3	(1.7)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Onychalgia	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Onychoclasis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Onycholysis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	3	(1.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**73**	**(41.5)**	**0**	**(0.0)**	**32**	**(15.8)**	**3**	**(1.5)**	**41**	**(21.4)**	**1**	**(0.5)**
Pruritus	1	(0.6)	0	(0.0)	11	(5.4)	0	(0.0)	17	(8.9)	0	(0.0)
Pruritus generalised	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Psoriasis	0	(0.0)	0	(0.0)	3	(1.5)	1	(0.5)	0	(0.0)	0	(0.0)
Rash	10	(5.7)	0	(0.0)	13	(6.4)	1	(0.5)	21	(10.9)	0	(0.0)
Rash macular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Rash maculo-papular	0	(0.0)	0	(0.0)	3	(1.5)	1	(0.5)	0	(0.0)	0	(0.0)
Rash pruritic	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Seborrhoeic dermatitis	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin exfoliation	2	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin induration	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin irritation	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin oedema	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders	**3**	**(1.7)**	**1**	**(0.6)**	**3**	**(1.5)**	**0**	**(0.0)**	**4**	**(2.1)**	**1**	**(0.5)**
Flushing	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hot flush	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperaemia	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertension	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)	1	(0.5)

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Subjects With Drug-Related Adverse Events by All Toxicity Grades vs. Grades 3-5 (Incidence > 0% in One or More Treatment Groups)
APaT Population (1% ≤ TPS < 50%)

	Docetaxel 75 mg/m2 Q3W				MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**3**	**(1.7)**	**1**	**(0.6)**	**3**	**(1.5)**	**0**	**(0.0)**	**4**	**(2.1)**	**1**	**(0.5)**
Hypotension	2	(1.1)	1	(0.6)	0	(0.0)	0	(0.0)	1	(0.5)	0	(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.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(Database Cutoff Date: 30SEP2015).

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付録 2.7.4- 29　　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 Adverse Events
(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	661	(96.9)	1,192	(96.8)	1,535	(98.0)	2,727	(97.4)
with no adverse events	21	(3.1)	40	(3.2)	32	(2.0)	72	(2.6)
Blood and lymphatic system disorders	**105**	**(15.4)**	**188**	**(15.3)**	**299**	**(19.1)**	**487**	**(17.4)**
Anaemia	66	(9.7)	135	(11.0)	212	(13.5)	347	(12.4)
Anaemia of chronic disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Autoimmune haemolytic anaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Coagulopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Disseminated intravascular coagulation	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Eosinopenia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eosinophilia	2	(0.3)	2	(0.2)	15	(1.0)	17	(0.6)
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)
Haemorrhagic diathesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypercoagulation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Increased tendency to bruise	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Iron deficiency anaemia	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Leukaemoid reaction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Leukocytosis	5	(0.7)	7	(0.6)	17	(1.1)	24	(0.9)
Leukopenia	6	(0.9)	10	(0.8)	12	(0.8)	22	(0.8)
Lymph node pain	3	(0.4)	5	(0.4)	5	(0.3)	10	(0.4)
Lymphadenitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Lymphadenopathy	3	(0.4)	4	(0.3)	9	(0.6)	13	(0.5)
Lymphatic obstruction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphoid tissue hyperplasia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphopenia	14	(2.1)	14	(1.1)	19	(1.2)	33	(1.2)
Microcytic anaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Neutropenia	3	(0.4)	7	(0.6)	10	(0.6)	17	(0.6)
Neutrophilia	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)

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Subjects With Adverse Events
(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	(%)
Blood and lymphatic system disorders	**105**	**(15.4)**	**188**	**(15.3)**	**299**	**(19.1)**	**487**	**(17.4)**
Normochromic normocytic anaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pancytopenia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Polycythaemia	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)
Splenomegaly	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Thrombocytopenia	7	(1.0)	15	(1.2)	35	(2.2)	50	(1.8)
Thrombocytosis	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Cardiac disorders	**55**	**(8.1)**	**109**	**(8.8)**	**144**	**(9.2)**	**253**	**(9.0)**
Acute coronary syndrome	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Acute myocardial infarction	2	(0.3)	5	(0.4)	3	(0.2)	8	(0.3)
Angina pectoris	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Angina unstable	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Aortic valve incompetence	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Aortic valve stenosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arrhythmia	3	(0.4)	3	(0.2)	0	(0.0)	3	(0.1)
Arrhythmia supraventricular	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Atrial fibrillation	7	(1.0)	16	(1.3)	19	(1.2)	35	(1.3)
Atrial flutter	2	(0.3)	7	(0.6)	5	(0.3)	12	(0.4)
Atrial thrombosis	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Atrioventricular block complete	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Atrioventricular block first degree	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bradycardia	2	(0.3)	4	(0.3)	9	(0.6)	13	(0.5)
Bundle branch block left	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bundle branch block right	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Cardiac aneurysm	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cardiac arrest	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cardiac failure	2	(0.3)	2	(0.2)	6	(0.4)	8	(0.3)
Cardiac failure congestive	2	(0.3)	5	(0.4)	9	(0.6)	14	(0.5)

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Subjects With Adverse Events
(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	**55**	**(8.1)**	**109**	**(8.8)**	**144**	**(9.2)**	**253**	**(9.0)**
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)
Cardiac ventricular thrombosis	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)
Cardiomegaly	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)
Congestive cardiomyopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Coronary artery disease	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cyanosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Left ventricular dysfunction	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Left ventricular failure	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Left ventricular hypertrophy	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Mitral valve incompetence	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)
Myocardial ischaemia	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Palpitations	4	(0.6)	7	(0.6)	22	(1.4)	29	(1.0)
Pericardial effusion	8	(1.2)	16	(1.3)	11	(0.7)	27	(1.0)
Pericarditis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Pericarditis constrictive	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Right ventricular failure	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Sinus bradycardia	1	(0.1)	6	(0.5)	5	(0.3)	11	(0.4)
Sinus tachycardia	4	(0.6)	10	(0.8)	12	(0.8)	22	(0.8)
Supraventricular tachycardia	3	(0.4)	6	(0.5)	7	(0.4)	13	(0.5)
Tachycardia	10	(1.5)	17	(1.4)	33	(2.1)	50	(1.8)
Ventricular extrasystoles	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Congenital, familial and genetic disorders	**3**	**(0.4)**	**4**	**(0.3)**	**3**	**(0.2)**	7	**(0.3)**
Accessory spleen	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	(%)
Congenital, familial and genetic disorders	**3**	**(0.4)**	**4**	**(0.3)**	**3**	**(0.2)**	**7**	**(0.3)**
Ichthyosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Naevus flammeus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pyloric stenosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Syndactyly	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tracheo-oesophageal fistula	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Ear and labyrinth disorders	**15**	**(2.2)**	**37**	**(3.0)**	**96**	**(6.1)**	**133**	**(4.8)**
Auricular swelling	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Cerumen impaction	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Deafness	1	(0.1)	3	(0.2)	6	(0.4)	9	(0.3)
Deafness unilateral	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Ear congestion	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Ear discomfort	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Ear haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Ear pain	1	(0.1)	3	(0.2)	25	(1.6)	28	(1.0)
Ear pruritus	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Ear swelling	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
External ear inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
External ear pain	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hearing impaired	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Hyperacusis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Hypoacusis	1	(0.1)	2	(0.2)	5	(0.3)	7	(0.3)
Middle ear inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Motion sickness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Otorrhoea	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tinnitus	5	(0.7)	9	(0.7)	13	(0.8)	22	(0.8)
Vertigo	5	(0.7)	13	(1.1)	34	(2.2)	47	(1.7)
Vertigo positional	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Vestibular disorder	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Endocrine disorders	**83**	**(12.2)**	**136**	**(11.0)**	**199**	**(12.7)**	**335**	**(12.0)**
Adrenal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Adrenal insufficiency	5	(0.7)	9	(0.7)	11	(0.7)	20	(0.7)
Adrenocortical insufficiency acute	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Autoimmune thyroiditis	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)

