表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	5(8.0)	30(6.7)	25(4.4)	8(2.6)	27(5.2)
Pruritus	そう痒症	2(3.2)	2(0.4)	5(0.9)	0(0.0)	5(1.0)
Eczema	湿疹	3(4.8)	3(0.7)	4(0.7)	1(0.3)	2(0.4)
Haemorrhage subcutaneous	皮下出血	0(0.0)	6(1.3)	0(0.0)	1(0.3)	5(1.0)
Dermatitis contact	接触皮膚炎	0(0.0)	2(0.4)	2(0.4)	0(0.0)	2(0.4)
Rash	発疹	0(0.0)	2(0.4)	5(0.9)	0(0.0)	0(0.0)
Skin exfoliation	皮膚剥脱	0(0.0)	4(0.9)	0(0.0)	0(0.0)	3(0.6)
Eczema asteatotic	皮脂欠乏性湿疹	0(0.0)	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Drug eruption	薬疹	0(0.0)	0(0.0)	2(0.4)	0(0.0)	2(0.4)
Ingrowing nail	嵌入爪	0(0.0)	2(0.4)	1(0.2)	1(0.3)	1(0.2)
Xeroderma	乾皮症	0(0.0)	1(0.2)	0(0.0)	1(0.3)	1(0.2)
Dermatitis	皮膚炎	0(0.0)	1(0.2)	0(0.0)	1(0.3)	1(0.2)
Dermal cyst	皮膚嚢腫	0(0.0)	1(0.2)	0(0.0)	0(0.0)	1(0.2)
Blister	水疱	0(0.0)	0(0.0)	1(0.2)	0(0.0)	2(0.4)
Hyperkeratosis	過角化	0(0.0)	1(0.2)	0(0.0)	2(0.7)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cold sweat	冷汗	0(0.0)	0(0.0)	2(0.4)	0(0.0)	0(0.0)
Acne	ざ瘡	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Alopecia	脱毛症	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Erythema	紅斑	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Neurodermatitis	神経皮膚炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Rash pruritic	そう痒性皮疹	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Skin disorder	皮膚障害	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Skin mass	皮膚腫瘤	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	5(8.0)	34(7.6)	37(6.5)	20(6.5)	27(5.2)
Back pain	背部痛	1(1.6)	5(1.1)	6(1.1)	7(2.3)	1(0.2)
Muscle spasms	筋痙縮	1(1.6)	2(0.4)	4(0.7)	2(0.7)	3(0.6)
Pain in extremity	四肢痛	1(1.6)	4(0.9)	4(0.7)	2(0.7)	3(0.6)
Arthralgia	関節痛	1(1.6)	4(0.9)	3(0.5)	2(0.7)	2(0.4)
Myalgia	筋肉痛	0(0.0)	2(0.4)	4(0.7)	0(0.0)	5(1.0)
Musculoskeletal pain	筋骨格痛	0(0.0)	1(0.2)	3(0.5)	3(1.0)	2(0.4)
Osteoarthritis	変形性関節症	0(0.0)	0(0.0)	3(0.5)	2(0.7)	2(0.4)
Spinal osteoarthritis	変形性脊椎症	0(0.0)	2(0.4)	2(0.4)	0(0.0)	0(0.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	1(0.2)	3(0.5)	1(0.3)	0(0.0)
Periarthritis	関節周囲炎	0(0.0)	5(1.1)	0(0.0)	0(0.0)	2(0.4)
Osteoporosis	骨粗鬆症	0(0.0)	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Neck pain	頚部痛	1(1.6)	1(0.2)	0(0.0)	0(0.0)	2(0.4)
Tenosynovitis	腱鞘炎	0(0.0)	0(0.0)	1(0.2)	1(0.3)	2(0.4)
Rotator cuff syndrome	肩回旋筋腱板症候群	0(0.0)	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Trigger finger	弾発指	0(0.0)	0(0.0)	1(0.2)	0(0.0)	1(0.2)
Bursitis	滑液包炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Intervertebral disc protrusion	椎間板突出	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Haemarthrosis	出血性関節症	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Joint swelling	関節腫脹	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Musculoskeletal chest pain	筋骨格系胸痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Musculoskeletal discomfort	筋骨格不快感	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Renal and urinary disorders	腎および尿路障害	0(0.0)	1(0.2)	1(0.2)	2(0.7)	2(0.4)
Chronic kidney disease	慢性腎臓病	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Haematuria	血尿	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Pollakiuria	頻尿	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Renal cyst	腎嚢胞	0(0.0)	1(0.2)	0(0.0)	0(0.0)	1(0.2)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	2(0.4)	2(0.4)	3(1.0)	0(0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	0(0.0)	0(0.0)	0(0.0)	2(0.7)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	0(0.0)	2(0.4)	1(0.3)	0(0.0)
Prostatitis	前立腺炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Erectile dysfunction	勃起不全	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(1.6)	4(0.9)	7(1.2)	4(1.3)	7(1.3)
Pyrexia	発熱	0(0.0)	1(0.2)	3(0.5)	2(0.7)	2(0.4)
Oedema peripheral	末梢性浮腫	1(1.6)	0(0.0)	1(0.2)	0(0.0)	3(0.6)
Chest discomfort	胸部不快感	0(0.0)	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Vessel puncture site bruise	血管穿刺部位内出血	0(0.0)	1(0.2)	0(0.0)	0(0.0)	1(0.2)
Fatigue	疲労	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Feeling abnormal	異常感	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Injection site reaction	注射部位反応	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Puncture site pain	穿刺部位疼痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Investigations	臨床検査	3(4.9)	3(0.7)	10(1.8)	2(0.7)	6(1.2)
Blood pressure increased	血圧上昇	1(1.6)	1(0.2)	1(0.2)	1(0.3)	1(0.2)
Blood pressure decreased	血圧低下	0(0.0)	1(0.2)	4(0.7)	0(0.0)	1(0.2)
Haemoglobin decreased	ヘモグロビン減少	1(1.6)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(1.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood urea increased	血中尿素増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Blood uric acid decreased	血中尿酸減少	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Blood urine present	尿中血陽性	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	12(19.2)	34(7.6)	43(7.6)	38(12.4)	70(13.5)
Contusion	挫傷	4(6.4)	10(2.2)	9(1.6)	7(2.3)	9(1.7)
Shunt stenosis	シャント狭窄	1(1.6)	9(2.0)	13(2.3)	7(2.3)	11(2.1)
Skin abrasion	皮膚擦過傷	2(3.2)	3(0.7)	1(0.2)	2(0.7)	7(1.3)
Procedural hypotension	処置による低血圧	1(1.6)	0(0.0)	0(0.0)	3(1.0)	13(2.5)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Wound	創傷	0(0.0)	2(0.4)	2(0.4)	3(1.0)	4(0.8)
Thermal burn	熱傷	0(0.0)	1(0.2)	3(0.5)	2(0.7)	2(0.4)
Limb injury	四肢損傷	2(3.2)	0(0.0)	2(0.4)	1(0.3)	1(0.2)
Shunt occlusion	シャント閉塞	0(0.0)	2(0.4)	1(0.2)	1(0.3)	2(0.4)
Rib fracture	肋骨骨折	0(0.0)	0(0.0)	0(0.0)	1(0.3)	1(0.2)
Skin laceration	皮膚裂傷	0(0.0)	0(0.0)	1(0.2)	0(0.0)	1(0.2)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Arteriovenous fistula site complication	動静脈瘻部位合併症	0(0.0)	0(0.0)	0(0.0)	1(0.3)	2(0.4)
Joint injury	関節損傷	0(0.0)	1(0.2)	1(0.2)	1(0.3)	0(0.0)
Clavicle fracture	鎖骨骨折	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Femoral neck fracture	大腿骨頚部骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Eye contusion	眼挫傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Animal bite	動物咬傷	0(0.0)	1(0.2)	0(0.0)	1(0.3)	0(0.0)
Foot fracture	足骨折	0(0.0)	1(0.2)	0(0.0)	0(0.0)	1(0.2)
Ligament sprain	靱帯捻挫	1(1.6)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Subcutaneous haematoma	皮下血腫	0(0.0)	0(0.0)	1(0.2)	0(0.0)	1(0.2)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Tibia fracture	脛骨骨折	0(0.0)	0(0.0)	0(0.0)	2(0.7)	0(0.0)
Procedural hypertension	処置による高血圧	0(0.0)	0(0.0)	0(0.0)	1(0.3)	1(0.2)
Shunt blood flow excessive	シャント血流過剰	0(0.0)	0(0.0)	0(0.0)	1(0.3)	1(0.2)
Skin wound	皮膚創傷	0(0.0)	0(0.0)	1(0.2)	1(0.3)	0(0.0)
Vascular access malfunction	血管アクセス機能不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Dental restoration failure	歯科修復不成功	0(0.0)	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Chilblains	凍瘡	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Foreign body in eye	眼内異物	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Muscle injury	筋損傷	0(0.0)	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Scratch	引っかき傷	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Scrotal haematoma	陰嚢血腫	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Subdural haematoma	硬膜下血腫	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Tooth injury	歯牙損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Wound complication	創合併症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Arteriovenous fistula site haemorrhage	動静脈瘻部位出血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Arteriovenous fistula occlusion	動静脈瘻閉塞	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Shunt thrombosis	シャント血栓症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Pelvic fracture	骨盤骨折	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Vascular access complication	血管確保合併症	0(0.0)	0(0.0)	0(0.0)	1(0.3)	0(0.0)
Post procedural inflammation	処置後炎症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Heat illness	熱中症	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
	Pubis fracture	恥骨骨折	1(1.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Vascular access site inflammation	血管確保部位炎症	0(0.0)	0(0.0)	1(0.2)	0(0.0)	0(0.0)
	Soft tissue foreign body	軟部組織内異物	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
PD(N=42)	Total exposure period (months)		12.3	34.6	69.8	41.7	55.8
	Number of adverse events		10(81.4)	17(49.1)	47(67.3)	29(69.6)	35(62.7)
	Infections and infestations	感染症および寄生虫症	3(24.4)	4(11.6)	9(12.9)	9(21.6)	9(16.1)
	Nasopharyngitis	上咽頭炎	1(8.1)	3(8.7)	1(1.4)	1(2.4)	1(1.8)
	Conjunctivitis	結膜炎	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Pneumonia	肺炎	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Upper respiratory tract infection	上気道感染	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
	Catheter site infection	カテーテル留置部位感染	0(0.0)	1(2.9)	2(2.9)	5(12.0)	3(5.4)
	Cellulitis	蜂巣炎	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Peritonitis	腹膜炎	1(8.1)	0(0.0)	1(1.4)	0(0.0)	3(5.4)
	Body tinea	体部白癬	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
	Diverticulitis	憩室炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
	Folliculitis	毛包炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
	Sepsis	敗血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
	Blood and lymphatic system disorders	血液およびリンパ系障害	1(8.1)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Anaemia	貧血	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Nephrogenic anaemia	腎性貧血	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Metabolism and nutrition disorders	代謝および栄養障害	0(0.0)	1(2.9)	4(5.7)	3(7.2)	1(1.8)
Decreased appetite	食欲減退	0(0.0)	1(2.9)	2(2.9)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Dehydration	脱水	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Psychiatric disorders	精神障害	1(8.1)	0(0.0)	3(4.3)	0(0.0)	0(0.0)
Insomnia	不眠症	1(8.1)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Nervous system disorders	神経系障害	1(8.1)	0(0.0)	2(2.9)	1(2.4)	1(1.8)
Dizziness	浮動性めまい	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Cerebral infarction	脳梗塞	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Eye disorders	眼障害	0(0.0)	0(0.0)	1(1.4)	2(4.8)	4(7.2)
Retinal haemorrhage	網膜出血	0(0.0)	0(0.0)	1(1.4)	0(0.0)	1(1.8)
Dry eye	ドライアイ	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Cardiac disorders	心臓障害	0(0.0)	0(0.0)	0(0.0)	1(2.4)	1(1.8)
Cardiac failure chronic	慢性心不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Myocardial ischaemia	心筋虚血	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Vascular disorders	血管障害	1(8.1)	1(2.9)	3(4.3)	1(2.4)	1(1.8)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1(8.1)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Hypotension	低血圧	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Orthostatic hypotension	起立性低血圧	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	1(1.4)	1(2.4)	0(0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0(0.0)	0(0.0)	1(1.4)	2(4.8)	0(0.0)
Cough	咳嗽	0(0.0)	0(0.0)	1(1.4)	1(2.4)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Gastrointestinal disorders	胃腸障害	1(8.1)	5(14.5)	16(22.9)	2(4.8)	9(16.1)
Diarrhoea	下痢	1(8.1)	0(0.0)	5(7.2)	1(2.4)	2(3.6)
Vomiting	嘔吐	0(0.0)	0(0.0)	2(2.9)	0(0.0)	2(3.6)
Nausea	悪心	0(0.0)	0(0.0)	2(2.9)	0(0.0)	2(3.6)
Constipation	便秘	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Dental caries	齲歯	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Abdominal discomfort	腹部不快感	0(0.0)	1(2.9)	1(1.4)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	1(2.9)	0(0.0)	1(2.4)	1(1.8)
Enterocolitis	腸炎	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Gastric polyps	胃ポリープ	0(0.0)	2(5.8)	1(1.4)	0(0.0)	0(0.0)
Gingival bleeding	歯肉出血	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Hiatus hernia	裂孔ヘルニア	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0(0.0)	0(0.0)	2(2.9)	2(4.8)	1(1.8)
Dermatitis contact	接触皮膚炎	0(0.0)	0(0.0)	0(0.0)	1(2.4)	1(1.8)
Rash	発疹	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Dermatitis	皮膚炎	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	0(0.0)	3(8.7)	0(0.0)	0(0.0)	2(3.6)
Back pain	背部痛	0(0.0)	1(2.9)	0(0.0)	0(0.0)	1(1.8)
Arthralgia	関節痛	0(0.0)	2(5.8)	0(0.0)	0(0.0)	0(0.0)
Arthritis	関節炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Renal and urinary disorders	腎および尿路障害	0(0.0)	1(2.9)	0(0.0)	1(2.4)	1(1.8)
Renal impairment	腎機能障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Haematuria	血尿	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	0(0.0)	0(0.0)	4(5.7)	0(0.0)	3(5.4)
Pyrexia	発熱	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Chest pain	胸痛	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(3.6)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Investigations	臨床検査	0(0.0)	2(5.8)	0(0.0)	1(2.4)	1(1.8)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Blood potassium decreased	血中カリウム減少	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Weight decreased	体重減少	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1(8.1)	0(0.0)	2(2.9)	3(7.2)	1(1.8)
Contusion	挫傷	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Shunt occlusion	シャント閉塞	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Heat stroke	熱射病	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Traumatic haemothorax	外傷性血胸	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Total(N=481)	Total exposure period (months)		124.0	828.3	1202.7	689.7	997.6
	Number of adverse events		99(79.8)	383(46.2)	617(51.3)	402(58.3)	522(52.3)
	Infections and infestations	感染症および寄生虫症	18(14.5)	86(10.4)	150(12.5)	92(13.3)	110(11.0)
	Nasopharyngitis	上咽頭炎	6(4.8)	44(5.3)	63(5.2)	48(7.0)	51(5.1)
	Conjunctivitis	結膜炎	0(0.0)	1(0.1)	11(0.9)	8(1.2)	2(0.2)
	Influenza	インフルエンザ	1(0.8)	5(0.6)	6(0.5)	0(0.0)	8(0.8)
	Gastroenteritis	胃腸炎	0(0.0)	3(0.4)	6(0.5)	4(0.6)	5(0.5)
	Pneumonia	肺炎	2(1.6)	2(0.2)	5(0.4)	3(0.4)	6(0.6)
	Upper respiratory tract infection	上気道感染	1(0.8)	2(0.2)	8(0.7)	2(0.3)	1(0.1)
	Bronchitis	気管支炎	0(0.0)	2(0.2)	5(0.4)	4(0.6)	2(0.2)
	Cystitis	膀胱炎	0(0.0)	2(0.2)	4(0.3)	3(0.4)	3(0.3)
	Catheter site infection	カテーテル留置部位感染	0(0.0)	1(0.1)	2(0.2)	5(0.7)	3(0.3)
	Urinary tract infection	尿路感染	0(0.0)	2(0.2)	4(0.3)	1(0.1)	2(0.2)
	Cellulitis	蜂巣炎	2(1.6)	0(0.0)	3(0.2)	1(0.1)	1(0.1)
	Periodontitis	歯周炎	0(0.0)	4(0.5)	1(0.1)	1(0.1)	1(0.1)
	Herpes zoster	帯状疱疹	0(0.0)	0(0.0)	3(0.2)	2(0.3)	2(0.2)
	Otitis media	中耳炎	1(0.8)	3(0.4)	1(0.1)	0(0.0)	0(0.0)
	Pharyngitis	咽頭炎	0(0.0)	1(0.1)	1(0.1)	1(0.1)	2(0.2)
	Hordeolum	麦粒腫	0(0.0)	1(0.1)	2(0.2)	0(0.0)	2(0.2)
	Peritonitis	腹膜炎	1(0.8)	0(0.0)	1(0.1)	0(0.0)	3(0.3)
	Renal cyst infection	腎嚢胞感染	0(0.0)	0(0.0)	2(0.2)	0(0.0)	1(0.1)
	Sinusitis	副鼻腔炎	0(0.0)	0(0.0)	1(0.1)	2(0.3)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	 150mg Events(%)	 300mg Events(%)	 450mg Events(%)	 600mg Events(%)
Dermatophytosis of nail	爪の皮膚糸状菌症	0(0.0)	0(0.0)	0(0.0)	2(0.3)	1(0.1)
Shunt infection	シャント感染	0(0.0)	1(0.1)	1(0.1)	0(0.0)	1(0.1)
Enteritis infectious	感染性腸炎	0(0.0)	1(0.1)	1(0.1)	0(0.0)	1(0.1)
Herpes simplex	単純ヘルペス	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Rhinitis	鼻炎	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Abscess limb	四肢膿瘍	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Gingivitis	歯肉炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Osteomyelitis	骨髄炎	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Paronychia	爪囲炎	1(0.8)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Pyelonephritis	腎盂腎炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Upper respiratory tract infection bacterial	細菌性上気道感染	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Body tinea	体部白癬	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Diverticulitis	憩室炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Hydrocele male infected	感染性陰嚢水瘤	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Otitis media chronic	慢性中耳炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Skin infection	皮膚感染	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Tinea pedis	足部白癬	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Infected dermal cyst	感染性皮膚嚢腫	0(0.0)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Aspergilloma	アスペルギローマ	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Mediastinal abscess	縦隔洞膿瘍	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Otitis externa	外耳炎	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pneumonia chlamydial	クラミジア性肺炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Pyelonephritis acute	急性腎盂腎炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Tinea cruris	股部白癬	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Tonsillitis	扁桃炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Lung infection	肺感染	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Chronic sinusitis	慢性副鼻腔炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Dermatitis infected	感染性皮膚炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Epididymitis	精巣上体炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Furuncle	せつ	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Gastroenteritis viral	ウイルス性胃腸炎	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Tracheobronchitis	気管気管支炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hepatic cyst infection	肝嚢胞感染	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Bacterial infection	細菌感染	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Oral herpes	口腔ヘルペス	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Vascular device infection	血管デバイス感染	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Folliculitis	毛包炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Sepsis	敗血症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0(0.0)	1(0.1)	2(0.2)	2(0.3)	6(0.6)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Colon adenoma	大腸腺腫	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Oral papilloma	口腔乳頭腫	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Breast cancer	乳癌	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cholesteatoma	真珠腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Gastric cancer	胃癌	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Uterine leiomyoma	子宮平滑筋腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Blood and lymphatic system disorders	血液およびリンパ系障害	1(0.8)	2(0.2)	2(0.2)	2(0.3)	7(0.7)
Anaemia	貧血	1(0.8)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Iron deficiency anaemia	鉄欠乏性貧血	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Anaemia macrocytic	大球性貧血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Nephrogenic anaemia	腎性貧血	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Eosinophilia	好酸球増加症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Lymphadenitis	リンパ節炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Polycythaemia	赤血球増加症	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Blood loss anaemia	失血性貧血	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Immune system disorders	免疫系障害	0(0.0)	2(0.2)	2(0.2)	0(0.0)	3(0.3)
Seasonal allergy	季節性アレルギー	0(0.0)	2(0.2)	0(0.0)	0(0.0)	3(0.3)
Allergy to arthropod sting	節足動物刺傷アレルギー	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	1(0.8)	2(0.2)	2(0.2)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	1(0.8)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Parathyroid gland enlargement	副甲状腺肥大	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Metabolism and nutrition disorders	代謝および栄養障害	5(4.0)	14(1.7)	25(2.1)	13(1.9)	11(1.1)
Decreased appetite	食欲減退	0(0.0)	5(0.6)	10(0.8)	1(0.1)	0(0.0)
Hyperkalaemia	高カリウム血症	2(1.6)	1(0.1)	1(0.1)	1(0.1)	1(0.1)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	3(0.4)	1(0.1)	1(0.1)	1(0.1)
Hyperuricaemia	高尿酸血症	0(0.0)	1(0.1)	3(0.2)	1(0.1)	0(0.0)
Dehydration	脱水	1(0.8)	0(0.0)	1(0.1)	2(0.3)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	2(0.2)
Diabetes mellitus	糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.1)	2(0.2)
Metabolic acidosis	代謝性アシドーシス	0(0.0)	0(0.0)	2(0.2)	0(0.0)	1(0.1)
Hypoglycaemia	低血糖	0(0.0)	2(0.2)	1(0.1)	0(0.0)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	1(0.8)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Fluid retention	体液貯留	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Hypocalcaemia	低カルシウム血症	0(0.0)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Dyslipidaemia	脂質異常症	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Hypoproteinaemia	低蛋白血症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Hyperlipidaemia	高脂血症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	2型糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Hypercalcaemia	高カルシウム血症	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Psychiatric disorders	精神障害	1(0.8)	3(0.4)	8(0.7)	7(1.0)	6(0.6)
Insomnia	不眠症	1(0.8)	1(0.1)	5(0.4)	5(0.7)	4(0.4)
Delirium	譫妄	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Anxiety	不安	0(0.0)	0(0.0)	0(0.0)	2(0.3)	0(0.0)
Depression	うつ病	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Abnormal behaviour	異常行動	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Nervous system disorders	神経系障害	5(4.0)	10(1.2)	23(1.9)	25(3.6)	20(2.0)
Headache	頭痛	2(1.6)	3(0.4)	6(0.5)	9(1.3)	9(0.9)
Dizziness	浮動性めまい	0(0.0)	1(0.1)	3(0.2)	4(0.6)	4(0.4)
Intracranial aneurysm	頭蓋内動脈瘤	0(0.0)	0(0.0)	1(0.1)	1(0.1)	1(0.1)
Facial paralysis	顔面麻痺	0(0.0)	0(0.0)	2(0.2)	0(0.0)	1(0.1)
Hypoaesthesia	感覚鈍麻	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Somnolence	傾眠	1(0.8)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Carpal tunnel syndrome	手根管症候群	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Myelopathy	脊髄症	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Thrombotic cerebral infarction	血栓性脳梗塞	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	1(0.8)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Loss of consciousness	意識消失	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Presyncope	失神寸前の状態	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Subarachnoid haemorrhage	くも膜下出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Carotid artery stenosis	頸動脈狭窄	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Cerebral haemorrhage	脳出血	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Dizziness postural	体位性めまい	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Myoclonus	ミオクローヌス	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Neuralgia	神経痛	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Sciatica	坐骨神経痛	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Tremor	振戦	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Intercostal neuralgia	肋間神経痛	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Cervical radiculopathy	頸髄神経根障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Lacunar infarction	ラクナ梗塞	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Eye disorders	眼障害	4(3.2)	10(1.2)	21(1.7)	16(2.3)	25(2.5)