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Subjects With Adverse Events
(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	**83**	**(12.2)**	**136**	**(11.0)**	**199**	**(12.7)**	**335**	**(12.0)**
Cushingoid	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Endocrine disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Goitre	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Hyperparathyroidism	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Hyperthyroidism	32	(4.7)	43	(3.5)	53	(3.4)	96	(3.4)
Hypogonadism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypoparathyroidism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypophysitis	0	(0.0)	1	(0.1)	8	(0.5)	9	(0.3)
Hypopituitarism	2	(0.3)	2	(0.2)	6	(0.4)	8	(0.3)
Hypothalamo-pituitary disorder	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hypothyroidism	56	(8.2)	98	(8.0)	138	(8.8)	236	(8.4)
Myxoedema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Primary hypothyroidism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Secondary adrenocortical insufficiency	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thyroiditis	2	(0.3)	2	(0.2)	9	(0.6)	11	(0.4)
Eye disorders	**63**	**(9.2)**	**113**	**(9.2)**	**245**	**(15.6)**	**358**	**(12.8)**
Abnormal sensation in eye	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Altered visual depth perception	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Asthenopia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Blepharitis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Blepharospasm	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blindness	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Blindness unilateral	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Cataract	6	(0.9)	10	(0.8)	12	(0.8)	22	(0.8)
Chalazion	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Ciliary muscle spasm	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Conjunctival haemorrhage	2	(0.3)	3	(0.2)	7	(0.4)	10	(0.4)
Conjunctival hyperaemia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Conjunctivitis allergic	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Corneal irritation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Corneal pigmentation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diabetic retinopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**63**	**(9.2)**	**113**	**(9.2)**	**245**	**(15.6)**	**358**	**(12.8)**
Diplopia	2	(0.3)	5	(0.4)	6	(0.4)	11	(0.4)
Dry age-related macular degeneration	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dry eye	11	(1.6)	15	(1.2)	34	(2.2)	49	(1.8)
Ectropion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eczema eyelids	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Entropion	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Erythema of eyelid	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Eye discharge	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Eye disorder	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Eye haemorrhage	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Eye inflammation	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Eye irritation	3	(0.4)	4	(0.3)	5	(0.3)	9	(0.3)
Eye movement disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eye oedema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Eye pain	4	(0.6)	4	(0.3)	12	(0.8)	16	(0.6)
Eye pruritus	0	(0.0)	2	(0.2)	13	(0.8)	15	(0.5)
Eye swelling	0	(0.0)	2	(0.2)	7	(0.4)	9	(0.3)
Eyelash discolouration	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Eyelid cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eyelid exfoliation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eyelid function disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eyelid irritation	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Eyelid oedema	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Eyelid ptosis	1	(0.1)	4	(0.3)	2	(0.1)	6	(0.2)
Eyelid rash	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Eyelids pruritus	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Foreign body sensation in eyes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Glaucoma	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Growth of eyelashes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypermetropia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypopigmentation of eyelid	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intraocular haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Iridocyclitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Iritis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Keratitis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Lacrimal gland enlargement	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**63**	**(9.2)**	**113**	**(9.2)**	**245**	**(15.6)**	**358**	**(12.8)**
Lacrimation increased	4	(0.6)	6	(0.5)	15	(1.0)	21	(0.8)
Macular degeneration	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Ocular discomfort	2	(0.3)	4	(0.3)	4	(0.3)	8	(0.3)
Ocular hyperaemia	1	(0.1)	2	(0.2)	9	(0.6)	11	(0.4)
Ophthalmoplegia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Optic neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Papilloedema	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Periorbital oedema	0	(0.0)	4	(0.3)	2	(0.1)	6	(0.2)
Photophobia	0	(0.0)	1	(0.1)	7	(0.4)	8	(0.3)
Photopsia	3	(0.4)	3	(0.2)	7	(0.4)	10	(0.4)
Pupils unequal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Retinal detachment	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Retinal exudates	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Retinal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Retinal pigment epitheliopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Retinal tear	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Retinal vein occlusion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Scintillating scotoma	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Scleral hyperaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Scleritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Uveitis	0	(0.0)	0	(0.0)	10	(0.6)	10	(0.4)
Vision blurred	15	(2.2)	23	(1.9)	48	(3.1)	71	(2.5)
Visual acuity reduced	1	(0.1)	4	(0.3)	10	(0.6)	14	(0.5)
Visual impairment	5	(0.7)	9	(0.7)	30	(1.9)	39	(1.4)
Vitreous detachment	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vitreous floaters	5	(0.7)	9	(0.7)	9	(0.6)	18	(0.6)
Xerophthalmia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal disorders	**354**	**(51.9)**	**657**	**(53.3)**	**1,048**	**(66.9)**	**1,705**	**(60.9)**
Abdominal discomfort	8	(1.2)	13	(1.1)	36	(2.3)	49	(1.8)
Abdominal distension	8	(1.2)	24	(1.9)	59	(3.8)	83	(3.0)
Abdominal mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Abdominal pain	38	(5.6)	83	(6.7)	191	(12.2)	274	(9.8)
Abdominal pain lower	3	(0.4)	5	(0.4)	12	(0.8)	17	(0.6)
Abdominal pain upper	21	(3.1)	36	(2.9)	79	(5.0)	115	(4.1)
Abdominal rigidity	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Abdominal tenderness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Acquired oesophageal web	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**354**	**(51.9)**	**657**	**(53.3)**	**1,048**	**(66.9)**	**1,705**	**(60.9)**
Aerophagia	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Anal fissure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Anal fistula	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Anal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Anal pruritus	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Anorectal disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Aphthous stomatitis	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Aptyalism	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Ascites	5	(0.7)	10	(0.8)	20	(1.3)	30	(1.1)
Auriculotemporal syndrome	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Autoimmune colitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Barrett's oesophagus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Breath odour	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Chapped lips	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cheilitis	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Chronic gastritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Colitis	6	(0.9)	13	(1.1)	33	(2.1)	46	(1.6)
Colitis microscopic	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Constipation	105	(15.4)	193	(15.7)	304	(19.4)	497	(17.8)
Defaecation urgency	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Dental caries	2	(0.3)	3	(0.2)	3	(0.2)	6	(0.2)
Diarrhoea	95	(13.9)	189	(15.3)	436	(27.8)	625	(22.3)
Diverticulitis intestinal haemorrhagic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Diverticulum	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Diverticulum gastric	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Dry mouth	22	(3.2)	39	(3.2)	103	(6.6)	142	(5.1)
Duodenal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Duodenitis	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Duodenogastric reflux	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dyspepsia	11	(1.6)	19	(1.5)	46	(2.9)	65	(2.3)
Dysphagia	22	(3.2)	33	(2.7)	26	(1.7)	59	(2.1)
Enteritis	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)
Epigastric discomfort	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Erosive duodenitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Eructation	1	(0.1)	3	(0.2)	6	(0.4)	9	(0.3)

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Subjects With Adverse Events
(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	**354**	**(51.9)**	**657**	**(53.3)**	**1,048**	**(66.9)**	**1,705**	**(60.9)**
Faecal incontinence	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Faecal volume increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Faecaloma	3	(0.4)	4	(0.3)	0	(0.0)	4	(0.1)
Faeces discoloured	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Faeces hard	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Faeces pale	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Faeces soft	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Femoral hernia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Flatulence	2	(0.3)	7	(0.6)	27	(1.7)	34	(1.2)
Food poisoning	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Frequent bowel movements	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
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	4	(0.6)	4	(0.3)	10	(0.6)	14	(0.5)
Gastritis erosive	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Gastrointestinal disorder	1	(0.1)	1	(0.1)	7	(0.4)	8	(0.3)
Gastrointestinal haemorrhage	0	(0.0)	2	(0.2)	6	(0.4)	8	(0.3)
Gastrointestinal pain	1	(0.1)	4	(0.3)	3	(0.2)	7	(0.3)
Gastrointestinal perforation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrointestinal sounds abnormal	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal ulcer	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Gastrooesophageal reflux disease	13	(1.9)	30	(2.4)	43	(2.7)	73	(2.6)
Gingival bleeding	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Gingival pain	0	(0.0)	0	(0.0)	8	(0.5)	8	(0.3)
Gingival swelling	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Glossitis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Glossodynia	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Haematemesis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Haematochezia	0	(0.0)	0	(0.0)	11	(0.7)	11	(0.4)

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Subjects With Adverse Events
(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	**354**	**(51.9)**	**657**	**(53.3)**	**1,048**	**(66.9)**	**1,705**	**(60.9)**
Haemorrhoidal haemorrhage	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Haemorrhoids	3	(0.4)	5	(0.4)	12	(0.8)	17	(0.6)
Haemorrhoids thrombosed	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hiatus hernia	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Hyperchlorhydria	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Ileus	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Impaired gastric emptying	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Inguinal hernia	1	(0.1)	4	(0.3)	1	(0.1)	5	(0.2)
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)	5	(0.3)	5	(0.2)
Irritable bowel syndrome	0	(0.0)	1	(0.1)	2	(0.1)	3	(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)
Large intestine polyp	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Leukoplakia oral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lip blister	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lip disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lip dry	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Lip oedema	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Lip pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Lip pruritus	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Lip swelling	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Lip ulceration	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Loose tooth	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Lower gastrointestinal haemorrhage	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)
Melaena	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Mouth haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Mouth ulceration	1	(0.1)	2	(0.2)	9	(0.6)	11	(0.4)
Mucous stools	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)

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Subjects With Adverse Events
(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	**354**	**(51.9)**	**657**	**(53.3)**	**1,048**	**(66.9)**	**1,705**	**(60.9)**
Nausea	139	(20.4)	247	(20.0)	438	(28.0)	685	(24.5)
Noninfective gingivitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Obstruction gastric	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Odynophagia	2	(0.3)	3	(0.2)	8	(0.5)	11	(0.4)
Oesophageal obstruction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Oesophageal pain	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Oesophageal stenosis	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Oesophageal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oesophagitis	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Oral discomfort	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Oral disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oral mucosal blistering	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oral mucosal discolouration	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oral mucosal erythema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oral pain	2	(0.3)	4	(0.3)	9	(0.6)	13	(0.5)
Painful defaecation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Palatal disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pancreatitis	2	(0.3)	2	(0.2)	5	(0.3)	7	(0.3)
Pancreatitis acute	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pancreatitis chronic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Paraesthesia oral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Peptic ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Periodontal disease	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Peritoneal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Post-tussive vomiting	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Proctalgia	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Proctitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rectal haemorrhage	3	(0.4)	8	(0.6)	9	(0.6)	17	(0.6)
Rectal polyp	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Rectal tenesmus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Reflux gastritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Regurgitation	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Retching	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Retroperitoneal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Saliva altered	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Salivary gland disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Salivary hypersecretion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**354**	**(51.9)**	**657**	**(53.3)**	**1,048**	**(66.9)**	**1,705**	**(60.9)**
Sensitivity of teeth	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Small intestinal obstruction	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Small intestinal perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Splenic artery aneurysm	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stomatitis	30	(4.4)	41	(3.3)	18	(1.1)	59	(2.1)
Stomatitis necrotising	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Subileus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Swollen tongue	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tongue coated	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Tongue discolouration	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Tongue haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tongue ulceration	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Tooth demineralisation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tooth disorder	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Tooth impacted	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Tooth loss	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Toothache	6	(0.9)	10	(0.8)	12	(0.8)	22	(0.8)
Umbilical hernia, obstructive	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Vomiting	88	(12.9)	157	(12.7)	230	(14.7)	387	(13.8)
General disorders and administration site conditions	**382**	**(56.0)**	**742**	**(60.2)**	**1,116**	**(71.2)**	**1,858**	**(66.4)**
Adverse drug reaction	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Application site pruritus	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Asthenia	76	(11.1)	132	(10.7)	230	(14.7)	362	(12.9)
Axillary pain	4	(0.6)	5	(0.4)	28	(1.8)	33	(1.2)
Catheter site erythema	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Catheter site haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Catheter site pain	1	(0.1)	3	(0.2)	3	(0.2)	6	(0.2)
Catheter site rash	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Chest discomfort	8	(1.2)	13	(1.1)	19	(1.2)	32	(1.1)

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Subjects With Adverse Events
(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	**382**	**(56.0)**	**742**	**(60.2)**	**1,116**	**(71.2)**	**1,858**	**(66.4)**
Chest pain	55	(8.1)	95	(7.7)	70	(4.5)	165	(5.9)
Chills	16	(2.3)	37	(3.0)	116	(7.4)	153	(5.5)
Crepitations	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Cyst	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Death	6	(0.9)	8	(0.6)	9	(0.6)	17	(0.6)
Device breakage	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Device dislocation	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Device failure	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Device occlusion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Discomfort	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Drug withdrawal syndrome	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Early satiety	1	(0.1)	5	(0.4)	1	(0.1)	6	(0.2)
Enanthema	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Exercise tolerance decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Face oedema	3	(0.4)	6	(0.5)	5	(0.3)	11	(0.4)
Facial pain	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Fatigue	171	(25.1)	374	(30.4)	670	(42.8)	1,044	(37.3)
Feeling abnormal	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Feeling cold	3	(0.4)	4	(0.3)	9	(0.6)	13	(0.5)
Feeling drunk	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Feeling hot	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Feeling jittery	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fibrosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gait disturbance	1	(0.1)	4	(0.3)	17	(1.1)	21	(0.8)
General physical health deterioration	8	(1.2)	11	(0.9)	19	(1.2)	30	(1.1)
Generalised oedema	3	(0.4)	4	(0.3)	13	(0.8)	17	(0.6)
Granuloma	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Hernia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hunger	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperthermia	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Hypothermia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Impaired healing	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Implant site inflammation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Implant site pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Inflammation	2	(0.3)	6	(0.5)	9	(0.6)	15	(0.5)

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Subjects With Adverse Events
(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	**382**	**(56.0)**	**742**	**(60.2)**	**1,116**	**(71.2)**	**1,858**	**(66.4)**
Inflammatory pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Influenza like illness	19	(2.8)	28	(2.3)	84	(5.4)	112	(4.0)
Infusion site bruising	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infusion site extravasation	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Infusion site pain	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Infusion site pruritus	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Infusion site swelling	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Injection site bruising	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Injection site discomfort	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Injection site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Injection site haematoma	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Injection site irritation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Injection site pain	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Injection site reaction	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Local swelling	0	(0.0)	3	(0.2)	4	(0.3)	7	(0.3)
Localised oedema	4	(0.6)	4	(0.3)	6	(0.4)	10	(0.4)
Malaise	24	(3.5)	26	(2.1)	21	(1.3)	47	(1.7)
Mass	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Medical device complication	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Medical device pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Mucosal discolouration	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Mucosal dryness	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Mucosal inflammation	5	(0.7)	16	(1.3)	22	(1.4)	38	(1.4)
Multi-organ failure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Necrosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Nodule	1	(0.1)	1	(0.1)	9	(0.6)	10	(0.4)
Non-cardiac chest pain	13	(1.9)	20	(1.6)	14	(0.9)	34	(1.2)
Oedema	9	(1.3)	25	(2.0)	24	(1.5)	49	(1.8)
Oedema peripheral	53	(7.8)	113	(9.2)	172	(11.0)	285	(10.2)
Pain	12	(1.8)	64	(5.2)	58	(3.7)	122	(4.4)
Performance status decreased	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Peripheral swelling	6	(0.9)	12	(1.0)	32	(2.0)	44	(1.6)
Puncture site erythema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**382**	**(56.0)**	**742**	**(60.2)**	**1,116**	**(71.2)**	**1,858**	**(66.4)**
Pyrexia	77	(11.3)	145	(11.8)	212	(13.5)	357	(12.8)
Secretion discharge	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Sensation of foreign body	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Sensitivity to weather change	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Serositis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Suprapubic pain	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Swelling	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Systemic inflammatory response syndrome	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Temperature intolerance	2	(0.3)	3	(0.2)	6	(0.4)	9	(0.3)
Thirst	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Thrombosis in device	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Vessel puncture site pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Xerosis	2	(0.3)	5	(0.4)	10	(0.6)	15	(0.5)
Hepatobiliary disorders	**17**	**(2.5)**	**26**	**(2.1)**	**63**	**(4.0)**	**89**	**(3.2)**
Autoimmune hepatitis	3	(0.4)	3	(0.2)	9	(0.6)	12	(0.4)
Bile duct obstruction	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
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	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Cholecystitis	0	(0.0)	2	(0.2)	6	(0.4)	8	(0.3)
Cholecystitis acute	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cholestasis	4	(0.6)	4	(0.3)	9	(0.6)	13	(0.5)
Drug-induced liver injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Gallbladder pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatic failure	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Hepatic function abnormal	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Hepatic pain	1	(0.1)	3	(0.2)	5	(0.3)	8	(0.3)
Hepatic steatosis	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Hepatitis	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Hepatocellular injury	3	(0.4)	3	(0.2)	4	(0.3)	7	(0.3)
Hepatomegaly	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)

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Subjects With Adverse Events
(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	**17**	**(2.5)**	**26**	**(2.1)**	**63**	**(4.0)**	**89**	**(3.2)**
Hepatorenal syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatotoxicity	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hyperbilirubinaemia	0	(0.0)	2	(0.2)	6	(0.4)	8	(0.3)
Jaundice	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
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)
Pneumobilia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Portal hypertension	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Immune system disorders	**12**	**(1.8)**	**24**	**(1.9)**	**52**	**(3.3)**	**76**	**(2.7)**
Allergy to animal	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Anaphylactic reaction	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Atopy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Autoimmune disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Contrast media allergy	1	(0.1)	3	(0.2)	5	(0.3)	8	(0.3)
Cytokine release syndrome	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Drug hypersensitivity	4	(0.6)	5	(0.4)	8	(0.5)	13	(0.5)
Food allergy	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hypersensitivity	1	(0.1)	8	(0.6)	14	(0.9)	22	(0.8)
Immune system disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Sarcoidosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Seasonal allergy	4	(0.6)	5	(0.4)	15	(1.0)	20	(0.7)
Serum sickness	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Infections and infestations	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Abdominal wall abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Abscess	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Abscess oral	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Acarodermatitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Acute sinusitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Acute tonsillitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Anal abscess	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
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)
Arthritis infective	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Aspergillus infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Asymptomatic bacteriuria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Atypical pneumonia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Bacillus bacteraemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Bacteraemia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Bacterial sepsis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Bacterial vaginosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bacteriuria	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Body tinea	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Bronchitis	18	(2.6)	28	(2.3)	37	(2.4)	65	(2.3)
Bronchopneumonia	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Campylobacter infection	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Candida infection	2	(0.3)	11	(0.9)	12	(0.8)	23	(0.8)
Catheter site infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cellulitis	1	(0.1)	3	(0.2)	31	(2.0)	34	(1.2)
Cellulitis streptococcal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chronic sinusitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Clostridium difficile colitis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Clostridium difficile infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Conjunctivitis	5	(0.7)	9	(0.7)	26	(1.7)	35	(1.3)
Conjunctivitis viral	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cystitis	7	(1.0)	11	(0.9)	15	(1.0)	26	(0.9)
Cytomegalovirus colitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dermatophytosis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Device related infection	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Device related sepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Diverticulitis	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Ear infection	0	(0.0)	3	(0.2)	7	(0.4)	10	(0.4)
Ear infection fungal	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)
Endocarditis	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Enterococcal infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Enterocolitis infectious	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Erysipelas	0	(0.0)	0	(0.0)	15	(1.0)	15	(0.5)
Erythema migrans	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erythrasma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Escherichia bacteraemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Escherichia infection	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Escherichia urinary tract infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eye infection	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Febrile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Folliculitis	1	(0.1)	1	(0.1)	14	(0.9)	15	(0.5)
Fungal infection	4	(0.6)	6	(0.5)	4	(0.3)	10	(0.4)
Fungal oesophagitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Fungal skin infection	2	(0.3)	3	(0.2)	8	(0.5)	11	(0.4)
Furuncle	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Gastroenteritis	2	(0.3)	5	(0.4)	16	(1.0)	21	(0.8)
Gastroenteritis viral	1	(0.1)	3	(0.2)	5	(0.3)	8	(0.3)
Gastrointestinal infection	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal viral infection	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Genital candidiasis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Genital herpes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Genital infection fungal	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Gingivitis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Helicobacter infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Herpes ophthalmic	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Herpes simplex	4	(0.6)	4	(0.3)	0	(0.0)	4	(0.1)
Herpes simplex encephalitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Herpes zoster	3	(0.4)	8	(0.6)	11	(0.7)	19	(0.7)
Hordeolum	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Incision site abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Incision site infection	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Infected cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infected dermal cyst	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Infected seroma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infected skin ulcer	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Infection	3	(0.4)	3	(0.2)	9	(0.6)	12	(0.4)
Infection parasitic	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Infectious colitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Infectious pleural effusion	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Infective exacerbation of chronic obstructive airways disease	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Influenza	12	(1.8)	18	(1.5)	39	(2.5)	57	(2.0)
Intervertebral discitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Kidney infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Klebsiella infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Laryngitis	2	(0.3)	4	(0.3)	7	(0.4)	11	(0.4)
Lip infection	1	(0.1)	1	(0.1)	0	(0.0)	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)
Lobar pneumonia	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Localised infection	0	(0.0)	2	(0.2)	6	(0.4)	8	(0.3)
Lower respiratory tract infection	9	(1.3)	28	(2.3)	16	(1.0)	44	(1.6)
Lower respiratory tract infection viral	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lung abscess	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Lung infection	14	(2.1)	27	(2.2)	18	(1.1)	45	(1.6)
Lyme disease	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Lymph gland infection	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Lymphangitis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Mastitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Mediastinitis	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)
Moraxella infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Mucosal infection	2	(0.3)	3	(0.2)	0	(0.0)	3	(0.1)
Nail bed infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nail infection	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Nasal herpes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nasopharyngitis	29	(4.3)	41	(3.3)	141	(9.0)	182	(6.5)
Nosocomial infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Oesophageal candidiasis	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Onychomycosis	1	(0.1)	1	(0.1)	7	(0.4)	8	(0.3)

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Subjects With Adverse Events
(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	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Ophthalmic herpes zoster	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oral candidiasis	15	(2.2)	24	(1.9)	18	(1.1)	42	(1.5)
Oral fungal infection	2	(0.3)	5	(0.4)	5	(0.3)	10	(0.4)
Oral herpes	4	(0.6)	6	(0.5)	20	(1.3)	26	(0.9)
Oral infection	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Oropharyngeal candidiasis	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Osteomyelitis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Otitis externa	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Otitis media	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Otitis media acute	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Paronychia	1	(0.1)	3	(0.2)	2	(0.1)	5	(0.2)
Pelvic abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Penile abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Penile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Perichondritis	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Periodontitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Peritonitis bacterial	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pharyngitis	5	(0.7)	7	(0.6)	13	(0.8)	20	(0.7)
Pharyngitis streptococcal	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
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	50	(7.3)	89	(7.2)	45	(2.9)	134	(4.8)
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 influenzal	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumonia klebsiella	0	(0.0)	0	(0.0)	1	(0.1)	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)
Post procedural cellulitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Post procedural infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Postoperative wound infection	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Proteus infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pseudomonas infection	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Pulmonary sepsis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pulpitis dental	0	(0.0)	0	(0.0)	1	(0.1)	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)
Pyuria	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Rash pustular	3	(0.4)	3	(0.2)	4	(0.3)	7	(0.3)
Respiratory tract infection	21	(3.1)	30	(2.4)	11	(0.7)	41	(1.5)
Respiratory tract infection viral	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Rhinitis	9	(1.3)	19	(1.5)	31	(2.0)	50	(1.8)
Salmonellosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Scarlet fever	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sepsis	2	(0.3)	5	(0.4)	12	(0.8)	17	(0.6)
Septic shock	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Sialoadenitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Sinusitis	10	(1.5)	23	(1.9)	52	(3.3)	75	(2.7)
Sinusitis bacterial	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Skin candida	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Skin infection	1	(0.1)	7	(0.6)	24	(1.5)	31	(1.1)
Soft tissue infection	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Spinal cord infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Sputum purulent	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Staphylococcal bacteraemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Staphylococcal infection	1	(0.1)	3	(0.2)	7	(0.4)	10	(0.4)
Staphylococcal skin infection	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Streptococcal infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Streptococcal urinary tract infection	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Subcutaneous abscess	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Thrombophlebitis septic	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**245**	**(35.9)**	**467**	**(37.9)**	**713**	**(45.5)**	**1,180**	**(42.2)**
Tinea cruris	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tinea infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tinea pedis	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Tinea versicolour	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Tonsillitis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Tooth abscess	2	(0.3)	8	(0.6)	7	(0.4)	15	(0.5)
Tooth infection	3	(0.4)	7	(0.6)	10	(0.6)	17	(0.6)
Tracheitis	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Trichophytosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tuberculosis gastrointestinal	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Upper respiratory tract infection	22	(3.2)	66	(5.4)	116	(7.4)	182	(6.5)
Urinary tract infection	25	(3.7)	49	(4.0)	113	(7.2)	162	(5.8)
Urinary tract infection fungal	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Urinary tract infection viral	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Urosepsis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Vaginal infection	3	(0.4)	3	(0.2)	3	(0.2)	6	(0.2)
Viral infection	2	(0.3)	12	(1.0)	14	(0.9)	26	(0.9)
Viral pharyngitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Viral rhinitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Viral sinusitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Viral upper respiratory tract infection	0	(0.0)	3	(0.2)	6	(0.4)	9	(0.3)
Vulvitis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Vulvovaginal candidiasis	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Vulvovaginal mycotic infection	1	(0.1)	3	(0.2)	1	(0.1)	4	(0.1)
Wound infection	0	(0.0)	1	(0.1)	16	(1.0)	17	(0.6)
Wound sepsis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Yersinia infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Injury, poisoning and procedural complications	**65**	**(9.5)**	**121**	**(9.8)**	**241**	**(15.4)**	**362**	**(12.9)**
Accident	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
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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	(%)
Injury, poisoning and procedural complications	**65**	**(9.5)**	**121**	**(9.8)**	**241**	**(15.4)**	**362**	**(12.9)**
Accidental overdose	0	(0.0)	0	(0.0)	12	(0.8)	12	(0.4)
Ankle fracture	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Arthropod bite	3	(0.4)	5	(0.4)	8	(0.5)	13	(0.5)
Back injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Brain herniation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Burns second degree	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chest injury	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Chillblains	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Clavicle fracture	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Concussion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Contrast media reaction	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Contusion	7	(1.0)	12	(1.0)	22	(1.4)	34	(1.2)
Corneal abrasion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ear abrasion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Epicondylitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Eschar	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Excoriation	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Eye penetration	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Eyelid contusion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Face injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Facial bones fracture	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Fall	6	(0.9)	24	(1.9)	38	(2.4)	62	(2.2)
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)
Fibula fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Foot fracture	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Fracture displacement	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fractured sacrum	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Gastrointestinal anastomotic complication	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hand fracture	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Heat stroke	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hip fracture	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Humerus fracture	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Incision site complication	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Incision site haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)