Retinal haemorrhage	網膜出血	3(2.4)	3(0.4)	3(0.2)	3(0.4)	8(0.8)
Cataract	白内障	0(0.0)	3(0.4)	2(0.2)	0(0.0)	3(0.3)
Conjunctival haemorrhage	結膜出血	0(0.0)	1(0.1)	3(0.2)	3(0.4)	1(0.1)
Dry eye	ドライアイ	0(0.0)	0(0.0)	4(0.3)	3(0.4)	0(0.0)
Blepharitis	眼瞼炎	0(0.0)	1(0.1)	0(0.0)	2(0.3)	1(0.1)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	1(0.1)	0(0.0)	2(0.2)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	0(0.0)	1(0.1)	1(0.1)	1(0.1)
Glaucoma	緑内障	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Macular oedema	黄斑浮腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Eczema eyelids	眼瞼湿疹	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Retinal exudates	網膜滲出物	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Diplopia	複視	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Keratitis	角膜炎	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Ocular hyperaemia	眼充血	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Trichiasis	睫毛乱生	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Eye pruritus	眼そう痒症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Chorioretinopathy	網脈絡膜症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Eyelid haematoma	眼瞼血腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Ear and labyrinth disorders	耳および迷路障害	0(0.0)	5(0.6)	3(0.2)	5(0.7)	4(0.4)
Vertigo	回転性めまい	0(0.0)	2(0.2)	2(0.2)	2(0.3)	4(0.4)
Vertigo positional	頭位性回転性めまい	0(0.0)	1(0.1)	0(0.0)	2(0.3)	0(0.0)
Ear congestion	耳閉	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Deafness	難聴	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Sudden hearing loss	突発性難聴	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Eustachian tube stenosis	耳管狭窄	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Cardiac disorders	心臓障害	3(2.4)	8(1.0)	11(0.9)	18(2.6)	9(0.9)
Palpitations	動悸	0(0.0)	0(0.0)	3(0.2)	4(0.6)	1(0.1)
Cardiac failure chronic	慢性心不全	0(0.0)	1(0.1)	1(0.1)	1(0.1)	3(0.3)
Cardiac failure congestive	うっ血性心不全	0(0.0)	0(0.0)	1(0.1)	4(0.6)	0(0.0)
Myocardial ischaemia	心筋虚血	1(0.8)	0(0.0)	0(0.0)	1(0.1)	2(0.2)
Atrial fibrillation	心房細動	0(0.0)	0(0.0)	0(0.0)	2(0.3)	1(0.1)
Cardiac failure	心不全	1(0.8)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Angina pectoris	狭心症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Arteriosclerosis coronary artery	冠動脈硬化症	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Coronary artery stenosis	冠動脈狭窄	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Cardiac dysfunction	心機能障害	1(0.8)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Atrial flutter	心房粗動	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Bradycardia	徐脈	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Ventricular tachycardia	心室性頻脈	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Angina unstable	不安定狭心症	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Aortic valve incompetence	大動脈弁閉鎖不全症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Arrhythmia	不整脈	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Mitral valve incompetence	僧帽弁閉鎖不全症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Mitral valve stenosis	僧帽弁狭窄症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Pericarditis	心膜炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Paroxysmal arrhythmia	発作性不整脈	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Vascular disorders	血管障害	3(2.4)	11(1.3)	14(1.2)	12(1.7)	10(1.0)
Hypertension	高血圧	0(0.0)	4(0.5)	4(0.3)	3(0.4)	2(0.2)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1(0.8)	0(0.0)	4(0.3)	2(0.3)	2(0.2)
Hypotension	低血圧	0(0.0)	1(0.1)	1(0.1)	1(0.1)	4(0.4)
Internal haemorrhage	内出血	1(0.8)	0(0.0)	1(0.1)	2(0.3)	1(0.1)
Orthostatic hypotension	起立性低血圧	0(0.0)	2(0.2)	0(0.0)	1(0.1)	0(0.0)
Aneurysm	動脈瘤	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Vascular pain	血管痛	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Haemorrhage	出血	1(0.8)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Aortic aneurysm	大動脈瘤	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Varicose vein	静脈瘤	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Vasculitis	血管炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Vascular rupture	血管破裂	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Vascular insufficiency	血行不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Respiratory, thoracic and mediastinal disorders	呼吸器，胸郭および縦隔障害	6(4.8)	7(0.8)	18(1.5)	9(1.3)	15(1.5)
Cough	咳嗽	0(0.0)	2(0.2)	4(0.3)	2(0.3)	1(0.1)
Rhinitis allergic	アレルギー性鼻炎	0(0.0)	2(0.2)	3(0.2)	1(0.1)	2(0.2)
Epistaxis	鼻出血	2(1.6)	0(0.0)	3(0.2)	0(0.0)	1(0.1)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	2(0.2)	2(0.3)	2(0.2)
Haemoptysis	喀血	1(0.8)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Pleural effusion	胸水	0(0.0)	1(0.1)	1(0.1)	0(0.0)	1(0.1)
Asthma	喘息	0(0.0)	0(0.0)	0(0.0)	2(0.3)	1(0.1)
Pulmonary oedema	肺水腫	0(0.0)	0(0.0)	3(0.2)	0(0.0)	0(0.0)
Pulmonary congestion	肺うっ血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Sleep apnoea syndrome	睡眠時無呼吸症候群	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Sputum increased	喀痰増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Oropharyngeal pain	口腔咽頭痛	1(0.8)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Interstitial lung disease	間質性肺疾患	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Pulmonary hypertension	肺高血圧症	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Rhinorrhoea	鼻漏	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Reflux laryngitis	逆流性喉頭炎	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hiccups	しゃっくり	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Pneumonia aspiration	誤嚥性肺炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Gastrointestinal disorders	胃腸障害	14(11.3)	64(7.7)	110(9.1)	57(8.3)	65(6.5)
Diarrhoea	下痢	3(2.4)	18(2.2)	31(2.6)	16(2.3)	21(2.1)
Vomiting	嘔吐	1(0.8)	5(0.6)	15(1.2)	9(1.3)	6(0.6)
Nausea	悪心	0(0.0)	3(0.4)	9(0.7)	10(1.4)	6(0.6)
Constipation	便秘	2(1.6)	6(0.7)	12(1.0)	1(0.1)	6(0.6)
Dental caries	齲歯	0(0.0)	1(0.1)	4(0.3)	4(0.6)	3(0.3)
Gastrooesophageal reflux disease	胃食道逆流性疾患	2(1.6)	2(0.2)	3(0.2)	1(0.1)	2(0.2)
Abdominal pain	腹痛	0(0.0)	2(0.2)	5(0.4)	0(0.0)	2(0.2)
Abdominal discomfort	腹部不快感	1(0.8)	1(0.1)	4(0.3)	1(0.1)	1(0.1)
Stomatitis	口内炎	1(0.8)	0(0.0)	4(0.3)	1(0.1)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	1(0.1)	0(0.0)	2(0.3)	3(0.3)
Enterocolitis	腸炎	0(0.0)	2(0.2)	2(0.2)	1(0.1)	1(0.1)
Haemorrhoids	痔核	0(0.0)	1(0.1)	2(0.2)	0(0.0)	2(0.2)
Abdominal distension	腹部膨満	0(0.0)	2(0.2)	0(0.0)	1(0.1)	1(0.1)
Chronic gastritis	慢性胃炎	2(1.6)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastritis	胃炎	1(0.8)	1(0.1)	2(0.2)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	1(0.8)	1(0.1)	0(0.0)	2(0.3)	0(0.0)
Gastric polyps	胃ポリープ	0(0.0)	2(0.2)	1(0.1)	1(0.1)	0(0.0)
Faeces soft	軟便	0(0.0)	1(0.1)	2(0.2)	0(0.0)	0(0.0)
Gastric ulcer	胃潰瘍	0(0.0)	0(0.0)	3(0.2)	0(0.0)	0(0.0)
Toothache	歯痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	3(0.3)
Periodontal disease	歯周病	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Angular cheilitis	口角口唇炎	0(0.0)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Diverticulum intestinal	腸憩室	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Mouth haemorrhage	口腔内出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Gingival bleeding	歯肉出血	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Abdominal pain lower	下腹部痛	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Dyspepsia	消化不良	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal disorder	胃腸障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Oesophageal achalasia	食道アカラシア	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Tooth loss	歯の脱落	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Barrett's oesophagus	バレット食道	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Dry mouth	口内乾燥	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Duodenal polyp	十二指腸ポリープ	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Food poisoning	食中毒	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Gastritis erosive	びらん性胃炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Gastritis haemorrhagic	出血性胃炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Glossitis	舌炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Melaena	メレナ	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Pancreatitis	膵炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Rectal ulcer	直腸潰瘍	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Gastric disorder	胃障害	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Loose tooth	弛緩歯	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Hiatus hernia	裂孔ヘルニア	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	2(1.6)	3(0.4)	10(0.8)	3(0.4)	1(0.1)
Cholelithiasis	胆石症	1(0.8)	1(0.1)	3(0.2)	1(0.1)	0(0.0)
Hepatic function abnormal	肝機能異常	0(0.0)	1(0.1)	2(0.2)	1(0.1)	1(0.1)
Bile duct stone	胆管結石	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Hepatic cirrhosis	肝硬変	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Drug-induced liver injury	薬物性肝障害	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Cholangitis	胆管炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	5(4.0)	37(4.5)	47(3.9)	21(3.0)	38(3.8)
Pruritus	そう痒症	2(1.6)	3(0.4)	9(0.7)	0(0.0)	7(0.7)
Eczema	湿疹	3(2.4)	4(0.5)	8(0.7)	1(0.1)	3(0.3)
Haemorrhage subcutaneous	皮下出血	0(0.0)	6(0.7)	0(0.0)	3(0.4)	6(0.6)
Dermatitis contact	接触皮膚炎	0(0.0)	2(0.2)	4(0.3)	2(0.3)	5(0.5)
Rash	発疹	0(0.0)	3(0.4)	7(0.6)	1(0.1)	0(0.0)
Skin exfoliation	皮膚剥脱	0(0.0)	4(0.5)	0(0.0)	0(0.0)	3(0.3)
Eczema asteatotic	皮脂欠乏性湿疹	0(0.0)	2(0.2)	3(0.2)	1(0.1)	0(0.0)
Drug eruption	薬疹	0(0.0)	0(0.0)	3(0.2)	0(0.0)	2(0.2)
Ingrowing nail	嵌入爪	0(0.0)	2(0.2)	1(0.1)	1(0.1)	1(0.1)
Xeroderma	乾皮症	0(0.0)	2(0.2)	0(0.0)	1(0.1)	1(0.1)
Dermatitis	皮膚炎	0(0.0)	1(0.1)	1(0.1)	1(0.1)	1(0.1)
Dry skin	皮膚乾燥	0(0.0)	0(0.0)	1(0.1)	2(0.3)	0(0.0)
Skin ulcer	皮膚潰瘍	0(0.0)	1(0.1)	1(0.1)	1(0.1)	0(0.0)
Dermal cyst	皮膚嚢腫	0(0.0)	1(0.1)	0(0.0)	0(0.0)	2(0.2)
Blister	水疱	0(0.0)	0(0.0)	1(0.1)	0(0.0)	2(0.2)
Hyperkeratosis	過角化	0(0.0)	1(0.1)	0(0.0)	2(0.3)	0(0.0)
Dermatomyositis	皮膚筋炎	0(0.0)	0(0.0)	0(0.0)	2(0.3)	0(0.0)
Skin erosion	皮膚びらん	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Urticaria	蕁麻疹	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Seborrhoeic dermatitis	脂漏性皮膚炎	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Cold sweat	冷汗	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Decubitus ulcer	褥瘡性潰瘍	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Prurigo	痒疹	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Pruritus generalised	全身性そう痒症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Reactive perforating collagenosis	反応性穿孔性膠原線維症	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Acne	ざ瘡	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Alopecia	脱毛症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Erythema	紅斑	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Neurodermatitis	神経皮膚炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Rash pruritic	そう痒性皮疹	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Skin disorder	皮膚障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Skin mass	皮膚腫瘤	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	8(6.5)	46(5.6)	50(4.2)	31(4.5)	40(4.0)
Back pain	背部痛	2(1.6)	8(1.0)	8(0.7)	10(1.4)	3(0.3)
Muscle spasms	筋痙縮	1(0.8)	2(0.2)	6(0.5)	2(0.3)	6(0.6)
Pain in extremity	四肢痛	1(0.8)	5(0.6)	6(0.5)	2(0.3)	3(0.3)
Arthralgia	関節痛	1(0.8)	6(0.7)	3(0.2)	5(0.7)	2(0.2)
Myalgia	筋肉痛	0(0.0)	3(0.4)	5(0.4)	0(0.0)	6(0.6)
Musculoskeletal pain	筋骨格痛	0(0.0)	1(0.1)	4(0.3)	3(0.4)	2(0.2)
Osteoarthritis	変形性関節症	0(0.0)	1(0.1)	3(0.2)	2(0.3)	2(0.2)
Spinal osteoarthritis	変形性脊椎症	0(0.0)	3(0.4)	4(0.3)	0(0.0)	0(0.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	1(0.1)	3(0.2)	1(0.1)	2(0.2)
Periarthritis	関節周囲炎	0(0.0)	5(0.6)	0(0.0)	0(0.0)	2(0.2)
Arthritis	関節炎	1(0.8)	1(0.1)	0(0.0)	0(0.0)	3(0.3)
Osteoporosis	骨粗鬆症	0(0.0)	1(0.1)	2(0.2)	1(0.1)	1(0.1)
Neck pain	頸部痛	1(0.8)	1(0.1)	0(0.0)	1(0.1)	2(0.2)
Tenosynovitis	腱鞘炎	1(0.8)	0(0.0)	1(0.1)	1(0.1)	2(0.2)
Rotator cuff syndrome	肩回旋筋腱板症候群	0(0.0)	2(0.2)	0(0.0)	1(0.1)	0(0.0)
Trigger finger	弾発指	0(0.0)	0(0.0)	1(0.1)	1(0.1)	1(0.1)
Synovial cyst	滑液嚢腫	0(0.0)	2(0.2)	0(0.0)	0(0.0)	0(0.0)
Bursitis	滑液包炎	0(0.0)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Intervertebral disc protrusion	椎間板突出	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Temporomandibular joint syndrome	顎関節症候群	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Spondylolisthesis	脊椎すべり症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Haemarthrosis	出血性関節症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Joint swelling	関節腫脹	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Musculoskeletal chest pain	筋骨格系胸痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Musculoskeletal discomfort	筋骨格不快感	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Renal and urinary disorders	腎および尿路障害	2(1.6)	7(0.8)	7(0.6)	17(2.5)	20(2.0)
Chronic kidney disease	慢性腎臓病	0(0.0)	1(0.1)	3(0.2)	4(0.6)	6(0.6)
Renal impairment	腎機能障害	1(0.8)	2(0.2)	2(0.2)	1(0.1)	8(0.8)
End stage renal disease	末期腎疾患	1(0.8)	0(0.0)	0(0.0)	4(0.6)	1(0.1)
Renal failure	腎不全	0(0.0)	0(0.0)	0(0.0)	2(0.3)	1(0.1)
Haematuria	血尿	0(0.0)	1(0.1)	0(0.0)	2(0.3)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Pollakiuria	頻尿	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Renal cyst	腎嚢胞	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Oliguria	乏尿	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Urinary retention	尿閉	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Acute kidney injury	急性腎障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Reproductive system and breast disorders	生殖系および乳房障害	1(0.8)	3(0.4)	4(0.3)	4(0.6)	2(0.2)
Benign prostatic hyperplasia	良性前立腺肥大症	0(0.0)	1(0.1)	0(0.0)	3(0.4)	2(0.2)
Acquired hydrocele	後天性陰嚢水瘤	1(0.8)	0(0.0)	2(0.2)	1(0.1)	0(0.0)
Menstruation irregular	不規則月経	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Nipple pain	乳頭痛	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Prostatitis	前立腺炎	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Erectile dysfunction	勃起不全	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(0.8)	9(1.1)	24(2.0)	14(2.0)	31(3.1)
Pyrexia	発熱	0(0.0)	1(0.1)	8(0.7)	6(0.9)	11(1.1)
Oedema peripheral	末梢性浮腫	1(0.8)	3(0.4)	4(0.3)	3(0.4)	11(1.1)
Malaise	倦怠感	0(0.0)	0(0.0)	2(0.2)	2(0.3)	1(0.1)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	1(0.1)	2(0.2)	1(0.1)	1(0.1)
Chest pain	胸痛	0(0.0)	0(0.0)	3(0.2)	0(0.0)	0(0.0)
Chest discomfort	胸部不快感	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Vessel puncture site bruise	血管穿刺部位内出血	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Chills	悪寒	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Face oedema	顔面浮腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Oedema	浮腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Thirst	口渇	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Vessel puncture site haemorrhage	血管穿刺部位出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Fatigue	疲労	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Feeling abnormal	異常感	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Injection site reaction	注射部位反応	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Puncture site pain	穿刺部位疼痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Investigations	臨床検査	4(3.2)	7(0.8)	20(1.7)	3(0.4)	10(1.0)
Blood pressure increased	血圧上昇	1(0.8)	1(0.1)	3(0.2)	1(0.1)	1(0.1)
Blood pressure decreased	血圧低下	0(0.0)	1(0.1)	4(0.3)	0(0.0)	1(0.1)
Blood creatinine increased	血中クレアチニン増加	0(0.0)	1(0.1)	1(0.1)	0(0.0)	1(0.1)
Haemoglobin decreased	ヘモグロビン減少	2(1.6)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	1(0.1)	1(0.1)	1(0.1)	0(0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Blood potassium decreased	血中カリウム減少	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Blood triglycerides increased	血中トリグリセリド増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood urea increased	血中尿素増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Blood uric acid decreased	血中尿酸減少	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Blood urine present	尿中血陽性	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Weight decreased	体重減少	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	13(10.5)	45(5.4)	64(5.3)	51(7.4)	89(8.9)
Contusion	挫傷	4(3.2)	13(1.6)	18(1.5)	11(1.6)	10(1.0)
Shunt stenosis	シャント狭窄	1(0.8)	9(1.1)	13(1.1)	9(1.3)	12(1.2)
Skin abrasion	皮膚擦過傷	2(1.6)	5(0.6)	2(0.2)	3(0.4)	8(0.8)
Procedural hypotension	処置による低血圧	1(0.8)	0(0.0)	0(0.0)	3(0.4)	13(1.3)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	1(0.1)	2(0.2)	0(0.0)	9(0.9)
Wound	創傷	0(0.0)	2(0.2)	3(0.2)	3(0.4)	4(0.4)
Thermal burn	熱傷	0(0.0)	1(0.1)	3(0.2)	3(0.4)	2(0.2)
Limb injury	四肢損傷	2(1.6)	0(0.0)	3(0.2)	1(0.1)	2(0.2)
Shunt occlusion	シャント閉塞	0(0.0)	2(0.2)	1(0.1)	2(0.3)	2(0.2)
Rib fracture	肋骨骨折	0(0.0)	0(0.0)	1(0.1)	2(0.3)	1(0.1)
Skin laceration	皮膚裂傷	0(0.0)	0(0.0)	1(0.1)	1(0.1)	2(0.2)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	1(0.1)	0(0.0)	2(0.2)
Arteriovenous fistula site complication	動静脈瘻部位合併症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	2(0.2)
Joint injury	関節損傷	0(0.0)	1(0.1)	1(0.1)	1(0.1)	0(0.0)
Clavicle fracture	鎖骨骨折	0(0.0)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Femoral neck fracture	大腿骨頚部骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Eye contusion	眼挫傷	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)
Animal bite	動物咬傷	0(0.0)	1(0.1)	0(0.0)	1(0.1)	0(0.0)
Foot fracture	足骨折	0(0.0)	1(0.1)	0(0.0)	0(0.0)	1(0.1)
Ligament sprain	靱帯捻挫	1(0.8)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Subcutaneous haematoma	皮下血腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.1)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	 150mg Events(%)	 300mg Events(%)	 450mg Events(%)	 600mg Events(%)
Tibia fracture	脛骨骨折	0(0.0)	0(0.0)	0(0.0)	2(0.3)	0(0.0)
Procedural hypertension	処置による高血圧	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Shunt blood flow excessive	シャント血流過剰	0(0.0)	0(0.0)	0(0.0)	1(0.1)	1(0.1)
Skin wound	皮膚創傷	0(0.0)	0(0.0)	1(0.1)	1(0.1)	0(0.0)
Vascular access malfunction	血管アクセス機能不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.2)
Dental restoration failure	歯科修復不成功	0(0.0)	1(0.1)	1(0.1)	0(0.0)	0(0.0)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Animal scratch	動物による引っかき傷	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Fall	転倒	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Hand fracture	手骨折	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Head injury	頭部損傷	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Injury	損傷	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Seroma	漿液腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Sternal fracture	胸骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Tendon rupture	腱断裂	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Lumbar vertebral fracture	腰椎骨折	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Procedural pain	処置による疼痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Nail injury	爪損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Chillblains	凍瘡	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Foreign body in eye	眼内異物	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Muscle injury	筋損傷	0(0.0)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Scratch	引っかき傷	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－67　発現直前の投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Scrotal haematoma	陰嚢血腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Subdural haematoma	硬膜下血腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Tooth injury	歯牙損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Wound complication	創合併症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Arteriovenous fistula site haemorrhage	動静脈瘻部位出血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Arteriovenous fistula occlusion	動静脈瘻閉塞	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Shunt thrombosis	シャント血栓症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Pelvic fracture	骨盤骨折	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Vascular access complication	血管確保合併症	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Post procedural inflammation	処置後炎症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Heat illness	熱中症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Pubis fracture	恥骨骨折	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vascular access site inflammation	血管確保部位炎症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Soft tissue foreign body	軟部組織内異物	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.1)
Heat stroke	熱射病	0(0.0)	0(0.0)	0(0.0)	1(0.1)	0(0.0)
Traumatic haemothorax	外傷性血胸	1(0.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Surgical and medical procedures	外科および内科処置	2(1.6)	1(0.1)	0(0.0)	0(0.0)	0(0.0)
Arteriovenous fistula operation	動静脈瘻手術	2(1.6)	1(0.1)	0(0.0)	0(0.0)	0(0.0)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Note(s): The dose at onset may not be the same as the randomized dose.
Note(s): Percentages are based on the total exposure period.
Source: t_14_3_1_11_1.sas