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Subjects With Adverse Events
(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	**65**	**(9.5)**	**121**	**(9.8)**	**241**	**(15.4)**	**362**	**(12.9)**
Incision site oedema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Incision site pain	0	(0.0)	1	(0.1)	6	(0.4)	7	(0.3)
Incision site pruritus	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Incision site ulcer	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)
Infusion related reaction	5	(0.7)	15	(1.2)	14	(0.9)	29	(1.0)
Injection related reaction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Joint dislocation	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Joint injury	2	(0.3)	3	(0.2)	2	(0.1)	5	(0.2)
Laceration	0	(0.0)	2	(0.2)	15	(1.0)	17	(0.6)
Ligament sprain	1	(0.1)	3	(0.2)	6	(0.4)	9	(0.3)
Limb crushing injury	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Limb injury	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Lip injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Lower limb fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Meniscus injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Muscle contusion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Muscle injury	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Muscle rupture	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Muscle strain	3	(0.4)	3	(0.2)	2	(0.1)	5	(0.2)
Periorbital contusion	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pneumonitis chemical	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Post procedural complication	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Post procedural discomfort	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Post procedural haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Post procedural haemorrhage	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Post procedural hypothyroidism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Post procedural inflammation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Post procedural urine leak	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**65**	**(9.5)**	**121**	**(9.8)**	**241**	**(15.4)**	**362**	**(12.9)**
Post-traumatic pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Procedural pain	4	(0.6)	6	(0.5)	20	(1.3)	26	(0.9)
Radiation necrosis	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Radiation pneumonitis	4	(0.6)	4	(0.3)	0	(0.0)	4	(0.1)
Radiation proctitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Radiation skin injury	0	(0.0)	1	(0.1)	8	(0.5)	9	(0.3)
Radius fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Rib fracture	3	(0.4)	4	(0.3)	10	(0.6)	14	(0.5)
Scratch	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Seroma	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Skeletal injury	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Skin abrasion	1	(0.1)	2	(0.2)	9	(0.6)	11	(0.4)
Skin wound	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Soft tissue injury	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Spinal compression fracture	3	(0.4)	3	(0.2)	3	(0.2)	6	(0.2)
Spinal fracture	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Sternal fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stress fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sunburn	1	(0.1)	3	(0.2)	12	(0.8)	15	(0.5)
Synovial rupture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tendon rupture	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Thermal burn	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Thoracic vertebral fracture	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Tooth fracture	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Toxicity to various agents	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tracheal haemorrhage	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Transfusion reaction	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Traumatic intracranial haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Upper limb fracture	3	(0.4)	3	(0.2)	0	(0.0)	3	(0.1)
Urinary retention postoperative	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vascular access complication	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Wound	0	(0.0)	0	(0.0)	13	(0.8)	13	(0.5)
Wound complication	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**65**	**(9.5)**	**121**	**(9.8)**	**241**	**(15.4)**	**362**	**(12.9)**
Wound decomposition	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Wound haemorrhage	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Wound necrosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Wound secretion	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Wrist fracture	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Investigations	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Activated partial thromboplastin time prolonged	3	(0.4)	5	(0.4)	5	(0.3)	10	(0.4)
Alanine aminotransferase	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Alanine aminotransferase increased	40	(5.9)	65	(5.3)	107	(6.8)	172	(6.1)
Amylase increased	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Anion gap increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Aortic bruit	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Aspartate aminotransferase	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Aspartate aminotransferase increased	31	(4.5)	61	(5.0)	107	(6.8)	168	(6.0)
Aspiration bronchial	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Autoantibody positive	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bilirubin conjugated increased	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Biopsy skin	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood acid phosphatase increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood albumin decreased	2	(0.3)	4	(0.3)	6	(0.4)	10	(0.4)
Blood albumin increased	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Blood alkaline phosphatase	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood alkaline phosphatase decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Blood alkaline phosphatase increased	27	(4.0)	51	(4.1)	61	(3.9)	112	(4.0)
Blood bicarbonate decreased	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Blood bicarbonate increased	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Blood bilirubin	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood bilirubin decreased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood bilirubin increased	6	(0.9)	13	(1.1)	38	(2.4)	51	(1.8)
Blood calcium decreased	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Blood calcium increased	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Blood chloride decreased	3	(0.4)	3	(0.2)	0	(0.0)	3	(0.1)
Blood cholesterol	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood cholesterol decreased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood cholesterol increased	8	(1.2)	21	(1.7)	32	(2.0)	53	(1.9)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood corticotrophin increased	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Blood cortisol decreased	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Blood cortisol increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood creatine increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood creatine phosphokinase increased	2	(0.3)	4	(0.3)	8	(0.5)	12	(0.4)
Blood creatinine decreased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood creatinine increased	33	(4.8)	49	(4.0)	59	(3.8)	108	(3.9)

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Subjects With Adverse Events
(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	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Blood electrolytes decreased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood folate decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood follicle stimulating hormone increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood glucose abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood glucose increased	0	(0.0)	5	(0.4)	4	(0.3)	9	(0.3)
Blood immunoglobulin G decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood immunoglobulin G increased	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Blood immunoglobulin M decreased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood iron decreased	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Blood lactate dehydrogenase increased	3	(0.4)	16	(1.3)	25	(1.6)	41	(1.5)
Blood lactic acid increased	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Blood luteinising hormone decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood luteinising hormone increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood magnesium decreased	3	(0.4)	5	(0.4)	1	(0.1)	6	(0.2)
Blood magnesium increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blood parathyroid hormone increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood phosphorus decreased	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Blood phosphorus increased	2	(0.3)	4	(0.3)	2	(0.1)	6	(0.2)
Blood potassium decreased	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Blood potassium increased	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)

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Subjects With Adverse Events
(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	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Blood pressure diastolic increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood pressure increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood prolactin increased	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Blood sodium decreased	3	(0.4)	3	(0.2)	4	(0.3)	7	(0.3)
Blood sodium increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood testosterone decreased	0	(0.0)	1	(0.1)	7	(0.4)	8	(0.3)
Blood testosterone increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Blood thyroid stimulating hormone decreased	1	(0.1)	6	(0.5)	17	(1.1)	23	(0.8)
Blood thyroid stimulating hormone increased	8	(1.2)	17	(1.4)	20	(1.3)	37	(1.3)
Blood triglycerides	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood triglycerides increased	5	(0.7)	6	(0.5)	22	(1.4)	28	(1.0)
Blood urea increased	4	(0.6)	5	(0.4)	15	(1.0)	20	(0.7)
Blood uric acid decreased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Blood uric acid increased	8	(1.2)	11	(0.9)	12	(0.8)	23	(0.8)
Blood urine present	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Body temperature	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Body temperature fluctuation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Body temperature increased	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Brain natriuretic peptide increased	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Breath sounds abnormal	3	(0.4)	3	(0.2)	4	(0.3)	7	(0.3)
C-reactive protein increased	10	(1.5)	10	(0.8)	6	(0.4)	16	(0.6)
Carbon dioxide increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
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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	(%)
Investigations	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Cardiac murmur	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac murmur functional	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chest X-ray abnormal	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Computerised tomogram thorax abnormal	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cortisol free urine decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Creatinine renal clearance decreased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Creatinine renal clearance increased	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Electrocardiogram QT prolonged	1	(0.1)	3	(0.2)	6	(0.4)	9	(0.3)
Electrocardiogram ST segment abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Electrocardiogram ST segment elevation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Electrocardiogram T wave abnormal	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Electrocardiogram T wave inversion	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Electrocardiogram abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Electrocardiogram change	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Electrocardiogram low voltage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Electrocardiogram repolarisation abnormality	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Eosinophil count increased	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Fibrin D dimer increased	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Forced expiratory volume	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Free thyroxine index increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Gamma-glutamyltransferase decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gamma-glutamyltransferase increased	18	(2.6)	22	(1.8)	32	(2.0)	54	(1.9)
General physical condition abnormal	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Glucose urine	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Grip strength decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haematocrit decreased	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Haemoglobin decreased	3	(0.4)	8	(0.6)	10	(0.6)	18	(0.6)
Haemoglobin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemoglobin urine	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Heart rate irregular	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hepatic enzyme increased	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Immunoglobulins increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Inflammatory marker increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
International normalised ratio increased	1	(0.1)	4	(0.3)	9	(0.6)	13	(0.5)
Intraocular pressure decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Intraocular pressure test abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lipase	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lipase increased	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Liver function test abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphocyte count decreased	6	(0.9)	12	(1.0)	32	(2.0)	44	(1.6)
Lymphocyte count increased	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Medical observation	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
N-terminal prohormone brain natriuretic peptide increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Neutrophil count decreased	5	(0.7)	11	(0.9)	10	(0.6)	21	(0.8)
Neutrophil count increased	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Nitrite urine present	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nuclear magnetic resonance imaging brain abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Occult blood	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Occult blood positive	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oxygen saturation decreased	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Pancreatic enzymes decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pancreatic enzymes increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Platelet count decreased	4	(0.6)	5	(0.4)	24	(1.5)	29	(1.0)
Platelet count increased	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Prostatic specific antigen increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Protein total decreased	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Protein total increased	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Protein urine present	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Prothrombin time prolonged	3	(0.4)	3	(0.2)	0	(0.0)	3	(0.1)
QRS axis abnormal	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Quality of life decreased	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Red blood cell count decreased	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Thyroglobulin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thyroxine decreased	0	(0.0)	1	(0.1)	7	(0.4)	8	(0.3)
Thyroxine free decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Thyroxine free increased	5	(0.7)	5	(0.4)	4	(0.3)	9	(0.3)
Thyroxine increased	3	(0.4)	5	(0.4)	5	(0.3)	10	(0.4)
Transaminases increased	3	(0.4)	6	(0.5)	4	(0.3)	10	(0.4)