5.3.5.3—4 Table 14.3.1.11.1 より引用

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
NDD	N1		202	138	81	42
MCD=205500	Average exposure days		137.9	263.6	325.2	361.3
	Subjects with at least one adverse event		148(73.3)	78(56.5)	42(51.9)	18(42.9)
	Infections and infestations	感染症および寄生虫症	58(28.7)	30(21.7)	23(28.4)	7(16.7)
	Nasopharyngitis	上咽頭炎	26(12.9)	17(12.3)	10(12.3)	3(7.1)
	Conjunctivitis	結膜炎	3(1.5)	1(0.7)	4(4.9)	0(0.0)
	Influenza	インフルエンザ	8(4.0)	1(0.7)	1(1.2)	1(2.4)
	Gastroenteritis	胃腸炎	3(1.5)	1(0.7)	0(0.0)	0(0.0)
	Pneumonia	肺炎	1(0.5)	3(2.2)	0(0.0)	0(0.0)
	Upper respiratory tract infection	上気道感染	2(1.0)	1(0.7)	0(0.0)	0(0.0)
	Cystitis	膀胱炎	5(2.5)	1(0.7)	2(2.5)	1(2.4)
	Bronchitis	気管支炎	2(1.0)	1(0.7)	1(1.2)	1(2.4)
	Urinary tract infection	尿路感染	5(2.5)	1(0.7)	2(2.5)	0(0.0)
	Herpes zoster	帯状疱疹	2(1.0)	0(0.0)	0(0.0)	0(0.0)
	Periodontitis	歯周炎	1(0.5)	0(0.0)	1(1.2)	0(0.0)
	Cellulitis	蜂巣炎	3(1.5)	0(0.0)	0(0.0)	0(0.0)
	Pharyngitis	咽頭炎	0(0.0)	1(0.7)	1(1.2)	0(0.0)
	Otitis media	中耳炎	1(0.5)	0(0.0)	1(1.2)	0(0.0)
	Sinusitis	副鼻腔炎	1(0.5)	1(0.7)	0(0.0)	0(0.0)
	Dermatophytosis of nail	爪の皮膚糸状菌症	0(0.0)	1(0.7)	0(0.0)	0(0.0)
	Herpes simplex	単純ヘルペス	2(1.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Rhinitis	鼻炎	0 (0.0)	1 (0.7)	1 (1.2)	0 (0.0)
Renal cyst infection	腎嚢胞感染	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Osteomyelitis	骨髄炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Paronychia	爪囲炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Pyelonephritis	腎盂腎炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Body tinea	体部白癬	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Diverticulitis	憩室炎	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Aspergilloma	アスペルギローマ	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
Mediastinal abscess	縦隔洞膿瘍	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
Otitis externa	外耳炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia chlamydial	クラミジア性肺炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Pyelonephritis acute	急性腎盂腎炎	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Tinea cruris	股部白癬	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Tonsillitis	扁桃炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
Abscess limb	四肢膿瘍	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Lung infection	肺感染	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Colon adenoma	大腸腺腫	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Oral papilloma	口腔乳頭腫	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Blood and lymphatic system disorders	血液およびリンパ系障害	1 (0.5)	1 (0.7)	0 (0.0)	0 (0.0)
Iron deficiency anaemia	鉄欠乏性貧血	1 (0.5)	1 (0.7)	0 (0.0)	0 (0.0)
Immune system disorders	免疫系障害	2 (1.0)	0 (0.0)	1 (1.2)	0 (0.0)
Seasonal allergy	季節性アレルギー	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Endocrine disorders	内分泌障害	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypothyroidism	甲状腺機能低下症	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Parathyroid gland enlargement	副甲状腺肥大	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Metabolism and nutrition disorders	代謝および栄養障害	20(9.9)	6(4.3)	5(6.2)	1(2.4)
Decreased appetite	食欲減退	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	3(1.5)	1(0.7)	1(1.2)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	2(1.0)	0(0.0)	1(1.2)	0(0.0)
Hyperuricaemia	高尿酸血症	3(1.5)	2(1.4)	0(0.0)	0(0.0)
Dehydration	脱水	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Diabetes mellitus	糖尿病	1(0.5)	0(0.0)	1(1.2)	1(2.4)
Metabolic acidosis	代謝性アシドーシス	2(1.0)	1(0.7)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Hypocalcaemia	低カルシウム血症	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Fluid retention	体液貯留	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypoproteinaemia	低蛋白血症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hyperlipidaemia	高脂血症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	2型糖尿病	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	1/4 * MCD <= to < 2/4 * MCD n (%)	2/4 * MCD <= to < 3/4 * MCD n (%)	>= 3/4 * MCD n (%)
Psychiatric disorders	精神障害	6(3.0)	1(0.7)	2(2.5)	0(0.0)
Insomnia	不眠症	3(1.5)	1(0.7)	2(2.5)	0(0.0)
Delirium	譫妄	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Anxiety	不安	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Depression	うつ病	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Nervous system disorders	神経系障害	8(4.0)	5(3.6)	2(2.5)	0(0.0)
Headache	頭痛	4(2.0)	1(0.7)	1(1.2)	0(0.0)
Dizziness	浮動性めまい	1(0.5)	2(1.4)	0(0.0)	0(0.0)
Intracranial aneurysm	頭蓋内動脈瘤	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Somnolence	傾眠	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Loss of consciousness	意識消失	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Presyncope	失神寸前の状態	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Subarachnoid haemorrhage	くも膜下出血	0(0.0)	0(0.0)	1(1.2)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Eye disorders	眼障害	10(5.0)	10(7.2)	2(2.5)	0(0.0)
Retinal haemorrhage	網膜出血	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Conjunctival haemorrhage	結膜出血	2(1.0)	1(0.7)	1(1.2)	0(0.0)
Cataract	白内障	3(1.5)	1(0.7)	1(1.2)	0(0.0)
Dry eye	ドライアイ	1(0.5)	3(2.2)	0(0.0)	0(0.0)
Blepharitis	眼瞼炎	1(0.5)	2(1.4)	0(0.0)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Glaucoma	緑内障	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Macular oedema	黄斑浮腫	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Eczema eyelids	眼瞼湿疹	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Retinal exudates	網膜滲出物	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Ear and labyrinth disorders	耳および迷路障害	1(0.5)	3(2.2)	0(0.0)	0(0.0)
Vertigo	回転性めまい	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Vertigo positional	頭位性回転性めまい	0(0.0)	2(1.4)	0(0.0)	0(0.0)
Ear congestion	耳閉	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Cardiac disorders	心臓障害	8(4.0)	4(2.9)	1(1.2)	0(0.0)
Cardiac failure chronic	慢性心不全	3(1.5)	1(0.7)	0(0.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Palpitations	動悸	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Atrial fibrillation	心房細動	1(0.5)	0(0.0)	1(1.2)	0(0.0)
Cardiac failure	心不全	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Myocardial ischaemia	心筋虚血	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Atrial flutter	心房粗動	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Bradycardia	徐脈	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Ventricular tachycardia	心室性頻脈	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Vascular disorders	血管障害	12(5.9)	1(0.7)	1(1.2)	0(0.0)
Hypertension	高血圧	7(3.5)	0(0.0)	0(0.0)	0(0.0)
Hypotension	低血圧	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Internal haemorrhage	内出血	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Orthostatic hypotension	起立性低血圧	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Aortic aneurysm	大動脈瘤	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Varicose vein	静脈瘤	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Vasculitis	血管炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Vascular rupture	血管破裂	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	7(3.5)	6(4.3)	2(2.5)	1(2.4)
Cough	咳嗽	2(1.0)	2(1.4)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	1(0.5)	0(0.0)	1(1.2)	0(0.0)
Epistaxis	鼻出血	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Pleural effusion	胸水	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Asthma	喘息	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Pulmonary congestion	肺うっ血	0(0.0)	1(0.7)	0(0.0)	1(2.4)
Haemoptysis	喀血	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Interstitial lung disease	間質性肺疾患	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Pulmonary hypertension	肺高血圧症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Rhinorrhoea	鼻漏	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Reflux laryngitis	逆流性喉頭炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastrointestinal disorders	胃腸障害	58(28.7)	16(11.6)	9(11.1)	2(4.8)
Diarrhoea	下痢	17(8.4)	2(1.4)	3(3.7)	0(0.0)
Vomiting	嘔吐	7(3.5)	3(2.2)	2(2.5)	1(2.4)
Constipation	便秘	10(5.0)	5(3.6)	1(1.2)	1(2.4)
Nausea	悪心	8(4.0)	1(0.7)	0(0.0)	0(0.0)
Dental caries	齲歯	3(1.5)	3(2.2)	0(0.0)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	4(2.0)	0(0.0)	1(1.2)	0(0.0)
Abdominal pain	腹痛	2(1.0)	1(0.7)	1(1.2)	0(0.0)
Abdominal discomfort	腹部不快感	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Stomatitis	口内炎	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Enterocolitis	腸炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Gastritis	胃炎	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Haemorrhoids	痔核	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Abdominal distension	腹部膨満	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Chronic gastritis	慢性胃炎	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Faeces soft	軟便	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Periodontal disease	歯周病	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Angular cheilitis	口角口唇炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Gingival bleeding	歯肉出血	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal disorder	胃腸障害	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Oesophageal achalasia	食道アカラシア	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Tooth loss	歯の脱落	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	5(2.5)	4(2.9)	1(1.2)	0(0.0)
Cholelithiasis	胆石症	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Hepatic function abnormal	肝機能異常	2(1.0)	1(0.7)	1(1.2)	0(0.0)
Cholecystitis	胆嚢炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Bile duct stone	胆管結石	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hepatic cirrhosis	肝硬変	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Drug-induced liver injury	薬物性肝障害	0(0.0)	1(0.7)	0(0.0)	0(0.0)

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Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	19(9.4)	12(8.7)	3(3.7)	7(16.7)
Pruritus	そう痒症	2(1.0)	3(2.2)	1(1.2)	1(2.4)
Eczema	湿疹	3(1.5)	1(0.7)	1(1.2)	1(2.4)
Haemorrhage subcutaneous	皮下出血	2(1.0)	0(0.0)	0(0.0)	1(2.4)
Dermatitis contact	接触皮膚炎	2(1.0)	0(0.0)	1(1.2)	1(2.4)
Rash	発疹	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	2(1.0)	2(1.4)	0(0.0)	0(0.0)
Drug eruption	薬疹	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Xeroderma	乾皮症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Dry skin	皮膚乾燥	0(0.0)	3(2.2)	0(0.0)	0(0.0)
Skin ulcer	皮膚潰瘍	1(0.5)	2(1.4)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	0(0.0)	0(0.0)	0(0.0)	1(2.4)
Skin erosion	皮膚びらん	1(0.5)	0(0.0)	0(0.0)	1(2.4)
Urticaria	蕁麻疹	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Decubitus ulcer	褥瘡性潰瘍	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Dermatomyositis	皮膚筋炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Prurigo	痒疹	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Pruritus generalised	全身性そう痒症	0(0.0)	0(0.0)	0(0.0)	1(2.4)
Reactive perforating collagenosis	反応性穿孔性膠原線維症	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	16(7.9)	15(10.9)	5(6.2)	2(4.8)
Back pain	背部痛	5(2.5)	4(2.9)	0(0.0)	0(0.0)
Pain in extremity	四肢痛	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Muscle spasms	筋痙縮	2(1.0)	2(1.4)	1(1.2)	0(0.0)
Arthralgia	関節痛	2(1.0)	0(0.0)	1(1.2)	0(0.0)
Myalgia	筋肉痛	1(0.5)	1(0.7)	1(1.2)	0(0.0)
Musculoskeletal pain	筋骨格痛	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Osteoarthritis	変形性関節症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	2(1.0)	1(0.7)	0(0.0)	0(0.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	0(0.0)	1(1.2)	1(2.4)
Arthritis	関節炎	1(0.5)	2(1.4)	0(0.0)	1(2.4)
Osteoporosis	骨粗鬆症	0(0.0)	3(2.2)	0(0.0)	0(0.0)
Neck pain	頚部痛	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Tenosynovitis	腱鞘炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Trigger finger	弾発指	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Bursitis	滑液包炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Rotator cuff syndrome	肩回旋筋腱板症候群	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Intervertebral disc protrusion	椎間板突出	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Temporomandibular joint syndrome	顎関節症候群	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Spondylolisthesis	脊椎すべり症	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Renal and urinary disorders	腎および尿路障害	20(9.9)	10(7.2)	4(4.9)	1(2.4)
Renal impairment	腎機能障害	6(3.0)	2(1.4)	2(2.5)	1(2.4)
Chronic kidney disease	慢性腎臓病	4(2.0)	4(2.9)	2(2.5)	0(0.0)
End stage renal disease	末期腎疾患	2(1.0)	2(1.4)	0(0.0)	0(0.0)
Haematuria	血尿	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	1(0.7)	1(1.2)	0(0.0)
Renal failure	腎不全	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Pollakiuria	頻尿	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Oliguria	乏尿	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Urinary retention	尿閉	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Acute kidney injury	急性腎障害	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	2(1.0)	3(2.2)	1(1.2)	0(0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	1(0.5)	2(1.4)	1(1.2)	0(0.0)
Menstruation irregular	不規則月経	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Nipple pain	乳頭痛	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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General disorders and administration site conditions	一般・全身障害および投与部位の状態	17(8.4)	12(8.7)	3(3.7)	3(7.1)
Pyrexia	発熱	2(1.0)	6(4.3)	2(2.5)	2(4.8)
Oedema peripheral	末梢性浮腫	6(3.0)	6(4.3)	1(1.2)	1(2.4)
Malaise	倦怠感	5(2.5)	0(0.0)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	4(2.0)	0(0.0)	0(0.0)	0(0.0)
Chest pain	胸痛	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Chills	悪寒	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Face oedema	顔面浮腫	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Oedema	浮腫	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Thirst	口渇	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Vessel puncture site haemorrhage	血管穿刺部位出血	0(0.0)	1(0.7)	0(0.0)	0(0.0)

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Investigations	臨床検査	11(5.4)	2(1.4)	2(2.5)	0(0.0)
Blood pressure increased	血圧上昇	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	1(0.5)	1(0.7)	1(1.2)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	1(0.5)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	1(0.5)	0(0.0)	1(1.2)	0(0.0)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)

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Injury, poisoning and procedural complications	傷害、中毒および処置合併症	21(10.4)	13(9.4)	7(8.6)	1(2.4)
Contusion	挫傷	11(5.4)	1(0.7)	2(2.5)	1(2.4)
Shunt stenosis	シャント狭窄	0(0.0)	2(1.4)	0(0.0)	0(0.0)
Skin abrasion	皮膚擦過傷	2(1.0)	2(1.4)	0(0.0)	1(2.4)
Wound	創傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Thermal burn	熱傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Spinal compression fracture	脊椎圧迫骨折	3(1.5)	2(1.4)	1(1.2)	0(0.0)
Limb injury	四肢損傷	0(0.0)	1(0.7)	1(1.2)	0(0.0)
Rib fracture	肋骨骨折	1(0.5)	1(0.7)	0(0.0)	0(0.0)
Skin laceration	皮膚裂傷	1(0.5)	0(0.0)	1(1.2)	0(0.0)
Tooth fracture	歯牙破折	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Clavicle fracture	鎖骨骨折	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Femoral neck fracture	大腿骨頚部骨折	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Eye contusion	眼挫傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Animal scratch	動物による引っかき傷	0(0.0)	0(0.0)	1(1.2)	0(0.0)
Fall	転倒	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hand fracture	手骨折	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Head injury	頭部損傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Injury	損傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Seroma	漿液腫	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Sternal fracture	胸骨骨折	1(0.5)	0(0.0)	0(0.0)	0(0.0)

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Tendon rupture	腱断裂	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Lumbar vertebral fracture	腰椎骨折	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Procedural pain	処置による疼痛	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Nail injury	爪損傷	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Surgical and medical procedures	外科および内科処置	3 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
Arteriovenous fistula operation	動静脈瘻手術	3 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
HD	N1		237	155	76	47
MCD=206850	Average exposure days		137.9	259.9	321.2	361.4
	Subjects with at least one adverse event		203(85.7)	114(73.5)	54(71.1)	29(61.7)
	Infections and infestations	感染症および寄生虫症	95(40.1)	52(33.5)	31(40.8)	9(19.1)
	Nasopharyngitis	上咽頭炎	56(23.6)	36(23.2)	17(22.4)	7(14.9)
	Conjunctivitis	結膜炎	9(3.8)	3(1.9)	0(0.0)	1(2.1)
	Influenza	インフルエンザ	3(1.3)	0(0.0)	5(6.6)	1(2.1)
	Gastroenteritis	胃腸炎	6(2.5)	5(3.2)	2(2.6)	0(0.0)
	Pneumonia	肺炎	5(2.1)	3(1.9)	3(3.9)	1(2.1)
	Upper respiratory tract infection	上気道感染	5(2.1)	2(1.3)	2(2.6)	0(0.0)
	Cystitis	膀胱炎	3(1.3)	0(0.0)	0(0.0)	0(0.0)
	Bronchitis	気管支炎	2(0.8)	3(1.9)	1(1.3)	0(0.0)
	Herpes zoster	帯状疱疹	4(1.7)	1(0.6)	0(0.0)	0(0.0)
	Periodontitis	歯周炎	4(1.7)	0(0.0)	0(0.0)	0(0.0)
	Cellulitis	蜂巣炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
	Pharyngitis	咽頭炎	2(0.8)	0(0.0)	1(1.3)	0(0.0)
	Hordeolum	麦粒腫	1(0.4)	2(1.3)	2(2.6)	0(0.0)
	Otitis media	中耳炎	2(0.8)	0(0.0)	0(0.0)	0(0.0)
	Sinusitis	副鼻腔炎	0(0.0)	1(0.6)	0(0.0)	0(0.0)
	Dermatophytosis of nail	爪の皮膚糸状菌症	0(0.0)	1(0.6)	1(1.3)	0(0.0)
	Shunt infection	シャント感染	1(0.4)	2(1.3)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Enteritis infectious	感染性腸炎	2 (0.8)	1 (0.6)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Osteomyelitis	骨髄炎	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Paronychia	爪囲炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Pyelonephritis	腎盂腎炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis media chronic	慢性中耳炎	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Skin infection	皮膚感染	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Infected dermal cyst	感染性皮膚嚢腫	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Chronic sinusitis	慢性副鼻腔炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Epididymitis	精巣上体炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Furuncle	せつ	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis viral	ウイルス性胃腸炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Hydrocele male infected	感染性陰嚢水瘤	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Tracheobronchitis	気管気管支炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic cyst infection	肝嚢胞感染	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial infection	細菌感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Oral herpes	口腔ヘルペス	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular device infection	血管デバイス感染	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性，悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3(1.3)	2(1.3)	3(3.9)	1(2.1)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	1(0.6)	1(1.3)	0(0.0)
Breast cancer	乳癌	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cholesteatoma	真珠腫	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Gastric cancer	胃癌	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Skin papilloma	皮膚乳頭腫	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Uterine leiomyoma	子宮平滑筋腫	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	6(2.5)	4(2.6)	0(0.0)	0(0.0)
Anaemia	貧血	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Anaemia macrocytic	大球性貧血	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Nephrogenic anaemia	腎性貧血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Eosinophilia	好酸球増加症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Lymphadenitis	リンパ節炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Polycythaemia	赤血球増加症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Blood loss anaemia	失血性貧血	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Immune system disorders	免疫系障害	1(0.4)	0(0.0)	2(2.6)	1(2.1)
Seasonal allergy	季節性アレルギー	1(0.4)	0(0.0)	2(2.6)	1(2.1)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Endocrine disorders	内分泌障害	2(0.8)	1(0.6)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Metabolism and nutrition disorders	代謝および栄養障害	14(5.9)	4(2.6)	1(1.3)	2(4.3)
Decreased appetite	食欲減退	8(3.4)	2(1.3)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	1(0.4)	1(0.6)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	1(0.4)	1(0.6)	1(1.3)	1(2.1)
Hypoglycaemia	低血糖	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypocalcaemia	低カルシウム血症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypercalcaemia	高カルシウム血症	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Psychiatric disorders	精神障害	9(3.8)	2(1.3)	0(0.0)	0(0.0)
Insomnia	不眠症	7(3.0)	1(0.6)	0(0.0)	0(0.0)
Anxiety	不安	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Depression	うつ病	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Abnormal behaviour	異常行動	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Nervous system disorders	神経系障害	30(12.7)	14(9.0)	3(3.9)	4(8.5)
Headache	頭痛	13(5.5)	6(3.9)	1(1.3)	2(4.3)
Dizziness	浮動性めまい	5(2.1)	2(1.3)	0(0.0)	1(2.1)
Intracranial aneurysm	頭蓋内動脈瘤	0(0.0)	1(0.6)	1(1.3)	0(0.0)
Hypoaesthesia	感覚鈍麻	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Somnolence	傾眠	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Carpal tunnel syndrome	手根管症候群	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	1(0.4)	1(0.6)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	1(0.4)	0(0.0)	0(0.0)	1(2.1)
Cerebral infarction	脳梗塞	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Carotid artery stenosis	頚動脈狭窄	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Cerebral haemorrhage	脳出血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Dizziness postural	体位性めまい	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Myelopathy	脊髄症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Myoclonus	ミオクローヌス	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Neuralgia	神経痛	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Sciatica	坐骨神経痛	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Tremor	振戦	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Intercostal neuralgia	肋間神経痛	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cervical radiculopathy	頚髄神経根障害	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Lacunar infarction	ラクナ梗塞	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Thrombotic cerebral infarction	血栓性脳梗塞	0(0.0)	1(0.6)	0(0.0)	0(0.0)

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Eye disorders	眼障害	12(5.1)	18(11.6)	5(6.6)	5(10.6)
Retinal haemorrhage	網膜出血	2(0.8)	9(5.8)	2(2.6)	3(6.4)
Conjunctival haemorrhage	結膜出血	2(0.8)	1(0.6)	0(0.0)	1(2.1)
Cataract	白内障	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Dry eye	ドライアイ	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Blepharitis	眼瞼炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Diabetic retinopathy	糖尿病網膜症	2(0.8)	1(0.6)	0(0.0)	0(0.0)
Glaucoma	緑内障	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Macular oedema	黄斑浮腫	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Diplopia	複視	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Keratitis	角膜炎	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Ocular hyperaemia	眼充血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Trichiasis	睫毛乱生	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	1(0.4)	0(0.0)	0(0.0)	0(0.0)

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Chorioretinopathy	網脈絡膜症	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Eyelid haematoma	眼瞼血腫	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	6 (2.5)	1 (0.6)	2 (2.6)	1 (2.1)
Vertigo	回転性めまい	3 (1.3)	0 (0.0)	2 (2.6)	1 (2.1)
Vertigo positional	頭位性回転性めまい	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Deafness	難聴	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Sudden hearing loss	突発性難聴	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Eustachian tube stenosis	耳管狭窄	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