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Subjects With Adverse Events
(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	**201**	**(29.5)**	**359**	**(29.1)**	**506**	**(32.3)**	**865**	**(30.9)**
Tri-iodothyronine decreased	2	(0.3)	2	(0.2)	4	(0.3)	6	(0.2)
Tri-iodothyronine free decreased	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Tri-iodothyronine free increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Tri-iodothyronine increased	1	(0.1)	2	(0.2)	5	(0.3)	7	(0.3)
Troponin I increased	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Troponin increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urine leukocyte esterase positive	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urine output decreased	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)
Vitamin D decreased	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Waist circumference increased	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Weight decreased	58	(8.5)	107	(8.7)	112	(7.1)	219	(7.8)
Weight increased	5	(0.7)	21	(1.7)	49	(3.1)	70	(2.5)
White blood cell count decreased	3	(0.4)	12	(1.0)	16	(1.0)	28	(1.0)
White blood cell count increased	1	(0.1)	4	(0.3)	4	(0.3)	8	(0.3)
White blood cells urine	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metabolism and nutrition disorders	**266**	**(39.0)**	**505**	**(41.0)**	**604**	**(38.5)**	**1,109**	**(39.6)**
Acidosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cachexia	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Cell death	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Cow's milk intolerance	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Decreased appetite	168	(24.6)	310	(25.2)	320	(20.4)	630	(22.5)
Dehydration	15	(2.2)	37	(3.0)	69	(4.4)	106	(3.8)
Diabetes mellitus	3	(0.4)	3	(0.2)	7	(0.4)	10	(0.4)
Diabetes mellitus inadequate control	0	(0.0)	0	(0.0)	2	(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	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Failure to thrive	1	(0.1)	2	(0.2)	5	(0.3)	7	(0.3)
Fluid overload	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)

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Subjects With Adverse Events
(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	**266**	**(39.0)**	**505**	**(41.0)**	**604**	**(38.5)**	**1,109**	**(39.6)**
Fluid retention	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Glucose tolerance impaired	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Gout	0	(0.0)	1	(0.1)	13	(0.8)	14	(0.5)
Hyperalbuminaemia	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Hyperamylasaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hypercalcaemia	19	(2.8)	29	(2.4)	28	(1.8)	57	(2.0)
Hypercholesterolaemia	9	(1.3)	13	(1.1)	12	(0.8)	25	(0.9)
Hyperglycaemia	28	(4.1)	64	(5.2)	66	(4.2)	130	(4.6)
Hyperkalaemia	10	(1.5)	23	(1.9)	38	(2.4)	61	(2.2)
Hyperlipidaemia	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Hypermagnesaemia	1	(0.1)	5	(0.4)	8	(0.5)	13	(0.5)
Hypernatraemia	2	(0.3)	3	(0.2)	2	(0.1)	5	(0.2)
Hyperphagia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hyperphosphataemia	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Hypertriglyceridaemia	17	(2.5)	25	(2.0)	55	(3.5)	80	(2.9)
Hyperuricaemia	5	(0.7)	8	(0.6)	30	(1.9)	38	(1.4)
Hypoalbuminaemia	17	(2.5)	38	(3.1)	51	(3.3)	89	(3.2)
Hypocalcaemia	12	(1.8)	20	(1.6)	30	(1.9)	50	(1.8)
Hypochloraemia	2	(0.3)	3	(0.2)	0	(0.0)	3	(0.1)
Hypoglycaemia	1	(0.1)	6	(0.5)	9	(0.6)	15	(0.5)
Hypokalaemia	21	(3.1)	49	(4.0)	75	(4.8)	124	(4.4)
Hypomagnesaemia	20	(2.9)	48	(3.9)	32	(2.0)	80	(2.9)
Hyponatraemia	27	(4.0)	58	(4.7)	88	(5.6)	146	(5.2)
Hypophagia	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Hypophosphataemia	8	(1.2)	21	(1.7)	35	(2.2)	56	(2.0)
Hypoproteinaemia	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Hypovolaemia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Increased appetite	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Insulin resistant diabetes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Iron deficiency	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Lactic acidosis	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Lactose intolerance	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Malnutrition	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Metabolic acidosis	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Obesity	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Polydipsia	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Tumour lysis syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**266**	**(39.0)**	**505**	**(41.0)**	**604**	**(38.5)**	**1,109**	**(39.6)**
Type 1 diabetes mellitus	3	(0.4)	3	(0.2)	2	(0.1)	5	(0.2)
Type 2 diabetes mellitus	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Vitamin B12 deficiency	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vitamin D deficiency	1	(0.1)	6	(0.5)	4	(0.3)	10	(0.4)
Musculoskeletal and connective tissue disorders	**295**	**(43.3)**	**531**	**(43.1)**	**881**	**(56.2)**	**1,412**	**(50.4)**
Amyotrophy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ankylosing spondylitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arthralgia	75	(11.0)	167	(13.6)	337	(21.5)	504	(18.0)
Arthritis	9	(1.3)	13	(1.1)	28	(1.8)	41	(1.5)
Arthropathy	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Axillary mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Back disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Back pain	73	(10.7)	133	(10.8)	216	(13.8)	349	(12.5)
Bone lesion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Bone pain	12	(1.8)	24	(1.9)	29	(1.9)	53	(1.9)
Bursa disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bursitis	6	(0.9)	7	(0.6)	3	(0.2)	10	(0.4)
Chondrocalcinosis pyrophosphate	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Clubbing	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Coccydynia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Costochondritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dupuytren's contracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Exostosis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Fibromyalgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Fistula	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Flank pain	5	(0.7)	13	(1.1)	37	(2.4)	50	(1.8)
Fracture pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Groin pain	5	(0.7)	12	(1.0)	21	(1.3)	33	(1.2)
Growing pains	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hypercreatinaemia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Inguinal mass	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Intervertebral disc protrusion	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Jaw disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**295**	**(43.3)**	**531**	**(43.1)**	**881**	**(56.2)**	**1,412**	**(50.4)**
Joint effusion	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Joint instability	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Joint range of motion decreased	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Joint stiffness	2	(0.3)	6	(0.5)	12	(0.8)	18	(0.6)
Joint swelling	5	(0.7)	9	(0.7)	18	(1.1)	27	(1.0)
Kyphosis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Limb discomfort	1	(0.1)	2	(0.2)	5	(0.3)	7	(0.3)
Lower extremity mass	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Mastication disorder	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Mobility decreased	2	(0.3)	3	(0.2)	5	(0.3)	8	(0.3)
Muscle atrophy	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Muscle fatigue	0	(0.0)	1	(0.1)	2	(0.1)	3	(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)
Muscle spasms	16	(2.3)	31	(2.5)	52	(3.3)	83	(3.0)
Muscle tightness	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Muscle twitching	0	(0.0)	1	(0.1)	6	(0.4)	7	(0.3)
Muscular weakness	12	(1.8)	25	(2.0)	64	(4.1)	89	(3.2)
Musculoskeletal chest pain	21	(3.1)	51	(4.1)	56	(3.6)	107	(3.8)
Musculoskeletal discomfort	8	(1.2)	11	(0.9)	11	(0.7)	22	(0.8)
Musculoskeletal pain	65	(9.5)	105	(8.5)	121	(7.7)	226	(8.1)
Musculoskeletal stiffness	3	(0.4)	9	(0.7)	30	(1.9)	39	(1.4)
Myalgia	35	(5.1)	73	(5.9)	180	(11.5)	253	(9.0)
Myalgia intercostal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Myopathy	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Myositis	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Neck mass	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Neck pain	22	(3.2)	39	(3.2)	55	(3.5)	94	(3.4)
Nodal osteoarthritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Osteitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Osteoarthritis	3	(0.4)	5	(0.4)	8	(0.5)	13	(0.5)
Osteolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Osteonecrosis of jaw	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Osteopenia	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Osteoporosis	2	(0.3)	2	(0.2)	2	(0.1)	4	(0.1)

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Subjects With Adverse Events
(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	**295**	**(43.3)**	**531**	**(43.1)**	**881**	**(56.2)**	**1,412**	**(50.4)**
Osteoporotic fracture	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Osteosclerosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pain in extremity	42	(6.2)	69	(5.6)	168	(10.7)	237	(8.5)
Pain in jaw	4	(0.6)	8	(0.6)	17	(1.1)	25	(0.9)
Pathological fracture	1	(0.1)	2	(0.2)	7	(0.4)	9	(0.3)
Periarthritis	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Plantar fasciitis	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Polyarthritis	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Polymyalgia rheumatica	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rheumatic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rotator cuff syndrome	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Sjogren's syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Spinal column stenosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Spinal osteoarthritis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Spinal pain	3	(0.4)	8	(0.6)	7	(0.4)	15	(0.5)
Spondylitis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Spondylolisthesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Synovial cyst	3	(0.4)	5	(0.4)	6	(0.4)	11	(0.4)
Synovitis	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Temporomandibular joint syndrome	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Tendon disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tendon pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tendonitis	1	(0.1)	5	(0.4)	4	(0.3)	9	(0.3)
Tenosynovitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Torticollis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Trigger finger	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Trismus	0	(0.0)	2	(0.2)	1	(0.1)	3	(0.1)
Upper extremity mass	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**36**	**(5.3)**	**68**	**(5.5)**	**190**	**(12.1)**	**258**	**(9.2)**
Abdominal neoplasm	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Acrochordon	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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)	**36**	**(5.3)**	**68**	**(5.5)**	**190**	**(12.1)**	**258**	**(9.2)**
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)	18	(1.1)	21	(0.8)
Basosquamous carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Benign lung neoplasm	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	8	(1.2)	11	(0.9)	11	(0.7)	22	(0.8)
Cerebral haemangioma	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)
Desmoplastic melanoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ear neoplasm malignant	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)
Haemangioma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemangioma of skin	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Infected neoplasm	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Intracranial tumour haemorrhage	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Invasive ductal breast carcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Keratoacanthoma	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)
Lipoma	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Lung neoplasm malignant	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Lymphangiosis carcinomatosa	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Malignant melanoma	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Malignant melanoma in situ	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)