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Cardiac disorders	心臓障害	9(3.8)	8(5.2)	3(3.9)	0(0.0)
Cardiac failure chronic	慢性心不全	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	1(0.4)	2(1.3)	0(0.0)	0(0.0)
Palpitations	動悸	1(0.4)	1(0.6)	1(1.3)	0(0.0)
Atrial fibrillation	心房細動	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cardiac failure	心不全	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Myocardial ischaemia	心筋虚血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Cardiac dysfunction	心機能障害	0(0.0)	1(0.6)	1(1.3)	0(0.0)
Angina pectoris	狭心症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Angina unstable	不安定狭心症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Aortic valve incompetence	大動脈弁閉鎖不全症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Arrhythmia	不整脈	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Arteriosclerosis coronary artery	冠動脈硬化症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Coronary artery stenosis	冠動脈狭窄	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Mitral valve incompetence	僧帽弁閉鎖不全症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Mitral valve stenosis	僧帽弁狭窄症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Pericarditis	心膜炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Paroxysmal arrhythmia	発作性不整脈	0(0.0)	0(0.0)	1(1.3)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Vascular disorders	血管障害	17(7.2)	6(3.9)	2(2.6)	1(2.1)
Hypertension	高血圧	4(1.7)	2(1.3)	0(0.0)	0(0.0)
Hypotension	低血圧	2(0.8)	2(1.3)	1(1.3)	0(0.0)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	3(1.3)	0(0.0)	1(1.3)	0(0.0)
Internal haemorrhage	内出血	3(1.3)	0(0.0)	0(0.0)	1(2.1)
Orthostatic hypotension	起立性低血圧	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Vascular pain	血管痛	1(0.4)	1(0.6)	0(0.0)	0(0.0)
Haemorrhage	出血	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Aneurysm	動脈瘤	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Vascular insufficiency	血行不全	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	17(7.2)	3(1.9)	6(7.9)	3(6.4)
Cough	咳嗽	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	4(1.7)	0(0.0)	2(2.6)	0(0.0)
Epistaxis	鼻出血	2(0.8)	1(0.6)	1(1.3)	1(2.1)
Upper respiratory tract inflammation	上気道の炎症	3(1.3)	0(0.0)	1(1.3)	1(2.1)
Pleural effusion	胸水	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Asthma	喘息	1(0.4)	0(0.0)	1(1.3)	0(0.0)
Haemoptysis	喀血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Pulmonary oedema	肺水腫	1(0.4)	0(0.0)	1(1.3)	0(0.0)
Sleep apnoea syndrome	睡眠時無呼吸症候群	1(0.4)	1(0.6)	0(0.0)	0(0.0)
Oropharyngeal pain	口腔咽頭痛	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Hiccups	しゃっくり	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Pneumonia aspiration	誤嚥性肺炎	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Sputum increased	喀痰増加	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	1/4 * MCD <= to < 2/4 * MCD n (%)	2/4 * MCD <= to < 3/4 * MCD n (%)	>= 3/4 * MCD n (%)
Gastrointestinal disorders	胃腸障害	71(30.0)	24(15.5)	9(11.8)	3(6.4)
Diarrhoea	下痢	27(11.4)	10(6.5)	4(5.3)	2(4.3)
Vomiting	嘔吐	11(4.6)	1(0.6)	1(1.3)	0(0.0)
Constipation	便秘	6(2.5)	3(1.9)	0(0.0)	0(0.0)
Nausea	悪心	7(3.0)	4(2.6)	3(3.9)	0(0.0)
Dental caries	齲歯	2(0.8)	2(1.3)	1(1.3)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	3(1.3)	3(1.9)	0(0.0)	0(0.0)
Abdominal pain	腹痛	3(1.3)	1(0.6)	0(0.0)	0(0.0)
Abdominal discomfort	腹部不快感	3(1.3)	0(0.0)	1(1.3)	0(0.0)
Stomatitis	口内炎	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Enterocolitis	腸炎	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Gastritis	胃炎	1(0.4)	2(1.3)	0(0.0)	0(0.0)
Haemorrhoids	痔核	0(0.0)	3(1.9)	1(1.3)	0(0.0)
Abdominal distension	腹部膨満	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Chronic gastritis	慢性胃炎	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	1(0.4)	2(1.3)	0(0.0)	0(0.0)
Faeces soft	軟便	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer	胃潰瘍	1(0.4)	2(1.3)	0(0.0)	0(0.0)
Toothache	歯痛	1(0.4)	1(0.6)	0(0.0)	1(2.1)
Gastric polyps	胃ポリープ	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Angular cheilitis	口角口唇炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Diverticulum intestinal	腸憩室	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Mouth haemorrhage	口腔内出血	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Duodenal ulcer	十二指腸潰瘍	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
Dyspepsia	消化不良	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain lower	下腹部痛	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Barrett's oesophagus	バレット食道	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Dry mouth	口内乾燥	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Duodenal polyp	十二指腸ポリープ	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Food poisoning	食中毒	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Gastritis erosive	びらん性胃炎	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Gastritis haemorrhagic	出血性胃炎	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Glossitis	舌炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Melaena	メレナ	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Pancreatitis	膵炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Rectal ulcer	直腸潰瘍	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Gastric disorder	胃障害	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal motility disorder	消化管運動障害	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Loose tooth	弛緩歯	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Hepatobiliary disorders	肝胆道系障害	5(2.1)	1(0.6)	0(0.0)	0(0.0)
Cholelithiasis	胆石症	3(1.3)	1(0.6)	0(0.0)	0(0.0)
Hepatic function abnormal	肝機能異常	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cholangitis	胆管炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	45(19.0)	19(12.3)	9(11.8)	3(6.4)
Pruritus	そう痒症	8(3.4)	4(2.6)	2(2.6)	0(0.0)
Eczema	湿疹	9(3.8)	1(0.6)	0(0.0)	1(2.1)
Haemorrhage subcutaneous	皮下出血	5(2.1)	3(1.9)	1(1.3)	1(2.1)
Dermatitis contact	接触皮膚炎	4(1.7)	2(1.3)	0(0.0)	0(0.0)
Rash	発疹	3(1.3)	1(0.6)	1(1.3)	1(2.1)
Eczema asteatotic	皮脂欠乏性湿疹	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Drug eruption	薬疹	4(1.7)	0(0.0)	0(0.0)	0(0.0)
Ingrowing nail	爪甲内向症	3(1.3)	2(1.3)	0(0.0)	0(0.0)
Skin exfoliation	皮膚剥脱	3(1.3)	1(0.6)	1(1.3)	0(0.0)
Xeroderma	乾皮症	1(0.4)	1(0.6)	1(1.3)	0(0.0)
Dermatitis	皮膚炎	0(0.0)	2(1.3)	1(1.3)	0(0.0)
Dermal cyst	皮膚嚢腫	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Hyperkeratosis	過角化	1(0.4)	1(0.6)	1(1.3)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blister	水疱	1(0.4)	0(0.0)	1(1.3)	0(0.0)
Cold sweat	冷汗	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Acne	ざ瘡	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Alopecia	脱毛症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Erythema	紅斑	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Neurodermatitis	神経皮膚炎	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Rash pruritic	そう痒性皮疹	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Skin disorder	皮膚障害	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Skin mass	皮膚腫瘤	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	45(19.0)	32(20.6)	11(14.5)	2(4.3)
Back pain	背部痛	10(4.2)	8(5.2)	1(1.3)	0(0.0)
Pain in extremity	四肢痛	10(4.2)	2(1.3)	2(2.6)	0(0.0)
Muscle spasms	筋痙縮	7(3.0)	3(1.9)	1(1.3)	0(0.0)
Arthralgia	関節痛	6(2.5)	5(3.2)	0(0.0)	1(2.1)
Myalgia	筋肉痛	6(2.5)	3(1.9)	2(2.6)	0(0.0)
Musculoskeletal pain	筋骨格痛	6(2.5)	3(1.9)	0(0.0)	0(0.0)
Osteoarthritis	変形性関節症	3(1.3)	2(1.3)	2(2.6)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	2(0.8)	2(1.3)	0(0.0)	0(0.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	2(0.8)	2(1.3)	1(1.3)	0(0.0)
Periarthritis	関節周囲炎	2(0.8)	3(1.9)	2(2.6)	0(0.0)
Osteoporosis	骨粗鬆症	1(0.4)	1(0.6)	0(0.0)	0(0.0)
Neck pain	頚部痛	2(0.8)	1(0.6)	0(0.0)	1(2.1)
Tenosynovitis	腱鞘炎	2(0.8)	0(0.0)	1(1.3)	0(0.0)
Trigger finger	弾発指	0(0.0)	1(0.6)	1(1.3)	0(0.0)
Bursitis	滑液包炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Rotator cuff syndrome	肩回旋筋腱板症候群	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Intervertebral disc protrusion	椎間板突出	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Haemarthrosis	出血性関節症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Joint swelling	関節腫脹	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Musculoskeletal chest pain	筋骨格系胸痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal discomfort	筋骨格不快感	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	2 (0.8)	2 (1.3)	2 (2.6)	0 (0.0)
Chronic kidney disease	慢性腎臓病	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Haematuria	血尿	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pollakiuria	頻尿	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Renal cyst	腎嚢胞	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)
Ureterolithiasis	尿管結石症	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Reproductive system and breast disorders	生殖系および乳房障害	4 (1.7)	2 (1.3)	0 (0.0)	0 (0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Acquired hydrocele	後天性陰嚢水瘤	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Prostatitis	前立腺炎	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Erectile dysfunction	勃起不全	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	14(5.9)	4(2.6)	3(3.9)	0(0.0)
Pyrexia	発熱	4(1.7)	3(1.9)	1(1.3)	0(0.0)
Oedema peripheral	末梢性浮腫	5(2.1)	0(0.0)	0(0.0)	0(0.0)
Chest discomfort	胸部不快感	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Vessel puncture site bruise	血管穿刺部位内出血	1(0.4)	0(0.0)	1(1.3)	0(0.0)
Fatigue	疲労	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Feeling abnormal	異常感	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Injection site reaction	注射部位反応	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Puncture site pain	穿刺部位疼痛	0(0.0)	0(0.0)	1(1.3)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Investigations	臨床検査	14(5.9)	6(3.9)	1(1.3)	0(0.0)
Blood pressure increased	血圧上昇	2(0.8)	3(1.9)	0(0.0)	0(0.0)
Blood pressure decreased	血圧低下	3(1.3)	3(1.9)	0(0.0)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	2(0.8)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood urea increased	血中尿素増加	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Blood uric acid decreased	血中尿酸減少	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood urine present	尿中血陽性	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	64(27.0)	41(26.5)	18(23.7)	8(17.0)
Contusion	挫傷	13(5.5)	14(9.0)	2(2.6)	1(2.1)
Shunt stenosis	シャント狭窄	24(10.1)	9(5.8)	2(2.6)	2(4.3)
Skin abrasion	皮膚擦過傷	8(3.4)	3(1.9)	2(2.6)	1(2.1)
Wound	創傷	5(2.1)	2(1.3)	4(5.3)	0(0.0)
Thermal burn	熱傷	2(0.8)	4(2.6)	1(1.3)	1(2.1)
Procedural hypotension	処置による低血圧	2(0.8)	1(0.6)	4(5.3)	2(4.3)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Limb injury	四肢損傷	2(0.8)	1(0.6)	1(1.3)	0(0.0)
Shunt occlusion	シャント閉塞	3(1.3)	2(1.3)	0(0.0)	0(0.0)
Rib fracture	肋骨骨折	1(0.4)	0(0.0)	1(1.3)	0(0.0)
Skin laceration	皮膚裂傷	0(0.0)	1(0.6)	1(1.3)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Arteriovenous fistula site complication	動静脈瘻部位合併症	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Joint injury	関節損傷	2(0.8)	1(0.6)	0(0.0)	0(0.0)
Clavicle fracture	鎖骨骨折	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Femoral neck fracture	大腿骨頚部骨折	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Eye contusion	眼挫傷	0(0.0)	0(0.0)	1(1.3)	0(0.0)
Animal bite	動物咬傷	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Foot fracture	足骨折	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Ligament sprain	靱帯捻挫	2(0.8)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Subcutaneous haematoma	皮下血腫	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
Procedural hypertension	処置による高血圧	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Shunt blood flow excessive	シャント血流過剰	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Vascular access malfunction	血管アクセス機能不全	1 (0.4)	1 (0.6)	0 (0.0)	0 (0.0)
Dental restoration failure	歯科修復不成功	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Chillblains	凍瘡	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Foreign body in eye	眼内異物	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Muscle injury	筋損傷	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Scratch	引っかき傷	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Scrotal haematoma	陰嚢血腫	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Subdural haematoma	硬膜下血腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Tibia fracture	脛骨骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Tooth injury	歯牙損傷	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Wound complication	創合併症	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Arteriovenous fistula site haemorrhage	動静脈瘻部位出血	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Arteriovenous fistula occlusion	動静脈瘻閉塞	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Shunt thrombosis	シャント血栓症	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pelvic fracture	骨盤骨折	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular access complication	血管確保合併症	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Post procedural inflammation	処置後炎症	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Heat illness	熱中症	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Pubis fracture	恥骨骨折	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Skin wound	皮膚創傷	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular access site inflammation	血管確保部位炎症	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Soft tissue foreign body	軟部組織内異物	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
PD	Ni		42	36	27	16
MCD=90300	Average exposure days		76.7	120.8	151.6	169.2
	Subjects with at least one adverse event		33(78.6)	20(55.6)	18(66.7)	7(43.8)
	Infections and infestations	感染症および寄生虫症	13(31.0)	10(27.8)	5(18.5)	1(6.3)
	Nasopharyngitis	上咽頭炎	5(11.9)	2(5.6)	0(0.0)	0(0.0)
	Conjunctivitis	結膜炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Pneumonia	肺炎	0(0.0)	0(0.0)	1(3.7)	0(0.0)
	Upper respiratory tract infection	上気道感染	2(4.8)	0(0.0)	0(0.0)	0(0.0)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	1(3.7)	0(0.0)
	Catheter site infection	カテーテル留置部位感染	3(7.1)	5(13.9)	3(11.1)	0(0.0)
	Cellulitis	蜂巣炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Peritonitis	腹膜炎	1(2.4)	3(8.3)	0(0.0)	1(6.3)
	Body tinea	体部白癬	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Diverticulitis	憩室炎	0(0.0)	1(2.8)	0(0.0)	0(0.0)
	Folliculitis	毛包炎	0(0.0)	1(2.8)	0(0.0)	0(0.0)
	Sepsis	敗血症	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Helicobacter infection	ヘリコバクター感染	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Blood and lymphatic system disorders	血液およびリンパ系障害	2(4.8)	0(0.0)	0(0.0)	0(0.0)
	Anaemia	貧血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Nephrogenic anaemia	腎性貧血	1(2.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Metabolism and nutrition disorders	代謝および栄養障害	2(4.8)	1(2.8)	3(11.1)	0(0.0)
Decreased appetite	食欲減退	2(4.8)	0(0.0)	1(3.7)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Dehydration	脱水	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Psychiatric disorders	精神障害	2(4.8)	0(0.0)	2(7.4)	0(0.0)
Insomnia	不眠症	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Sleep disorder	睡眠障害	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Nervous system disorders	神経系障害	3(7.1)	0(0.0)	1(3.7)	1(6.3)
Dizziness	浮動性めまい	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Cerebral infarction	脳梗塞	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dizziness exertional	労作性めまい	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	1(2.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Eye disorders	眼障害	1(2.4)	0(0.0)	3(11.1)	2(12.5)
Retinal haemorrhage	網膜出血	0(0.0)	0(0.0)	1(3.7)	1(6.3)
Dry eye	ドライアイ	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Meibomian gland dysfunction	マイボーム腺機能不全	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Cardiac disorders	心臓障害	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Cardiac failure chronic	慢性心不全	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Myocardial ischaemia	心筋虚血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Vascular disorders	血管障害	3(7.1)	1(2.8)	1(3.7)	1(6.3)
Hypotension	低血圧	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Orthostatic hypotension	起立性低血圧	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	1(2.8)	1(3.7)	0(0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	2(4.8)	0(0.0)	1(3.7)	0(0.0)
Cough	咳嗽	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	1(3.7)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Gastrointestinal disorders	胃腸障害	11(26.2)	8(22.2)	4(14.8)	2(12.5)
Diarrhoea	下痢	3(7.1)	3(8.3)	3(11.1)	0(0.0)
Vomiting	嘔吐	2(4.8)	2(5.6)	0(0.0)	0(0.0)
Constipation	便秘	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Nausea	悪心	2(4.8)	0(0.0)	1(3.7)	1(6.3)
Dental caries	齲歯	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Abdominal discomfort	腹部不快感	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	3(8.3)	0(0.0)	0(0.0)
Enterocolitis	腸炎	1(2.4)	1(2.8)	0(0.0)	0(0.0)
Gastric polyps	胃ポリープ	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Gingival bleeding	歯肉出血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Hiatus hernia	裂孔ヘルニア	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Traumatic occlusion	外傷性咬合	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4(9.5)	0(0.0)	1(3.7)	0(0.0)