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Subjects With Adverse Events
(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)	**36**	**(5.3)**	**68**	**(5.5)**	**190**	**(12.1)**	**258**	**(9.2)**
Malignant pleural effusion	3	(0.4)	6	(0.5)	0	(0.0)	6	(0.2)
Melanocytic naevus	0	(0.0)	0	(0.0)	12	(0.8)	12	(0.4)
Metastases to bone	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Metastases to central nervous system	3	(0.4)	5	(0.4)	7	(0.4)	12	(0.4)
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)
Metastases to muscle	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metastatic malignant melanoma	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Metastatic pain	2	(0.3)	2	(0.2)	5	(0.3)	7	(0.3)
Neoplasm malignant	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Neoplasm skin	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Neoplasm swelling	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Oncologic complication	1	(0.1)	1	(0.1)	5	(0.3)	6	(0.2)
Papillary thyroid cancer	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Papilloma	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Paraneoplastic syndrome	1	(0.1)	1	(0.1)	0	(0.0)	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)
Seborrhoeic keratosis	1	(0.1)	2	(0.2)	16	(1.0)	18	(0.6)
Skin neoplasm bleeding	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Skin papilloma	1	(0.1)	4	(0.3)	6	(0.4)	10	(0.4)
Squamous cell carcinoma	0	(0.0)	1	(0.1)	19	(1.2)	20	(0.7)
Squamous cell carcinoma of skin	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Thyroid neoplasm	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 exudation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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)	**36**	**(5.3)**	**68**	**(5.5)**	**190**	**(12.1)**	**258**	**(9.2)**
Tumour haemorrhage	0	(0.0)	0	(0.0)	9	(0.6)	9	(0.3)
Tumour necrosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Tumour pain	10	(1.5)	22	(1.8)	38	(2.4)	60	(2.1)
Vulval cancer metastatic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nervous system disorders	**207**	**(30.4)**	**386**	**(31.3)**	**651**	**(41.5)**	**1,037**	**(37.0)**
Action tremor	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ageusia	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Akathisia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Altered state of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Amnesia	2	(0.3)	6	(0.5)	10	(0.6)	16	(0.6)
Amnestic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Anosmia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Aphasia	1	(0.1)	2	(0.2)	9	(0.6)	11	(0.4)
Aphonia	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Apraxia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Ataxia	1	(0.1)	4	(0.3)	7	(0.4)	11	(0.4)
Axonal neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Balance disorder	3	(0.4)	5	(0.4)	18	(1.1)	23	(0.8)
Brain oedema	1	(0.1)	4	(0.3)	5	(0.3)	9	(0.3)
Burning sensation	1	(0.1)	2	(0.2)	6	(0.4)	8	(0.3)
Carpal tunnel syndrome	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Cerebellar syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cerebral haematoma	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cerebral haemorrhage	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Cerebral infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cerebral ischaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Cerebrovascular accident	2	(0.3)	6	(0.5)	6	(0.4)	12	(0.4)
Cervical radiculopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cognitive disorder	1	(0.1)	3	(0.2)	3	(0.2)	6	(0.2)
Coordination abnormal	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Depressed level of consciousness	1	(0.1)	3	(0.2)	2	(0.1)	5	(0.2)

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Subjects With Adverse Events
(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	**207**	**(30.4)**	**386**	**(31.3)**	**651**	**(41.5)**	**1,037**	**(37.0)**
Developmental coordination disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Disturbance in attention	2	(0.3)	3	(0.2)	7	(0.4)	10	(0.4)
Dizziness	48	(7.0)	94	(7.6)	150	(9.6)	244	(8.7)
Dizziness postural	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Dysaesthesia	2	(0.3)	3	(0.2)	5	(0.3)	8	(0.3)
Dysarthria	1	(0.1)	1	(0.1)	7	(0.4)	8	(0.3)
Dysgeusia	14	(2.1)	24	(1.9)	45	(2.9)	69	(2.5)
Dyskinesia	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	2	(0.3)	3	(0.2)	2	(0.1)	5	(0.2)
Epilepsy	2	(0.3)	2	(0.2)	6	(0.4)	8	(0.3)
Extensor plantar response	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Facial nerve disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Facial neuralgia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Facial paresis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
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)
Head discomfort	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Headache	64	(9.4)	122	(9.9)	278	(17.7)	400	(14.3)
Hemiparesis	2	(0.3)	6	(0.5)	4	(0.3)	10	(0.4)
Hemiplegia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Horner's syndrome	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Hydrocephalus	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hyperaesthesia	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Hypersomnia	2	(0.3)	3	(0.2)	3	(0.2)	6	(0.2)
Hypoaesthesia	18	(2.6)	24	(1.9)	37	(2.4)	61	(2.2)
Hypogeusia	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Hypotonia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Incoherent	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Intracranial aneurysm	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Ischaemic stroke	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Judgement impaired	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lacunar infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lethargy	5	(0.7)	15	(1.2)	18	(1.1)	33	(1.2)
Loss of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
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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	**207**	**(30.4)**	**386**	**(31.3)**	**651**	**(41.5)**	**1,037**	**(37.0)**
Lumbar radiculopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Memory impairment	0	(0.0)	2	(0.2)	21	(1.3)	23	(0.8)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Migraine	1	(0.1)	2	(0.2)	6	(0.4)	8	(0.3)
Migraine with aura	1	(0.1)	3	(0.2)	1	(0.1)	4	(0.1)
Monoparesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Muscle contractions involuntary	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Muscle spasticity	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Myasthenic syndrome	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Myelitis transverse	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Myoclonus	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Nerve compression	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Nerve root compression	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nervous system disorder	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Neuralgia	0	(0.0)	3	(0.2)	13	(0.8)	16	(0.6)
Neurological decompensation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Neuropathy peripheral	14	(2.1)	30	(2.4)	46	(2.9)	76	(2.7)
Neurotoxicity	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Normal pressure hydrocephalus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nystagmus	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Optic neuritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Paraesthesia	15	(2.2)	28	(2.3)	59	(3.8)	87	(3.1)
Paralysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Parosmia	2	(0.3)	3	(0.2)	4	(0.3)	7	(0.3)
Partial seizures	0	(0.0)	1	(0.1)	6	(0.4)	7	(0.3)
Peripheral motor neuropathy	3	(0.4)	3	(0.2)	3	(0.2)	6	(0.2)
Peripheral sensory neuropathy	11	(1.6)	14	(1.1)	15	(1.0)	29	(1.0)
Peroneal nerve palsy	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Phantom pain	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Polyneuropathy	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Poor quality sleep	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Post herpetic neuralgia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Presyncope	0	(0.0)	2	(0.2)	15	(1.0)	17	(0.6)

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	P010		PN001 Lung, PN010		PN001 Mel, PN002, PN006		PN001 PN002 PN006 PN010	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**207**	**(30.4)**	**386**	**(31.3)**	**651**	**(41.5)**	**1,037**	**(37.0)**
Psychomotor hyperactivity	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Radial nerve palsy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Radiculopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Restless legs syndrome	2	(0.3)	5	(0.4)	5	(0.3)	10	(0.4)
Sciatica	3	(0.4)	9	(0.7)	22	(1.4)	31	(1.1)
Seizure	1	(0.1)	4	(0.3)	22	(1.4)	26	(0.9)
Sensory disturbance	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Sensory loss	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Sinus headache	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Slow speech	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Somnolence	5	(0.7)	9	(0.7)	13	(0.8)	22	(0.8)
Spinal cord compression	2	(0.3)	3	(0.2)	10	(0.6)	13	(0.5)
Syncope	9	(1.3)	13	(1.1)	20	(1.3)	33	(1.2)
Tension headache	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Toxic leukoencephalopathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Toxic neuropathy	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Transient ischaemic attack	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Tremor	3	(0.4)	4	(0.3)	21	(1.3)	25	(0.9)
Trigeminal neuralgia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
VIIth nerve paralysis	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Vasogenic cerebral oedema	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Visual field defect	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vocal cord paralysis	1	(0.1)	3	(0.2)	0	(0.0)	3	(0.1)
Psychiatric disorders	**106**	**(15.5)**	**208**	**(16.9)**	**315**	**(20.1)**	**523**	**(18.7)**
Abnormal dreams	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Adjustment disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Adjustment disorder with depressed mood	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Affect lability	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Affective disorder	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Aggression	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Agitation	4	(0.6)	5	(0.4)	12	(0.8)	17	(0.6)
Anhedonia	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Anxiety	32	(4.7)	60	(4.9)	81	(5.2)	141	(5.0)

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Subjects With Adverse Events
(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	(%)
Psychiatric disorders	**106**	**(15.5)**	**208**	**(16.9)**	**315**	**(20.1)**	**523**	**(18.7)**
Anxiety disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Apathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Binge eating	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Bradyphrenia	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Bulimia nervosa	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Claustrophobia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Completed suicide	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Confusional state	8	(1.2)	21	(1.7)	37	(2.4)	58	(2.1)
Delirium	5	(0.7)	9	(0.7)	2	(0.1)	11	(0.4)
Depressed mood	3	(0.4)	6	(0.5)	2	(0.1)	8	(0.3)
Depression	23	(3.4)	42	(3.4)	61	(3.9)	103	(3.7)
Disorientation	3	(0.4)	3	(0.2)	6	(0.4)	9	(0.3)
Dysphoria	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Food aversion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hallucination	2	(0.3)	5	(0.4)	4	(0.3)	9	(0.3)
Hallucination, auditory	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hallucination, visual	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Insomnia	42	(6.2)	85	(6.9)	133	(8.5)	218	(7.8)
Irritability	1	(0.1)	2	(0.2)	9	(0.6)	11	(0.4)
Libido decreased	2	(0.3)	2	(0.2)	5	(0.3)	7	(0.3)
Mental disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Mental status changes	6	(0.9)	7	(0.6)	5	(0.3)	12	(0.4)
Middle insomnia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Mood altered	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Mood swings	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Nervousness	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Nightmare	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Panic attack	3	(0.4)	3	(0.2)	1	(0.1)	4	(0.1)
Personality change	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Phobia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Psychomotor retardation	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Psychosomatic disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Psychotic disorder	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Restlessness	2	(0.3)	3	(0.2)	1	(0.1)	4	(0.1)
Sleep disorder	2	(0.3)	2	(0.2)	11	(0.7)	13	(0.5)
Stress	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Substance-induced psychotic disorder	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Suicidal ideation	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Tension	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)

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Subjects With Adverse Events
(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	(%)
Psychiatric disorders	**106**	**(15.5)**	**208**	**(16.9)**	**315**	**(20.1)**	**523**	**(18.7)**
Trance	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Renal and urinary disorders	**52**	**(7.6)**	**99**	**(8.0)**	**172**	**(11.0)**	**271**	**(9.7)**
Acute kidney injury	7	(1.0)	13	(1.1)	27	(1.7)	40	(1.4)
Azotaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Bladder spasm	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Calculus ureteric	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Chromaturia	1	(0.1)	1	(0.1)	9	(0.6)	10	(0.4)
Chronic kidney disease	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Cystitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dysuria	11	(1.6)	20	(1.6)	26	(1.7)	46	(1.6)
Haematuria	7	(1.0)	13	(1.1)	26	(1.7)	39	(1.4)
Haemoglobinuria	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hydronephrosis	0	(0.0)	1	(0.1)	6	(0.4)	7	(0.3)
Hypertonic bladder	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Incontinence	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Microalbuminuria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Micturition disorder	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Micturition urgency	2	(0.3)	3	(0.2)	6	(0.4)	9	(0.3)
Nephrolithiasis	1	(0.1)	1	(0.1)	7	(0.4)	8	(0.3)
Nocturia	3	(0.4)	5	(0.4)	6	(0.4)	11	(0.4)
Obstructive uropathy	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pelvi-ureteric obstruction	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pneumaturia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pollakiuria	8	(1.2)	12	(1.0)	34	(2.2)	46	(1.6)
Polyuria	3	(0.4)	3	(0.2)	0	(0.0)	3	(0.1)
Postrenal failure	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Proteinuria	6	(0.9)	9	(0.7)	5	(0.3)	14	(0.5)
Pyelocaliectasis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Renal colic	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Renal cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Renal failure	5	(0.7)	8	(0.6)	17	(1.1)	25	(0.9)
Renal impairment	3	(0.4)	4	(0.3)	2	(0.1)	6	(0.2)
Renal infarct	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Renal pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Tubulointerstitial nephritis	1	(0.1)	1	(0.1)	3	(0.2)	4	(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 Adverse Events
(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	**52**	**(7.6)**	**99**	**(8.0)**	**172**	**(11.0)**	**271**	**(9.7)**
Urinary hesitation	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Urinary incontinence	0	(0.0)	2	(0.2)	13	(0.8)	15	(0.5)
Urinary retention	1	(0.1)	6	(0.5)	8	(0.5)	14	(0.5)
Urinary tract disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urinary tract obstruction	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Urinary tract pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Urine flow decreased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urine odour abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Reproductive system and breast disorders	**19**	**(2.8)**	**31**	**(2.5)**	**98**	**(6.3)**	**129**	**(4.6)**
Amenorrhoea	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Atrophic vulvovaginitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Balanoposthitis	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Benign prostatic hyperplasia	0	(0.0)	3	(0.2)	5	(0.3)	8	(0.3)
Breast cyst	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Breast haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Breast oedema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Breast pain	1	(0.1)	2	(0.2)	10	(0.6)	12	(0.4)
Breast swelling	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Breast tenderness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Cervix oedema	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dysfunctional uterine bleeding	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dysmenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Erectile dysfunction	2	(0.3)	3	(0.2)	9	(0.6)	12	(0.4)
Genital discomfort	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Genital haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Genital rash	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Gynaecomastia	2	(0.3)	2	(0.2)	3	(0.2)	5	(0.2)
Haematospermia	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Menopausal symptoms	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Menorrhagia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Menstrual disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Menstruation irregular	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Metrorrhagia	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Nipple pain	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Nipple swelling	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	(%)
Reproductive system and breast disorders	**19**	**(2.8)**	**31**	**(2.5)**	**98**	**(6.3)**	**129**	**(4.6)**
Oedema genital	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pelvic pain	2	(0.3)	5	(0.4)	18	(1.1)	23	(0.8)
Penile erythema	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)
Pruritus genital	1	(0.1)	2	(0.2)	3	(0.2)	5	(0.2)
Scrotal erythema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Scrotal oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Scrotal pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sexual dysfunction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Testicular atrophy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Testicular pain	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Testicular swelling	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Vaginal discharge	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vaginal haemorrhage	4	(0.6)	4	(0.3)	9	(0.6)	13	(0.5)
Vulval disorder	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Vulvar erosion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vulvovaginal burning sensation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Vulvovaginal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vulvovaginal dryness	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Vulvovaginal pain	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Vulvovaginal pruritus	1	(0.1)	1	(0.1)	4	(0.3)	5	(0.2)
Respiratory, thoracic and mediastinal disorders	**350**	**(51.3)**	**671**	**(54.5)**	**720**	**(45.9)**	**1,391**	**(49.7)**
Acute respiratory failure	2	(0.3)	7	(0.6)	3	(0.2)	10	(0.4)
Allergic cough	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Allergic respiratory disease	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Allergic sinusitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Asthma	3	(0.4)	5	(0.4)	7	(0.4)	12	(0.4)
Atelectasis	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Bronchial hyperreactivity	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Bronchial obstruction	2	(0.3)	3	(0.2)	1	(0.1)	4	(0.1)
Bronchiectasis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Bronchitis chronic	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)

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Subjects With Adverse Events
(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	**350**	**(51.3)**	**671**	**(54.5)**	**720**	**(45.9)**	**1,391**	**(49.7)**
Bronchospasm	3	(0.4)	3	(0.2)	2	(0.1)	5	(0.2)
Bronchostenosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Catarrh	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Choking sensation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Chronic obstructive pulmonary disease	15	(2.2)	23	(1.9)	7	(0.4)	30	(1.1)
Chronic respiratory failure	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cough	130	(19.1)	256	(20.8)	359	(22.9)	615	(22.0)
Diaphragmatic disorder	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)
Diffuse panbronchiolitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Dry throat	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Dysaesthesia pharynx	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dysphonia	21	(3.1)	40	(3.2)	28	(1.8)	68	(2.4)
Dyspnoea	156	(22.9)	286	(23.2)	248	(15.8)	534	(19.1)
Dyspnoea at rest	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dyspnoea exertional	10	(1.5)	36	(2.9)	44	(2.8)	80	(2.9)
Epistaxis	13	(1.9)	17	(1.4)	32	(2.0)	49	(1.8)
Haemoptysis	49	(7.2)	87	(7.1)	20	(1.3)	107	(3.8)
Haemothorax	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Hiccups	2	(0.3)	5	(0.4)	7	(0.4)	12	(0.4)
Hypercapnia	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Hyperventilation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypoxia	12	(1.8)	23	(1.9)	13	(0.8)	36	(1.3)
Increased bronchial secretion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Increased upper airway secretion	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Increased viscosity of nasal secretion	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Interstitial lung disease	3	(0.4)	4	(0.3)	3	(0.2)	7	(0.3)
Laryngeal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Laryngeal haemorrhage	2	(0.3)	3	(0.2)	0	(0.0)	3	(0.1)
Laryngeal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Laryngeal pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)

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Subjects With Adverse Events
(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	**350**	**(51.3)**	**671**	**(54.5)**	**720**	**(45.9)**	**1,391**	**(49.7)**
Lower respiratory tract congestion	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Lung consolidation	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Lung disorder	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Lung infiltration	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Nasal congestion	6	(0.9)	22	(1.8)	61	(3.9)	83	(3.0)
Nasal discomfort	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Nasal disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nasal dryness	1	(0.1)	1	(0.1)	6	(0.4)	7	(0.3)
Nasal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nasal mucosal disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nasal obstruction	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Nasal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Obstructive airways disorder	1	(0.1)	2	(0.2)	0	(0.0)	2	(0.1)
Oesophagobronchial fistula	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Oropharyngeal discomfort	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Oropharyngeal pain	17	(2.5)	27	(2.2)	63	(4.0)	90	(3.2)
Orthopnoea	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Painful respiration	2	(0.3)	3	(0.2)	5	(0.3)	8	(0.3)
Paranasal sinus discomfort	2	(0.3)	2	(0.2)	5	(0.3)	7	(0.3)
Paranasal sinus hypersecretion	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Pharyngeal erythema	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Pharyngeal inflammation	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Pharyngeal oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pleural effusion	25	(3.7)	72	(5.8)	35	(2.2)	107	(3.8)
Pleurisy	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Pleuritic pain	5	(0.7)	10	(0.8)	10	(0.6)	20	(0.7)
Pneumonia aspiration	4	(0.6)	4	(0.3)	2	(0.1)	6	(0.2)
Pneumonitis	28	(4.1)	50	(4.1)	37	(2.4)	87	(3.1)
Pneumothorax	1	(0.1)	10	(0.8)	6	(0.4)	16	(0.6)
Pneumothorax spontaneous	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Productive cough	43	(6.3)	81	(6.6)	61	(3.9)	142	(5.1)

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Subjects With Adverse Events
(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	**350**	**(51.3)**	**671**	**(54.5)**	**720**	**(45.9)**	**1,391**	**(49.7)**
Pulmonary congestion	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pulmonary embolism	20	(2.9)	36	(2.9)	25	(1.6)	61	(2.2)
Pulmonary haemorrhage	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Pulmonary hypertension	2	(0.3)	4	(0.3)	1	(0.1)	5	(0.2)
Pulmonary infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pulmonary oedema	2	(0.3)	4	(0.3)	3	(0.2)	7	(0.3)
Pulmonary pain	1	(0.1)	2	(0.2)	0	(0.0)	2	(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)	1	(0.1)	2	(0.1)
Pulmonary venous thrombosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Rales	2	(0.3)	4	(0.3)	4	(0.3)	8	(0.3)
Respiration abnormal	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Respiratory acidosis	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Respiratory disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Respiratory distress	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Respiratory failure	5	(0.7)	15	(1.2)	4	(0.3)	19	(0.7)
Respiratory tract congestion	1	(0.1)	7	(0.6)	9	(0.6)	16	(0.6)
Respiratory tract haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rhinitis allergic	5	(0.7)	13	(1.1)	21	(1.3)	34	(1.2)
Rhinorrhoea	16	(2.3)	23	(1.9)	30	(1.9)	53	(1.9)
Sinus congestion	1	(0.1)	3	(0.2)	24	(1.5)	27	(1.0)
Sinus disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sleep apnoea syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Sneezing	2	(0.3)	2	(0.2)	5	(0.3)	7	(0.3)
Sputum discoloured	3	(0.4)	4	(0.3)	0	(0.0)	4	(0.1)
Sputum increased	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Stridor	4	(0.6)	4	(0.3)	0	(0.0)	4	(0.1)
Tachypnoea	3	(0.4)	4	(0.3)	3	(0.2)	7	(0.3)
Throat irritation	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Throat tightness	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Tonsillar disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Tracheal inflammation	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**350**	**(51.3)**	**671**	**(54.5)**	**720**	**(45.9)**	**1,391**	**(49.7)**
Upper respiratory tract congestion	2	(0.3)	3	(0.2)	1	(0.1)	4	(0.1)
Upper respiratory tract inflammation	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Upper-airway cough syndrome	3	(0.4)	8	(0.6)	21	(1.3)	29	(1.0)
Vocal cord cyst	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Wheezing	14	(2.1)	27	(2.2)	25	(1.6)	52	(1.9)
Skin and subcutaneous tissue disorders	**222**	**(32.6)**	**419**	**(34.0)**	**941**	**(60.1)**	**1,360**	**(48.6)**
Acantholysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Acne	2	(0.3)	5	(0.4)	8	(0.5)	13	(0.5)
Actinic keratosis	1	(0.1)	2	(0.2)	18	(1.1)	20	(0.7)
Alopecia	9	(1.3)	18	(1.5)	34	(2.2)	52	(1.9)
Angioedema	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Anhidrosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Blister	0	(0.0)	0	(0.0)	6	(0.4)	6	(0.2)
Blood blister	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Cold sweat	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Dandruff	2	(0.3)	2	(0.2)	0	(0.0)	2	(0.1)
Decubitus ulcer	3	(0.4)	4	(0.3)	7	(0.4)	11	(0.4)
Dermal cyst	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Dermatitis	2	(0.3)	6	(0.5)	14	(0.9)	20	(0.7)
Dermatitis acneiform	3	(0.4)	16	(1.3)	16	(1.0)	32	(1.1)
Dermatitis allergic	1	(0.1)	3	(0.2)	3	(0.2)	6	(0.2)
Dermatitis atopic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Dermatitis bullous	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Dermatitis contact	0	(0.0)	1	(0.1)	6	(0.4)	7	(0.3)
Dermatitis exfoliative	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Dermatitis psoriasiform	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Diffuse alopecia	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Drug eruption	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Dry skin	28	(4.1)	66	(5.4)	99	(6.3)	165	(5.9)
Dyshidrotic eczema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ecchymosis	0	(0.0)	1	(0.1)	7	(0.4)	8	(0.3)
Eczema	8	(1.2)	9	(0.7)	33	(2.1)	42	(1.5)
Eczema asteatotic	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Eczema nummular	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)