Dermatitis contact	接触皮膚炎	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Rash	発疹	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dermatitis	皮膚炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(2.4)	1(2.8)	0(0.0)	2(12.5)
Back pain	背部痛	0(0.0)	1(2.8)	0(0.0)	1(6.3)
Arthralgia	関節痛	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Arthritis	関節炎	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Renal and urinary disorders	腎および尿路障害	1(2.4)	2(5.6)	0(0.0)	0(0.0)
Renal impairment	腎機能障害	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Haematuria	血尿	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	0(0.0)	1(3.7)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	3(7.1)	2(5.6)	2(7.4)	0(0.0)
Pyrexia	発熱	1(2.4)	1(2.8)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Chest pain	胸痛	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	1(2.4)	1(2.8)	0(0.0)	0(0.0)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Investigations	臨床検査	1(2.4)	2(5.6)	1(3.7)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Weight decreased	体重減少	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	1(3.7)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0 (0.0)	2 (5.6)	4 (14.8)	0 (0.0)
Contusion	挫傷	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)
Shunt occlusion	シャント閉塞	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)
Tooth fracture	歯牙破折	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)
Heat stroke	熱射病	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)
Peritoneal dialysis complication	腹膜透析合併症	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)
Traumatic haemothorax	外傷性血胸	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Total	Ni		481	318	156	89
MCD=206850	Average exposure days		137.1	254.7	323.5	361.3
	Subjects with at least one adverse event		386(80.2)	211(66.4)	95(60.9)	47(52.8)
	Infections and infestations	感染症および寄生虫症	171(35.6)	88(27.7)	54(34.6)	16(18.0)
	Nasopharyngitis	上咽頭炎	88(18.3)	53(16.7)	27(17.3)	10(11.2)
	Conjunctivitis	結膜炎	13(2.7)	4(1.3)	4(2.6)	1(1.1)
	Influenza	インフルエンザ	11(2.3)	1(0.3)	6(3.8)	2(2.2)
	Gastroenteritis	胃腸炎	9(1.9)	6(1.9)	2(1.3)	0(0.0)
	Pneumonia	肺炎	6(1.2)	7(2.2)	3(1.9)	1(1.1)
	Upper respiratory tract infection	上気道感染	9(1.9)	3(0.9)	2(1.3)	0(0.0)
	Cystitis	膀胱炎	8(1.7)	1(0.3)	2(1.3)	1(1.1)
	Bronchitis	気管支炎	4(0.8)	5(1.6)	2(1.3)	1(1.1)
	Catheter site infection	カテーテル留置部位感染	8(1.7)	3(0.9)	0(0.0)	0(0.0)
	Urinary tract infection	尿路感染	5(1.0)	1(0.3)	2(1.3)	0(0.0)
	Herpes zoster	帯状疱疹	6(1.2)	1(0.3)	0(0.0)	0(0.0)
	Periodontitis	歯周炎	5(1.0)	0(0.0)	1(0.6)	0(0.0)
	Cellulitis	蜂巣炎	5(1.0)	0(0.0)	0(0.0)	0(0.0)
	Pharyngitis	咽頭炎	2(0.4)	1(0.3)	2(1.3)	0(0.0)
	Hordeolum	麦粒腫	1(0.2)	2(0.6)	2(1.3)	0(0.0)
	Peritonitis	腹膜炎	4(0.8)	1(0.3)	0(0.0)	0(0.0)
	Otitis media	中耳炎	3(0.6)	0(0.0)	1(0.6)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Sinusitis	副鼻腔炎	1 (0.2)	2 (0.6)	0 (0.0)	0 (0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	0 (0.0)	2 (0.6)	1 (0.6)	0 (0.0)
Shunt infection	シャント感染	1 (0.2)	2 (0.6)	0 (0.0)	0 (0.0)
Enteritis infectious	感染性腸炎	2 (0.4)	1 (0.3)	0 (0.0)	0 (0.0)
Herpes simplex	単純ヘルペス	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	1 (0.3)	1 (0.6)	0 (0.0)
Renal cyst infection	腎嚢胞感染	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Osteomyelitis	骨髄炎	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Paronychia	爪囲炎	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Pyelonephritis	腎盂腎炎	1 (0.2)	0 (0.0)	1 (0.6)	0 (0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Body tinea	体部白癬	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Diverticulitis	憩室炎	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Otitis media chronic	慢性中耳炎	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Skin infection	皮膚感染	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Infected dermal cyst	感染性皮膚嚢腫	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Aspergilloma	アスペルギローマ	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)
Mediastinal abscess	縦隔洞膿瘍	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Otitis externa	外耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Pneumonia chlamydial	クラミジア性肺炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pyelonephritis acute	急性腎盂腎炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Tinea cruris	股部白癬	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Tonsillitis	扁桃炎	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Abscess limb	四肢膿瘍	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Lung infection	肺感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Chronic sinusitis	慢性副鼻腔炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Epididymitis	精巣上体炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Furuncle	せつ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis viral	ウイルス性胃腸炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hydrocele male infected	感染性陰嚢水瘤	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Tracheobronchitis	気管気管支炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic cyst infection	肝嚢胞感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial infection	細菌感染	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Oral herpes	口腔ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular device infection	血管デバイス感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Folliculitis	毛包炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Sepsis	敗血症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Helicobacter infection	ヘリコバクター感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5(1.0)	2(0.6)	3(1.9)	1(1.1)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	1(0.3)	1(0.6)	0(0.0)
Colon adenoma	大腸腺腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Oral papilloma	口腔乳頭腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Breast cancer	乳癌	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cholesteatoma	真珠腫	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Gastric cancer	胃癌	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Skin papilloma	皮膚乳頭腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0(0.0)	0(0.0)	0(0.0)	1(1.1)
Uterine leiomyoma	子宮平滑筋腫	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	9(1.9)	5(1.6)	0(0.0)	0(0.0)
Anaemia	貧血	1(0.2)	2(0.6)	0(0.0)	0(0.0)
Iron deficiency anaemia	鉄欠乏性貧血	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Anaemia macrocytic	大球性貧血	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Nephrogenic anaemia	腎性貧血	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Eosinophilia	好酸球増加症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Lymphadenitis	リンパ節炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Polycythaemia	赤血球増加症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Blood loss anaemia	失血性貧血	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Immune system disorders	免疫系障害	3(0.6)	0(0.0)	3(1.9)	1(1.1)
Seasonal allergy	季節性アレルギー	1(0.2)	0(0.0)	3(1.9)	1(1.1)
Allergy to arthropod sting	節足動物刺傷アレルギー	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	4(0.8)	1(0.3)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Parathyroid gland enlargement	副甲状腺肥大	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Metabolism and nutrition disorders	代謝および栄養障害	38(7.9)	13(4.1)	5(3.2)	3(3.4)
Decreased appetite	食欲減退	13(2.7)	3(0.9)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	4(0.8)	1(0.3)	1(0.6)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	4(0.8)	1(0.3)	1(0.6)	0(0.0)
Hyperuricaemia	高尿酸血症	3(0.6)	2(0.6)	0(0.0)	0(0.0)
Dehydration	脱水	4(0.8)	0(0.0)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	1(0.2)	1(0.3)	1(0.6)	1(1.1)
Diabetes mellitus	糖尿病	1(0.2)	1(0.3)	0(0.0)	1(1.1)
Metabolic acidosis	代謝性アシドーシス	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	2(0.4)	0(0.0)	1(0.6)	0(0.0)
Hypocalcaemia	低カルシウム血症	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Fluid retention	体液貯留	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Hypoproteinaemia	低蛋白血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hyperlipidaemia	高脂血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	２型糖尿病	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hypercalcaemia	高カルシウム血症	0(0.0)	0(0.0)	0(0.0)	1(1.1)
Fluid overload	水分過負荷	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Hypokalaemia	低カリウム血症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Psychiatric disorders	精神障害	17 (3.5)	5 (1.6)	2 (1.3)	0 (0.0)
Insomnia	不眠症	11 (2.3)	3 (0.9)	2 (1.3)	0 (0.0)
Delirium	譫妄	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	0 (0.0)	1 (0.3)	1 (0.6)	0 (0.0)
Sleep disorder	睡眠障害	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Abnormal behaviour	異常行動	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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Nervous system disorders	神経系障害	42(8.7)	20(6.3)	5(3.2)	4(4.5)
Headache	頭痛	17(3.5)	7(2.2)	2(1.3)	2(2.2)
Dizziness	浮動性めまい	6(1.2)	5(1.6)	0(0.0)	1(1.1)
Intracranial aneurysm	頭蓋内動脈瘤	0(0.0)	2(0.6)	1(0.6)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.2)	0(0.0)	1(0.6)	0(0.0)
Somnolence	傾眠	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Carpal tunnel syndrome	手根管症候群	0(0.0)	2(0.6)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	1(0.2)	0(0.0)	0(0.0)	1(1.1)
Cerebral infarction	脳梗塞	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Loss of consciousness	意識消失	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Presyncope	失神寸前の状態	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Subarachnoid haemorrhage	くも膜下出血	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Carotid artery stenosis	頸動脈狭窄	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cerebral haemorrhage	脳出血	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dizziness postural	体位性めまい	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Myelopathy	脊髄症	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Myoclonus	ミオクローヌス	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Neuralgia	神経痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Sciatica	坐骨神経痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Tremor	振戦	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Intercostal neuralgia	肋間神経痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cervical radiculopathy	頚髄神経根障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Lacunar infarction	ラクナ梗塞	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Thrombotic cerebral infarction	血栓性脳梗塞	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Dizziness exertional	労作性めまい	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Eye disorders	眼障害	24(5.0)	32(10.1)	7(4.5)	5(5.6)
Retinal haemorrhage	網膜出血	4(0.8)	11(3.5)	2(1.3)	3(3.4)
Conjunctival haemorrhage	結膜出血	4(0.8)	2(0.6)	1(0.6)	1(1.1)
Cataract	白内障	3(0.6)	3(0.9)	1(0.6)	0(0.0)
Dry eye	ドライアイ	1(0.2)	6(1.9)	0(0.0)	0(0.0)
Blepharitis	眼瞼炎	2(0.4)	2(0.6)	0(0.0)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	1(0.2)	2(0.6)	0(0.0)	0(0.0)
Diabetic retinopathy	糖尿病網膜症	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Glaucoma	緑内障	0(0.0)	1(0.3)	1(0.6)	0(0.0)
Macular oedema	黄斑浮腫	1(0.2)	0(0.0)	0(0.0)	1(1.1)
Eczema eyelids	眼瞼湿疹	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Retinal exudates	網膜滲出物	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Diplopia	複視	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Keratitis	角膜炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Ocular hyperaemia	眼充血	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Trichiasis	睫毛乱生	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Vitreous floaters	硝子体浮遊物	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Chorioretinopathy	網脈絡膜症	0(0.0)	0(0.0)	0(0.0)	1(1.1)
Eyelid haematoma	眼瞼血腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Macular degeneration	黄斑変性	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Meibomian gland dysfunction	マイボーム腺機能不全	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Ear and labyrinth disorders	耳および迷路障害	7(1.5)	4(1.3)	2(1.3)	1(1.1)
Vertigo	回転性めまい	4(0.8)	1(0.3)	2(1.3)	1(1.1)
Vertigo positional	頭位性回転性めまい	0(0.0)	3(0.9)	0(0.0)	0(0.0)
Ear congestion	耳閉	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Deafness	難聴	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Sudden hearing loss	突発性難聴	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Eustachian tube stenosis	耳管狭窄	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Cardiac disorders	心臓障害	18(3.7)	13(4.1)	4(2.6)	0(0.0)
Cardiac failure chronic	慢性心不全	4(0.8)	2(0.6)	0(0.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	2(0.4)	3(0.9)	0(0.0)	0(0.0)
Palpitations	動悸	2(0.4)	1(0.3)	1(0.6)	0(0.0)
Atrial fibrillation	心房細動	2(0.4)	0(0.0)	1(0.6)	0(0.0)
Cardiac failure	心不全	1(0.2)	2(0.6)	0(0.0)	0(0.0)
Myocardial ischaemia	心筋虚血	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Cardiac dysfunction	心機能障害	0(0.0)	1(0.3)	1(0.6)	0(0.0)
Atrial flutter	心房粗動	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Bradycardia	徐脈	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Ventricular tachycardia	心室性頻脈	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Angina pectoris	狭心症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Angina unstable	不安定狭心症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Aortic valve incompetence	大動脈弁閉鎖不全症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Arrhythmia	不整脈	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Arteriosclerosis coronary artery	冠動脈硬化症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Coronary artery stenosis	冠動脈狭窄	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Mitral valve incompetence	僧帽弁閉鎖不全症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Mitral valve stenosis	僧帽弁狭窄症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Pericarditis	心膜炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Paroxysmal arrhythmia	発作性不整脈	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Vascular disorders	血管障害	34 (7.1)	8 (2.5)	3 (1.9)	1 (1.1)
Hypertension	高血圧	11 (2.3)	2 (0.6)	0 (0.0)	0 (0.0)
Hypotension	低血圧	3 (0.6)	3 (0.9)	1 (0.6)	0 (0.0)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	5 (1.0)	0 (0.0)	1 (0.6)	0 (0.0)
Internal haemorrhage	内出血	3 (0.6)	0 (0.0)	1 (0.6)	1 (1.1)
Orthostatic hypotension	起立性低血圧	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular pain	血管痛	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Haemorrhage	出血	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Arteriosclerosis	動脈硬化症	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Aortic aneurysm	大動脈瘤	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Varicose vein	静脈瘤	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vasculitis	血管炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Vascular rupture	血管破裂	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Aneurysm	動脈瘤	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular insufficiency	血行不全	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	27(5.6)	9(2.8)	8(5.1)	4(4.5)
Cough	咳嗽	7(1.5)	2(0.6)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	5(1.0)	0(0.0)	3(1.9)	0(0.0)
Epistaxis	鼻出血	2(0.4)	2(0.6)	1(0.6)	1(1.1)
Upper respiratory tract inflammation	上気道の炎症	4(0.8)	0(0.0)	1(0.6)	1(1.1)
Pleural effusion	胸水	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Asthma	喘息	2(0.4)	0(0.0)	1(0.6)	0(0.0)
Pulmonary congestion	肺うっ血	0(0.0)	1(0.3)	0(0.0)	1(1.1)
Haemoptysis	喀血	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Pulmonary oedema	肺水腫	1(0.2)	0(0.0)	1(0.6)	0(0.0)
Sleep apnoea syndrome	睡眠時無呼吸症候群	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Oropharyngeal pain	口腔咽頭痛	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Interstitial lung disease	間質性肺疾患	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Pulmonary hypertension	肺高血圧症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Rhinorrhoea	鼻漏	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Reflux laryngitis	逆流性喉頭炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hiccups	しゃっくり	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Pneumonia aspiration	誤嚥性肺炎	0(0.0)	0(0.0)	0(0.0)	1(1.1)
Sputum increased	喀痰増加	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Gastrointestinal disorders	胃腸障害	146(30.4)	45(14.2)	13(11.5)	5(5.6)
Diarrhoea	下痢	50(10.4)	15(4.7)	7(4.5)	2(2.2)
Vomiting	嘔吐	22(4.6)	4(1.3)	3(1.9)	1(1.1)
Constipation	便秘	17(3.5)	8(2.5)	1(0.6)	1(1.1)
Nausea	悪心	17(3.5)	7(2.2)	3(1.9)	0(0.0)
Dental caries	齲歯	5(1.0)	6(1.9)	1(0.6)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	7(1.5)	3(0.9)	1(0.6)	0(0.0)
Abdominal pain	腹痛	5(1.0)	2(0.6)	1(0.6)	0(0.0)
Abdominal discomfort	腹部不快感	7(1.5)	0(0.0)	1(0.6)	0(0.0)
Stomatitis	口内炎	6(1.2)	0(0.0)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	6(1.2)	0(0.0)	0(0.0)	0(0.0)
Enterocolitis	腸炎	6(1.2)	0(0.0)	0(0.0)	0(0.0)
Gastritis	胃炎	3(0.6)	2(0.6)	0(0.0)	0(0.0)
Haemorrhoids	痔核	0(0.0)	4(1.3)	1(0.6)	0(0.0)
Abdominal distension	腹部膨満	4(0.8)	0(0.0)	0(0.0)	0(0.0)
Chronic gastritis	慢性胃炎	1(0.2)	3(0.9)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	2(0.4)	2(0.6)	0(0.0)	0(0.0)
Faeces soft	軟便	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer	胃潰瘍	1(0.2)	2(0.6)	0(0.0)	0(0.0)
Toothache	歯痛	1(0.2)	1(0.3)	0(0.0)	1(1.1)
Gastric polyps	胃ポリープ	2(0.4)	0(0.0)	1(0.6)	0(0.0)