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Subjects With Adverse Events
(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	**222**	**(32.6)**	**419**	**(34.0)**	**941**	**(60.1)**	**1,360**	**(48.6)**
Erythema	10	(1.5)	21	(1.7)	71	(4.5)	92	(3.3)
Erythema multiforme	2	(0.3)	3	(0.2)	0	(0.0)	3	(0.1)
Erythema nodosum	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Excessive granulation tissue	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Exfoliative rash	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Generalised erythema	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Granuloma annulare	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Granuloma skin	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Haemorrhage subcutaneous	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hair colour changes	0	(0.0)	0	(0.0)	20	(1.3)	20	(0.7)
Hair disorder	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Hair growth abnormal	0	(0.0)	1	(0.1)	3	(0.2)	4	(0.1)
Hair texture abnormal	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hyperhidrosis	7	(1.0)	15	(1.2)	41	(2.6)	56	(2.0)
Hyperkeratosis	2	(0.3)	4	(0.3)	13	(0.8)	17	(0.6)
Hypertrichosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ichthyosis acquired	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ingrowing nail	2	(0.3)	2	(0.2)	1	(0.1)	3	(0.1)
Intertrigo	0	(0.0)	0	(0.0)	7	(0.4)	7	(0.3)
Keratosis pilaris	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Leukoplakia	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Lichen planus	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Lichen sclerosus	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Lichenification	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lichenoid keratosis	0	(0.0)	1	(0.1)	4	(0.3)	5	(0.2)
Linear IgA disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Macule	2	(0.3)	3	(0.2)	5	(0.3)	8	(0.3)
Madarosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Melanocytic hyperplasia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Miliaria	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Mucocutaneous rash	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nail discolouration	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Nail disorder	1	(0.1)	3	(0.2)	2	(0.1)	5	(0.2)
Nail dystrophy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nail growth abnormal	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nail ridging	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Nail toxicity	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)

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Subjects With Adverse Events
(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	**222**	**(32.6)**	**419**	**(34.0)**	**941**	**(60.1)**	**1,360**	**(48.6)**
Neurodermatitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Neutrophilic dermatosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Night sweats	10	(1.5)	18	(1.5)	69	(4.4)	87	(3.1)
Onychalgia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Onychoclasis	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Onycholysis	0	(0.0)	1	(0.1)	2	(0.1)	3	(0.1)
Onychomadesis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Pain of skin	1	(0.1)	3	(0.2)	8	(0.5)	11	(0.4)
Palmar erythema	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Palmar-plantar erythrodysaesthesia syndrome	1	(0.1)	1	(0.1)	9	(0.6)	10	(0.4)
Panniculitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Papule	0	(0.0)	1	(0.1)	17	(1.1)	18	(0.6)
Parapsoriasis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Pemphigoid	1	(0.1)	1	(0.1)	2	(0.1)	3	(0.1)
Penile ulceration	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Petechiae	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Photosensitivity reaction	1	(0.1)	2	(0.2)	16	(1.0)	18	(0.6)
Pigmentation disorder	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Pityriasis rosea	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Prurigo	0	(0.0)	0	(0.0)	4	(0.3)	4	(0.1)
Pruritus	73	(10.7)	148	(12.0)	414	(26.4)	562	(20.1)
Pruritus allergic	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Pruritus generalised	2	(0.3)	4	(0.3)	18	(1.1)	22	(0.8)
Pseudofolliculitis barbae	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Psoriasis	5	(0.7)	9	(0.7)	11	(0.7)	20	(0.7)
Purpura	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Pustular psoriasis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Rash	94	(13.8)	161	(13.1)	338	(21.6)	499	(17.8)
Rash erythematous	0	(0.0)	2	(0.2)	14	(0.9)	16	(0.6)
Rash follicular	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Rash generalised	0	(0.0)	3	(0.2)	17	(1.1)	20	(0.7)
Rash macular	2	(0.3)	6	(0.5)	16	(1.0)	22	(0.8)
Rash maculo-papular	11	(1.6)	24	(1.9)	76	(4.9)	100	(3.6)
Rash papular	1	(0.1)	3	(0.2)	9	(0.6)	12	(0.4)
Rash pruritic	7	(1.0)	10	(0.8)	25	(1.6)	35	(1.3)
Rash vesicular	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)

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Subjects With Adverse Events
(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	**222**	**(32.6)**	**419**	**(34.0)**	**941**	**(60.1)**	**1,360**	**(48.6)**
Rosacea	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Scab	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Scar pain	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Sebaceous gland disorder	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Seborrhoea	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Seborrhoeic dermatitis	4	(0.6)	6	(0.5)	5	(0.3)	11	(0.4)
Skin burning sensation	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Skin depigmentation	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.1)
Skin discolouration	0	(0.0)	2	(0.2)	5	(0.3)	7	(0.3)
Skin disorder	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Skin exfoliation	1	(0.1)	1	(0.1)	9	(0.6)	10	(0.4)
Skin fissures	0	(0.0)	2	(0.2)	3	(0.2)	5	(0.2)
Skin haemorrhage	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Skin hyperpigmentation	0	(0.0)	0	(0.0)	9	(0.6)	9	(0.3)
Skin hypertrophy	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Skin hypopigmentation	1	(0.1)	2	(0.2)	32	(2.0)	34	(1.2)
Skin irritation	0	(0.0)	2	(0.2)	2	(0.1)	4	(0.1)
Skin lesion	6	(0.9)	11	(0.9)	39	(2.5)	50	(1.8)
Skin maceration	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Skin mass	1	(0.1)	2	(0.2)	11	(0.7)	13	(0.5)
Skin plaque	0	(0.0)	0	(0.0)	5	(0.3)	5	(0.2)
Skin reaction	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Skin striae	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Skin ulcer	4	(0.6)	5	(0.4)	14	(0.9)	19	(0.7)
Skin ulcer haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Solar dermatitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Stasis dermatitis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Stevens-Johnson syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Swelling face	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)
Telangiectasia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Toxic skin eruption	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Transient acantholytic dermatosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Urticaria	2	(0.3)	5	(0.4)	10	(0.6)	15	(0.5)
Urticaria papular	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Vitiligo	1	(0.1)	1	(0.1)	170	(10.8)	171	(6.1)
Xanthelasma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Xeroderma	0	(0.0)	2	(0.2)	4	(0.3)	6	(0.2)

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Subjects With Adverse Events
(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	(%)
Social circumstances	**0**	**(0.0)**	**1**	**(0.1)**	**0**	**(0.0)**	**1**	**(0.0)**
Activities of daily living impaired	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Surgical and medical procedures	**0**	**(0.0)**	**4**	**(0.3)**	**1**	**(0.1)**	**5**	**(0.2)**
Astringent therapy	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
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)
Tooth extraction	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Vascular disorders	**86**	**(12.6)**	**156**	**(12.7)**	**254**	**(16.2)**	**410**	**(14.6)**
Aortic stenosis	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Aortic thrombosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Arterial stenosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Arterial thrombosis	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Deep vein thrombosis	6	(0.9)	24	(1.9)	16	(1.0)	40	(1.4)
Embolism	5	(0.7)	12	(1.0)	5	(0.3)	17	(0.6)
Embolism venous	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Extremity necrosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Femoral artery occlusion	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Flushing	5	(0.7)	6	(0.5)	16	(1.0)	22	(0.8)
Haematoma	2	(0.3)	4	(0.3)	12	(0.8)	16	(0.6)
Haemorrhage	1	(0.1)	2	(0.2)	4	(0.3)	6	(0.2)
Haemorrhagic infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hot flush	10	(1.5)	17	(1.4)	35	(2.2)	52	(1.9)
Hyperaemia	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Hypertension	25	(3.7)	40	(3.2)	66	(4.2)	106	(3.8)
Hypertensive crisis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Hypotension	17	(2.5)	26	(2.1)	40	(2.6)	66	(2.4)
Intermittent claudication	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Intra-abdominal haematoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Ischaemia	1	(0.1)	1	(0.1)	1	(0.1)	2	(0.1)
Jugular vein thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphatic fistula	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Lymphoedema	0	(0.0)	0	(0.0)	30	(1.9)	30	(1.1)
Orthostatic hypotension	1	(0.1)	5	(0.4)	8	(0.5)	13	(0.5)

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Subjects With Adverse Events
(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	**86**	**(12.6)**	**156**	**(12.7)**	**254**	**(16.2)**	**410**	**(14.6)**
Pallor	0	(0.0)	1	(0.1)	5	(0.3)	6	(0.2)
Pelvic venous thrombosis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Peripheral arterial occlusive disease	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Peripheral coldness	1	(0.1)	1	(0.1)	3	(0.2)	4	(0.1)
Peripheral embolism	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Peripheral ischaemia	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Peripheral vascular disorder	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Peripheral venous disease	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Phlebitis	1	(0.1)	3	(0.2)	5	(0.3)	8	(0.3)
Poor venous access	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Prehypertension	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Raynaud's phenomenon	0	(0.0)	0	(0.0)	7	(0.4)	7	(0.3)
Shock haemorrhagic	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Subclavian vein thrombosis	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Superior vena cava occlusion	1	(0.1)	2	(0.2)	1	(0.1)	3	(0.1)
Superior vena cava stenosis	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.0)
Superior vena cava syndrome	4	(0.6)	5	(0.4)	0	(0.0)	5	(0.2)
Thrombophlebitis	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
Thrombophlebitis superficial	1	(0.1)	2	(0.2)	2	(0.1)	4	(0.1)
Thrombosis	4	(0.6)	7	(0.6)	0	(0.0)	7	(0.3)
Varicophlebitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.0)
Varicose vein	0	(0.0)	2	(0.2)	0	(0.0)	2	(0.1)
Vasculitis	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.1)
Vasospasm	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)	4	(0.3)	4	(0.1)
Venous thrombosis limb	1	(0.1)	1	(0.1)	0	(0.0)	1	(0.0)
NULL	**0**	**(0.0)**	**2**	**(0.2)**	**0**	**(0.0)**	**2**	**(0.1)**

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Subjects With Adverse Events
(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)**	**2**	**(0.2)**	**0**	**(0.0)**	**2**	**(0.1)**
NULL	0	(0.0)	2	(0.2)	0	(0.0)	2	(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.

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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