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Periodontal disease	歯周病	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Angular cheilitis	口角口唇炎	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	0(0.0)	1(0.3)	1(0.6)	0(0.0)
Gingival bleeding	歯肉出血	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	2(0.6)	0(0.0)	0(0.0)
Dyspepsia	消化不良	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal disorder	胃腸障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Oesophageal achalasia	食道アカラシア	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Tooth loss	歯の脱落	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Abdominal pain lower	下腹部痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Barrett's oesophagus	バレット食道	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dry mouth	口内乾燥	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Duodenal polyp	十二指腸ポリープ	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Food poisoning	食中毒	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastritis erosive	びらん性胃炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Gastritis haemorrhagic	出血性胃炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Glossitis	舌炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)

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Melaena	メレナ	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Pancreatitis	膵炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Rectal ulcer	直腸潰瘍	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastric disorder	胃障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Loose tooth	弛緩歯	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hiatus hernia	裂孔ヘルニア	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Traumatic occlusion	外傷性咬合	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	10(2.1)	5(1.6)	1(0.6)	0(0.0)
Cholelithiasis	胆石症	4(0.8)	2(0.6)	0(0.0)	0(0.0)
Hepatic function abnormal	肝機能異常	3(0.6)	1(0.3)	1(0.6)	0(0.0)
Cholecystitis	胆嚢炎	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Bile duct stone	胆管結石	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Hepatic cirrhosis	肝硬変	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Drug-induced liver injury	薬物性肝障害	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cholangitis	胆管炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	68(14.1)	32(10.1)	12(7.7)	10(11.2)
Pruritus	そう痒症	10(2.1)	7(2.2)	3(1.9)	1(1.1)
Eczema	湿疹	12(2.5)	2(0.6)	1(0.6)	2(2.2)
Haemorrhage subcutaneous	皮下出血	7(1.5)	3(0.9)	1(0.6)	2(2.2)
Dermatitis contact	接触皮膚炎	7(1.5)	3(0.9)	1(0.6)	1(1.1)
Rash	発疹	7(1.5)	1(0.3)	1(0.6)	1(1.1)
Eczema asteatotic	皮脂欠乏性湿疹	2(0.4)	4(1.3)	0(0.0)	0(0.0)
Drug eruption	薬疹	5(1.0)	0(0.0)	0(0.0)	0(0.0)
Ingrowing nail	嵌入爪	3(0.6)	2(0.6)	0(0.0)	0(0.0)
Skin exfoliation	皮膚剥脱	3(0.6)	1(0.3)	1(0.6)	0(0.0)
Xeroderma	乾皮症	2(0.4)	1(0.3)	1(0.6)	0(0.0)
Dermatitis	皮膚炎	1(0.2)	2(0.6)	1(0.6)	0(0.0)
Dry skin	皮膚乾燥	0(0.0)	3(0.9)	0(0.0)	0(0.0)
Skin ulcer	皮膚潰瘍	1(0.2)	2(0.6)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	2(0.4)	0(0.0)	0(0.0)	1(1.1)
Hyperkeratosis	過角化	1(0.2)	1(0.3)	1(0.6)	0(0.0)
Skin erosion	皮膚びらん	1(0.2)	0(0.0)	0(0.0)	1(1.1)
Urticaria	蕁麻疹	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Blister	水疱	1(0.2)	0(0.0)	1(0.6)	0(0.0)
Cold sweat	冷汗	2(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6546 0 <= to < 1/4 * MCD n (%)	 1/4 * MCD <= to < 2/4 * MCD n (%)	 2/4 * MCD <= to < 3/4 * MCD n (%)	 >= 3/4 * MCD n (%)
Decubitus ulcer	褥瘡性潰瘍	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dermatomyositis	皮膚筋炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Prurigo	痒疹	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Pruritus generalised	全身性そう痒症	0(0.0)	0(0.0)	0(0.0)	1(1.1)
Reactive perforating collagenosis	反応性穿孔性膠原線維症	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Acne	ざ瘡	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Alopecia	脱毛症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Erythema	紅斑	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Neurodermatitis	神経皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Rash pruritic	そう痒性皮疹	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Skin disorder	皮膚障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Skin mass	皮膚腫瘤	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	63(13.1)	49(15.4)	16(10.3)	4(4.5)
Back pain	背部痛	16(3.3)	13(4.1)	1(0.6)	0(0.0)
Pain in extremity	四肢痛	13(2.7)	2(0.6)	2(1.3)	0(0.0)
Muscle spasms	筋痙縮	9(1.9)	5(1.6)	2(1.3)	0(0.0)
Arthralgia	関節痛	9(1.9)	5(1.6)	1(0.6)	1(1.1)
Myalgia	筋肉痛	7(1.5)	4(1.3)	3(1.9)	0(0.0)
Musculoskeletal pain	筋骨格痛	7(1.5)	3(0.9)	0(0.0)	0(0.0)
Osteoarthritis	変形性関節症	4(0.8)	2(0.6)	2(1.3)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	4(0.8)	3(0.9)	0(0.0)	0(0.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	2(0.4)	2(0.6)	2(1.3)	1(1.1)
Periarthritis	関節周囲炎	2(0.4)	3(0.9)	2(1.3)	0(0.0)
Arthritis	関節炎	1(0.2)	3(0.9)	0(0.0)	1(1.1)
Osteoporosis	骨粗鬆症	1(0.2)	4(1.3)	0(0.0)	0(0.0)
Neck pain	頸部痛	2(0.4)	1(0.3)	1(0.6)	1(1.1)
Tenosynovitis	腱鞘炎	2(0.4)	1(0.3)	1(0.6)	0(0.0)
Trigger finger	弾発指	1(0.2)	1(0.3)	1(0.6)	0(0.0)
Synovial cyst	滑液嚢腫	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Bursitis	滑液包炎	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Rotator cuff syndrome	肩回旋筋腱板症候群	0(0.0)	1(0.3)	1(0.6)	0(0.0)
Intervertebral disc protrusion	椎間板突出	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Temporomandibular joint syndrome	顎関節症候群	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Spondylolisthesis	脊椎すべり症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Haemarthrosis	出血性関節症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Joint swelling	関節腫脹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal chest pain	筋骨格系胸痛	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal discomfort	筋骨格不快感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Renal and urinary disorders	腎および尿路障害	25(5.2)	12(3.8)	6(3.8)	1(1.1)
Renal impairment	腎機能障害	7(1.5)	2(0.6)	2(1.3)	1(1.1)
Chronic kidney disease	慢性腎臓病	4(0.8)	5(1.6)	2(1.3)	0(0.0)
End stage renal disease	末期腎疾患	2(0.4)	2(0.6)	0(0.0)	0(0.0)
Haematuria	血尿	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	1(0.3)	1(0.6)	0(0.0)
Renal failure	腎不全	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Pollakiuria	頻尿	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Renal cyst	腎嚢胞	0(0.0)	0(0.0)	2(1.3)	0(0.0)
Oliguria	乏尿	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Urinary retention	尿閉	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Acute kidney injury	急性腎障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Ureterolithiasis	尿管結石症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Azotaemia	高窒素血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Reproductive system and breast disorders	生殖系および乳房障害	6(1.2)	6(1.9)	1(0.6)	0(0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	3(0.6)	2(0.6)	1(0.6)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	1(0.2)	2(0.6)	0(0.0)	0(0.0)
Menstruation irregular	不規則月経	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Nipple pain	乳頭痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Prostatitis	前立腺炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Erectile dysfunction	勃起不全	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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General disorders and administration site conditions	一般・全身障害および投与部位の状態	36(7.5)	17(5.3)	6(3.8)	3(3.4)
Pyrexia	発熱	8(1.7)	9(2.8)	3(1.9)	2(2.2)
Oedema peripheral	末梢性浮腫	11(2.3)	6(1.9)	1(0.6)	1(1.1)
Malaise	倦怠感	5(1.0)	0(0.0)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	4(0.8)	1(0.3)	0(0.0)	0(0.0)
Chest pain	胸痛	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Chest discomfort	胸部不快感	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Vessel puncture site bruise	血管穿刺部位内出血	1(0.2)	0(0.0)	1(0.6)	0(0.0)
Chills	悪寒	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Face oedema	顔面浮腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Oedema	浮腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Thirst	口渇	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Vessel puncture site haemorrhage	血管穿刺部位出血	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Fatigue	疲労	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Feeling abnormal	異常感	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Injection site reaction	注射部位反応	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Puncture site pain	穿刺部位疼痛	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Catheter site haemorrhage	カテーテル留置部位出血	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Investigations	臨床検査	27(5.6)	9(2.8)	3(1.9)	0(0.0)
Blood pressure increased	血圧上昇	4(0.8)	3(0.9)	0(0.0)	0(0.0)
Blood pressure decreased	血圧低下	3(0.6)	3(0.9)	0(0.0)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	1(0.2)	1(0.3)	1(0.6)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	3(0.6)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	1(0.2)	0(0.0)	1(0.6)	0(0.0)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood urea increased	血中尿素増加	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Blood uric acid decreased	血中尿酸減少	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood urine present	尿中血陽性	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Weight decreased	体重減少	1(0.2)	0(0.0)	0(0.0)	0(0.0)

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Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

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Injury, poisoning and procedural complications	傷害、中毒および処置合併症	88(18.3)	57(17.9)	25(16.0)	9(10.1)
Contusion	挫傷	25(5.2)	15(4.7)	4(2.6)	2(2.2)
Shunt stenosis	シャント狭窄	24(5.0)	11(3.5)	2(1.3)	2(2.2)
Skin abrasion	皮膚擦過傷	10(2.1)	5(1.6)	2(1.3)	2(2.2)
Wound	創傷	6(1.2)	2(0.6)	4(2.6)	0(0.0)
Thermal burn	熱傷	3(0.6)	4(1.3)	1(0.6)	1(1.1)
Procedural hypotension	処置による低血圧	2(0.4)	1(0.3)	4(2.6)	2(2.2)
Spinal compression fracture	脊椎圧迫骨折	3(0.6)	2(0.6)	2(1.3)	0(0.0)
Limb injury	四肢損傷	2(0.4)	2(0.6)	2(1.3)	0(0.0)
Shunt occlusion	シャント閉塞	4(0.8)	2(0.6)	0(0.0)	0(0.0)
Rib fracture	肋骨骨折	2(0.4)	1(0.3)	1(0.6)	0(0.0)
Skin laceration	皮膚裂傷	1(0.2)	1(0.3)	2(1.3)	0(0.0)
Tooth fracture	歯牙破折	1(0.2)	1(0.3)	0(0.0)	1(1.1)
Arteriovenous fistula site complication	動静脈瘻部位合併症	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Joint injury	関節損傷	2(0.4)	1(0.3)	0(0.0)	0(0.0)
Clavicle fracture	鎖骨骨折	1(0.2)	1(0.3)	0(0.0)	0(0.0)
Femoral neck fracture	大腿骨頸部骨折	0(0.0)	0(0.0)	1(0.6)	1(1.1)
Eye contusion	眼挫傷	1(0.2)	0(0.0)	1(0.6)	0(0.0)
Animal bite	動物咬傷	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Foot fracture	足骨折	0(0.0)	2(0.6)	0(0.0)	0(0.0)
Ligament sprain	靱帯捻挫	2(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Subcutaneous haematoma	皮下血腫	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)
Procedural hypertension	処置による高血圧	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Shunt blood flow excessive	シャント血流過剰	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Vascular access malfunction	血管アクセス機能不全	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Dental restoration failure	歯科修復不成功	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Animal scratch	動物による引っかき傷	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Fall	転倒	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hand fracture	手骨折	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Injury	損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Seroma	漿液腫	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Sternal fracture	胸骨骨折	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Tendon rupture	腱断裂	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Lumbar vertebral fracture	腰椎骨折	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Procedural pain	処置による疼痛	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Nail injury	爪損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Chillblains	凍瘡	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Foreign body in eye	眼内異物	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Muscle injury	筋損傷	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Scratch	引っかき傷	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Scrotal haematoma	陰嚢血腫	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)

表 2.7.4.9－68　発現時までの累積投与量別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Subdural haematoma	硬膜下血腫	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Tibia fracture	脛骨骨折	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Tooth injury	歯牙損傷	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Wound complication	創合併症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Arteriovenous fistula site haemorrhage	動静脈瘻部位出血	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Arteriovenous fistula occlusion	動静脈瘻閉塞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Shunt thrombosis	シャント血栓症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Pelvic fracture	骨盤骨折	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular access complication	血管確保合併症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Post procedural inflammation	処置後炎症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)
Heat illness	熱中症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pubis fracture	恥骨骨折	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Skin wound	皮膚創傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular access site inflammation	血管確保部位炎症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Soft tissue foreign body	軟部組織内異物	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Heat stroke	熱射病	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Peritoneal dialysis complication	腹膜透析合併症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Traumatic haemothorax	外傷性血胸	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Surgical and medical procedures	外科および内科処置	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Arteriovenous fistula operation	動静脈瘻手術	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Note(s): MCD Maximum cumulative dose.
Note(s): Percentages are based on the number of subjects in each category (N1).
Source: t_14_3_1_12_1.sas

5.3.5.3—4 Table 14.3.1.12.1 より引用

表 2.7.4.9－69　休薬前後別の有害事象の内訳（MT-6548-J01 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=33) 4 weeks before drug interruption n (%)	MT-6548(N*=33) 4 weeks after drug interruption n (%)	darbepoetin(N*=57) 4 weeks before drug interruption n (%)	darbepoetin(N*=57) 4 weeks after drug interruption n (%)
Subjects with at least one adverse event		5(15.2)	7(21.2)	15(26.3)	16(28.1)
Infections and infestations	感染症および寄生虫症	1(3.0)	2(6.1)	4(7.0)	6(10.5)
Nasopharyngitis	上咽頭炎	1(3.0)	1(3.0)	1(1.8)	2(3.5)
Cellulitis	蜂巣炎	0(0.0)	1(3.0)	0(0.0)	0(0.0)
Conjunctivitis	結膜炎	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Urethritis	尿道炎	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Dermatophytosis of nail	爪の皮膚糸状菌症	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Herpes zoster	帯状疱疹	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Otitis media	中耳炎	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Metabolism and nutrition disorders	代謝および栄養障害	0(0.0)	2(6.1)	1(1.8)	1(1.8)
Dehydration	脱水	0(0.0)	1(3.0)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	0(0.0)	1(3.0)	0(0.0)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Psychiatric disorders	精神障害	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Depression	うつ病	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Insomnia	不眠症	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Nervous system disorders	神経系障害	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Sciatica	坐骨神経痛	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Eye disorders	眼障害	0(0.0)	1(3.0)	3(5.3)	1(1.8)
Retinal haemorrhage	網膜出血	0(0.0)	1(3.0)	2(3.5)	1(1.8)
Cataract	白内障	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Asthenopia	眼精疲労	0(0.0)	0(0.0)	1(1.8)	0(0.0)

表 2.7.4.9－69　休薬前後別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=33) 4 weeks before drug interruption n (%)	MT-6548(N*=33) 4 weeks after drug interruption n (%)	darbepoetin(N*=57) 4 weeks before drug interruption n (%)	darbepoetin(N*=57) 4 weeks after drug interruption n (%)
Vascular disorders	血管障害	0(0.0)	0(0.0)	2(3.5)	1(1.8)
Hypertension	高血圧	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Hot flush	ほてり	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Epistaxis	鼻出血	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Gastrointestinal disorders	胃腸障害	2(6.1)	1(3.0)	4(7.0)	5(8.8)
Nausea	悪心	1(3.0)	0(0.0)	1(1.8)	0(0.0)
Abdominal pain	腹痛	1(3.0)	0(0.0)	0(0.0)	0(0.0)
Chronic gastritis	慢性胃炎	0(0.0)	1(3.0)	0(0.0)	0(0.0)
Aphthous ulcer	アフタ性潰瘍	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Gastrocesophageal reflux disease	胃食道逆流性疾患	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Large intestine polyp	大腸ポリープ	0(0.0)	0(0.0)	0(0.0)	2(3.5)
Abdominal pain upper	上腹部痛	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Gastrointestinal disorder	胃腸障害	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	1(3.0)	0(0.0)	0(0.0)	1(1.8)
Drug-induced liver injury	薬物性肝障害	1(3.0)	0(0.0)	0(0.0)	0(0.0)
Hepatic function abnormal	肝機能異常	0(0.0)	0(0.0)	0(0.0)	1(1.8)

表 2.7.4.9－69　休薬前後別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=33) 4 weeks before drug interruption n (%)	MT-6548(N*=33) 4 weeks after drug interruption n (%)	darbepoetin(N*=57) 4 weeks before drug interruption n (%)	darbepoetin(N*=57) 4 weeks after drug interruption n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(3.0)	3(9.1)	2(3.5)	3(5.3)
Back pain	背部痛	0(0.0)	1(3.0)	0(0.0)	1(1.8)
Arthritis	関節炎	0(0.0)	1(3.0)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	1(3.0)	0(0.0)	0(0.0)	0(0.0)
Tenosynovitis	腱鞘炎	0(0.0)	1(3.0)	0(0.0)	0(0.0)
Osteoarthritis	変形性関節症	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Intervertebral disc protrusion	椎間板突出	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Renal and urinary disorders	腎および尿路障害	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Renal impairment	腎機能障害	0(0.0)	0(0.0)	0(0.0)	1(1.8)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Fatigue	疲労	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Investigations	臨床検査	0(0.0)	0(0.0)	2(3.5)	1(1.8)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Weight decreased	体重減少	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0(0.0)	0(0.0)	1(1.8)	1(1.8)
Radius fracture	橈骨骨折	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Contusion	挫傷	0(0.0)	0(0.0)	1(1.8)	0(0.0)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Note(s): N*: number of subjects interrupted the study drug.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_19_1.sas

5.3.5.1—8 表 14.3.1.19.1 より引用

表 2.7.4.9－70　休薬前後別の有害事象の内訳（MT-6548-J03 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=38) 4 weeks before drug interruption n (%)	MT-6548(N*=38) 4 weeks after drug interruption n (%)	darbepoetin(N*=30) 4 weeks before drug interruption n (%)	darbepoetin(N*=30) 4 weeks after drug interruption n (%)
Subjects with at least one adverse event		3(7.9)	4(10.5)	2(6.7)	6(20.0)
Infections and infestations	感染症および寄生虫症	0(0.0)	2(5.3)	2(6.7)	2(6.7)
Cellulitis	蜂巣炎	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Bacterial infection	細菌感染	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Nasopharyngitis	上咽頭炎	0(0.0)	0(0.0)	1(3.3)	1(3.3)
Pharyngitis	咽頭炎	0(0.0)	0(0.0)	1(3.3)	0(0.0)
Infected dermal cyst	感染性皮膚嚢腫	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Endocrine disorders	内分泌障害	0(0.0)	0(0.0)	1(3.3)	1(3.3)
Hypothyroidism	甲状腺機能低下症	0(0.0)	0(0.0)	1(3.3)	1(3.3)
Metabolism and nutrition disorders	代謝および栄養障害	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Cardiac disorders	心臓障害	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Coronary artery stenosis	冠動脈狭窄	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Vascular disorders	血管障害	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Peripheral artery occlusion	末梢動脈閉塞	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	2(5.3)	1(2.6)	0(0.0)	0(0.0)
Oropharyngeal pain	口腔咽頭痛	1(2.6)	1(2.6)	0(0.0)	0(0.0)
Pulmonary oedema	肺水腫	1(2.6)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－70　休薬前後別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=38) 4 weeks before drug interruption n (%)	MT-6548(N*=38) 4 weeks after drug interruption n (%)	darbepoetin(N*=30) 4 weeks before drug interruption n (%)	darbepoetin(N*=30) 4 weeks after drug interruption n (%)
Gastrointestinal disorders	胃腸障害	1(2.6)	1(2.6)	0(0.0)	2(6.7)
Diarrhoea	下痢	1(2.6)	0(0.0)	0(0.0)	1(3.3)
Nausea	悪心	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Abdominal pain	腹痛	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(2.6)	0(0.0)	0(0.0)	0(0.0)
Intervertebral disc protrusion	椎間板突出	1(2.6)	0(0.0)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Erectile dysfunction	勃起不全	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Investigations	臨床検査	0(0.0)	0(0.0)	2(6.7)	2(6.7)
Blood pressure increased	血圧上昇	0(0.0)	0(0.0)	1(3.3)	1(3.3)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0(0.0)	0(0.0)	1(3.3)	1(3.3)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0(0.0)	0(0.0)	1(3.3)	1(3.3)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1(2.6)	1(2.6)	1(3.3)	2(6.7)
Shunt occlusion	シャント閉塞	1(2.6)	0(0.0)	0(0.0)	0(0.0)
Procedural hypotension	処置による低血圧	0(0.0)	1(2.6)	0(0.0)	0(0.0)
Contusion	挫傷	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Dialysis related complication	透析関連合併症	0(0.0)	0(0.0)	0(0.0)	1(3.3)
Closed globe injury	閉鎖性眼球損傷	0(0.0)	0(0.0)	1(3.3)	0(0.0)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Note(s): N*: number of subjects interrupted the study drug.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_19_1.sas

5.3.5.1—9 表 14.3.1.19.1 より引用

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
NDD(N1=59)	Subjects with at least one adverse event		17(28.8)	18(30.5)
	Infections and infestations	感染症および寄生虫症	2(3.4)	4(6.8)
	Nasopharyngitis	上咽頭炎	1(1.7)	1(1.7)
	Cellulitis	蜂巣炎	0(0.0)	1(1.7)
	Upper respiratory tract infection	上気道感染	0(0.0)	1(1.7)
	Influenza	インフルエンザ	1(1.7)	0(0.0)
	Otitis externa	外耳炎	0(0.0)	1(1.7)
	Upper respiratory tract infection bacterial	細菌性上気道感染	1(1.7)	0(0.0)
	Endocrine disorders	内分泌障害	1(1.7)	1(1.7)
	Hypothyroidism	甲状腺機能低下症	1(1.7)	1(1.7)
	Metabolism and nutrition disorders	代謝および栄養障害	2(3.4)	3(5.1)
	Dehydration	脱水	0(0.0)	2(3.4)
	Hyperkalaemia	高カリウム血症	1(1.7)	1(1.7)
	Hyperphosphataemia	高リン酸塩血症	1(1.7)	0(0.0)
	Eye disorders	眼障害	0(0.0)	1(1.7)
	Retinal haemorrhage	網膜出血	0(0.0)	1(1.7)
	Vascular disorders	血管障害	2(3.4)	0(0.0)
	Hypertension	高血圧	2(3.4)	0(0.0)
	Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1(1.7)	2(3.4)
	Haemoptysis	喀血	1(1.7)	1(1.7)
	Pulmonary hypertension	肺高血圧症	0(0.0)	1(1.7)
	Reflux laryngitis	逆流性喉頭炎	0(0.0)	1(1.7)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Gastrointestinal disorders	胃腸障害	5(8.5)	4(6.8)
Diarrhoea	下痢	1(1.7)	1(1.7)
Constipation	便秘	0(0.0)	2(3.4)
Nausea	悪心	1(1.7)	0(0.0)
Abdominal pain	腹痛	1(1.7)	0(0.0)
Chronic gastritis	慢性胃炎	0(0.0)	1(1.7)
Dental caries	齲歯	1(1.7)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0(0.0)	1(1.7)
Vomiting	嘔吐	1(1.7)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	2(3.4)	0(0.0)
Hepatic function abnormal	肝機能異常	1(1.7)	0(0.0)
Drug-induced liver injury	薬物性肝障害	1(1.7)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1(1.7)	2(3.4)
Eczema asteatotic	皮脂欠乏性湿疹	1(1.7)	1(1.7)
Eczema	湿疹	0(0.0)	1(1.7)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(1.7)	3(5.1)
Back pain	背部痛	0(0.0)	1(1.7)
Tenosynovitis	腱鞘炎	0(0.0)	1(1.7)
Arthritis	関節炎	0(0.0)	1(1.7)
Synovial cyst	滑液嚢腫	1(1.7)	0(0.0)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Renal and urinary disorders	腎および尿路障害	4(6.8)	2(3.4)
Diabetic nephropathy	糖尿病性腎症	1(1.7)	1(1.7)
End stage renal disease	末期腎疾患	1(1.7)	1(1.7)
Hypertensive nephropathy	高血圧性腎症	1(1.7)	0(0.0)
Renal impairment	腎機能障害	1(1.7)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	0(0.0)	1(1.7)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	1(1.7)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1(1.7)	2(3.4)
Wound	創傷	1(1.7)	1(1.7)
Contusion	挫傷	0(0.0)	1(1.7)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	1(1.7)
Surgical and medical procedures	外科および内科処置	0(0.0)	2(3.4)
Arteriovenous fistula operation	動静脈瘻手術	0(0.0)	2(3.4)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
HD(N1=70)	Subjects with at least one adverse event		16(22.9)	25(35.7)
	Infections and infestations	感染症および寄生虫症	6(8.6)	7(10.0)
	Nasopharyngitis	上咽頭炎	3(4.3)	2(2.9)
	Cellulitis	蜂巣炎	0(0.0)	1(1.4)
	Upper respiratory tract infection	上気道感染	0(0.0)	1(1.4)
	Enteritis infectious	感染性腸炎	1(1.4)	1(1.4)
	Bronchitis	気管支炎	0(0.0)	1(1.4)
	Gingivitis	歯肉炎	0(0.0)	1(1.4)
	Herpes zoster	帯状疱疹	1(1.4)	0(0.0)
	Periodontitis	歯周炎	0(0.0)	1(1.4)
	Shunt infection	シャント感染	1(1.4)	0(0.0)
	Bacterial infection	細菌感染	0(0.0)	1(1.4)
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0(0.0)	1(1.4)
	Skin papilloma	皮膚乳頭腫	0(0.0)	1(1.4)
	Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	1(1.4)
	Anaemia macrocytic	大球性貧血	0(0.0)	1(1.4)
	Metabolism and nutrition disorders	代謝および栄養障害	1(1.4)	2(2.9)
	Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(1.4)
	Hypocalcaemia	低カルシウム血症	1(1.4)	1(1.4)
	Hypoglycaemia	低血糖	0(0.0)	1(1.4)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Nervous system disorders	神経系障害	2(2.9)	4(5.7)
Headache	頭痛	1(1.4)	2(2.9)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(1.4)
Toxic encephalopathy	中毒性脳症	1(1.4)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	1(1.4)
Cardiac disorders	心臓障害	0(0.0)	1(1.4)
Pericarditis	心膜炎	0(0.0)	1(1.4)
Vascular disorders	血管障害	0(0.0)	1(1.4)
Haemorrhage	出血	0(0.0)	1(1.4)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3(4.3)	2(2.9)
Upper respiratory tract inflammation	上気道の炎症	1(1.4)	1(1.4)
Oropharyngeal pain	口腔咽頭痛	1(1.4)	1(1.4)
Pulmonary oedema	肺水腫	1(1.4)	0(0.0)
Gastrointestinal disorders	胃腸障害	3(4.3)	5(7.1)
Diarrhoea	下痢	2(2.9)	4(5.7)
Constipation	便秘	1(1.4)	0(0.0)
Nausea	悪心	1(1.4)	1(1.4)
Abdominal pain	腹痛	0(0.0)	1(1.4)
Hepatobiliary disorders	肝胆道系障害	2(2.9)	1(1.4)
Cholecystitis acute	急性胆嚢炎	1(1.4)	1(1.4)
Cholelithiasis	胆石症	1(1.4)	0(0.0)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1(1.4)	2(2.9)
Eczema	湿疹	0(0.0)	1(1.4)
Dermal cyst	皮膚嚢腫	1(1.4)	0(0.0)
Rash pruritic	そう痒性皮疹	0(0.0)	1(1.4)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	2(2.9)	2(2.9)
Back pain	背部痛	0(0.0)	1(1.4)
Tenosynovitis	腱鞘炎	0(0.0)	1(1.4)
Arthralgia	関節痛	1(1.4)	0(0.0)
Intervertebral disc protrusion	椎間板突出	1(1.4)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	1(1.4)
Erectile dysfunction	勃起不全	0(0.0)	1(1.4)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(1.4)	1(1.4)
Pyrexia	発熱	1(1.4)	1(1.4)
Investigations	臨床検査	1(1.4)	2(2.9)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(1.4)	1(1.4)
Blood pressure increased	血圧上昇	0(0.0)	1(1.4)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
	Injury, poisoning and procedural complications	傷害、中毒および処置合併症	5(7.1)	8(11.4)
	Arteriovenous fistula site complication	動静脈瘻部位合併症	3(4.3)	2(2.9)
	Shunt stenosis	シャント狭窄	1(1.4)	4(5.7)
	Contusion	挫傷	0(0.0)	1(1.4)
	Ligament sprain	靱帯捻挫	0(0.0)	1(1.4)
	Shunt occlusion	シャント閉塞	1(1.4)	0(0.0)
	Procedural hypotension	処置による低血圧	0(0.0)	1(1.4)
PD(N1=10)	Subjects with at least one adverse event		3(30.0)	5(50.0)
	Infections and infestations	感染症および寄生虫症	1(10.0)	1(10.0)
	Nasopharyngitis	上咽頭炎	0(0.0)	1(10.0)
	Catheter site infection	カテーテル留置部位感染	1(10.0)	0(0.0)
	Psychiatric disorders	精神障害	0(0.0)	1(10.0)
	Insomnia	不眠症	0(0.0)	1(10.0)
	Nervous system disorders	神経系障害	1(10.0)	1(10.0)
	Cerebral infarction	脳梗塞	1(10.0)	1(10.0)
	Eye disorders	眼障害	1(10.0)	0(0.0)
	Dry eye	ドライアイ	1(10.0)	0(0.0)
	Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1(10.0)	0(0.0)
	Upper respiratory tract inflammation	上気道の炎症	1(10.0)	0(0.0)
	Gastrointestinal disorders	胃腸障害	0(0.0)	1(10.0)
	Diarrhoea	下痢	0(0.0)	1(10.0)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
	Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	1(10.0)
	Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	1(10.0)
	Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0(0.0)	1(10.0)
	Traumatic haemothorax	外傷性血胸	0(0.0)	1(10.0)
Total(N1=139)	Subjects with at least one adverse event		36(25.9)	48(34.5)
	Infections and infestations	感染症および寄生虫症	9(6.5)	12(8.6)
	Nasopharyngitis	上咽頭炎	4(2.9)	4(2.9)
	Cellulitis	蜂巣炎	0(0.0)	2(1.4)
	Upper respiratory tract infection	上気道感染	0(0.0)	2(1.4)
	Enteritis infectious	感染性腸炎	1(0.7)	1(0.7)
	Influenza	インフルエンザ	1(0.7)	0(0.0)
	Otitis externa	外耳炎	0(0.0)	1(0.7)
	Upper respiratory tract infection bacterial	細菌性上気道感染	1(0.7)	0(0.0)
	Bronchitis	気管支炎	0(0.0)	1(0.7)
	Gingivitis	歯肉炎	0(0.0)	1(0.7)
	Herpes zoster	帯状疱疹	1(0.7)	0(0.0)
	Periodontitis	歯周炎	0(0.0)	1(0.7)
	Shunt infection	シャント感染	1(0.7)	0(0.0)
	Bacterial infection	細菌感染	0(0.0)	1(0.7)
	Catheter site infection	カテーテル留置部位感染	1(0.7)	0(0.0)
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0(0.0)	1(0.7)
	Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.7)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	1(0.7)
Anaemia macrocytic	大球性貧血	0(0.0)	1(0.7)
Endocrine disorders	内分泌障害	1(0.7)	1(0.7)
Hypothyroidism	甲状腺機能低下症	1(0.7)	1(0.7)
Metabolism and nutrition disorders	代謝および栄養障害	3(2.2)	5(3.6)
Dehydration	脱水	0(0.0)	2(1.4)
Hyperkalaemia	高カリウム血症	1(0.7)	1(0.7)
Hyperphosphataemia	高リン酸塩血症	1(0.7)	1(0.7)
Hypocalcaemia	低カルシウム血症	1(0.7)	1(0.7)
Hypoglycaemia	低血糖	0(0.0)	1(0.7)
Psychiatric disorders	精神障害	0(0.0)	1(0.7)
Insomnia	不眠症	0(0.0)	1(0.7)
Nervous system disorders	神経系障害	3(2.2)	5(3.6)
Headache	頭痛	1(0.7)	2(1.4)
Cerebral infarction	脳梗塞	1(0.7)	1(0.7)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(0.7)
Toxic encephalopathy	中毒性脳症	1(0.7)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	1(0.7)
Eye disorders	眼障害	1(0.7)	1(0.7)
Retinal haemorrhage	網膜出血	0(0.0)	1(0.7)
Dry eye	ドライアイ	1(0.7)	0(0.0)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Cardiac disorders	心臓障害	0(0.0)	1(0.7)
Pericarditis	心膜炎	0(0.0)	1(0.7)
Vascular disorders	血管障害	2(1.4)	1(0.7)
Hypertension	高血圧	2(1.4)	0(0.0)
Haemorrhage	出血	0(0.0)	1(0.7)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	5(3.6)	4(2.9)
Upper respiratory tract inflammation	上気道の炎症	2(1.4)	1(0.7)
Haemoptysis	喀血	1(0.7)	1(0.7)
Oropharyngeal pain	口腔咽頭痛	1(0.7)	1(0.7)
Pulmonary hypertension	肺高血圧症	0(0.0)	1(0.7)
Reflux laryngitis	逆流性喉頭炎	0(0.0)	1(0.7)
Pulmonary oedema	肺水腫	1(0.7)	0(0.0)
Gastrointestinal disorders	胃腸障害	8(5.8)	10(7.2)
Diarrhoea	下痢	3(2.2)	6(4.3)
Constipation	便秘	1(0.7)	2(1.4)
Nausea	悪心	2(1.4)	1(0.7)
Abdominal pain	腹痛	1(0.7)	1(0.7)
Chronic gastritis	慢性胃炎	0(0.0)	1(0.7)
Dental caries	齲歯	1(0.7)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0(0.0)	1(0.7)
Vomiting	嘔吐	1(0.7)	0(0.0)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Hepatobiliary disorders	肝胆道系障害	4(2.9)	1(0.7)
Cholecystitis acute	急性胆嚢炎	1(0.7)	1(0.7)
Hepatic function abnormal	肝機能異常	1(0.7)	0(0.0)
Drug-induced liver injury	薬物性肝障害	1(0.7)	0(0.0)
Cholelithiasis	胆石症	1(0.7)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	2(1.4)	4(2.9)
Eczema asteatotic	皮脂欠乏性湿疹	1(0.7)	1(0.7)
Eczema	湿疹	0(0.0)	2(1.4)
Dermal cyst	皮膚嚢腫	1(0.7)	0(0.0)
Rash pruritic	そう痒性皮疹	0(0.0)	1(0.7)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	3(2.2)	5(3.6)
Back pain	背部痛	0(0.0)	2(1.4)
Tenosynovitis	腱鞘炎	0(0.0)	2(1.4)
Arthritis	関節炎	0(0.0)	1(0.7)
Synovial cyst	滑液嚢腫	1(0.7)	0(0.0)
Arthralgia	関節痛	1(0.7)	0(0.0)
Intervertebral disc protrusion	椎間板突出	1(0.7)	0(0.0)
Renal and urinary disorders	腎および尿路障害	4(2.9)	2(1.4)
Diabetic nephropathy	糖尿病性腎症	1(0.7)	1(0.7)
End stage renal disease	末期腎疾患	1(0.7)	1(0.7)
Hypertensive nephropathy	高血圧性腎症	1(0.7)	0(0.0)
Renal impairment	腎機能障害	1(0.7)	0(0.0)

表 2.7.4.9－71　休薬前後別の有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Reproductive system and breast disorders	生殖系および乳房障害	0 (0.0)	2 (1.4)
Erectile dysfunction	勃起不全	0 (0.0)	1 (0.7)
Acquired hydrocele	後天性陰嚢水瘤	0 (0.0)	1 (0.7)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1 (0.7)	2 (1.4)
Pyrexia	発熱	1 (0.7)	1 (0.7)
Oedema due to renal disease	腎疾患による浮腫	0 (0.0)	1 (0.7)
Investigations	臨床検査	1 (0.7)	2 (1.4)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1 (0.7)	1 (0.7)
Blood pressure increased	血圧上昇	0 (0.0)	1 (0.7)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	6 (4.3)	11 (7.9)
Arteriovenous fistula site complication	動静脈瘻部位合併症	3 (2.2)	2 (1.4)
Shunt stenosis	シャント狭窄	1 (0.7)	4 (2.9)
Wound	創傷	1 (0.7)	1 (0.7)
Contusion	挫傷	0 (0.0)	2 (1.4)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	1 (0.7)
Ligament sprain	靱帯捻挫	0 (0.0)	1 (0.7)
Shunt occlusion	シャント閉塞	1 (0.7)	0 (0.0)
Procedural hypotension	処置による低血圧	0 (0.0)	1 (0.7)
Traumatic haemothorax	外傷性血胸	0 (0.0)	1 (0.7)
Surgical and medical procedures	外科および内科処置	0 (0.0)	2 (1.4)
Arteriovenous fistula operation	動静脈瘻手術	0 (0.0)	2 (1.4)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Note(s): N1: number of subjects interrupted the study drug.
Source: t_14_3_1_13_1.sas

5.3.5.3—4 Table 14.3.1.13.1 より引用

表 2.7.4.9－72　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Subjects with at least one adverse event		136(90.1)	141(92.2)
Infections and infestations	感染症および寄生虫症	74(49.0)	76(49.7)
Nasopharyngitis	上咽頭炎	37(24.5)	43(28.1)
Conjunctivitis	結膜炎	7(4.6)	4(2.6)
Influenza	インフルエンザ	7(4.6)	2(1.3)
Cystitis	膀胱炎	6(4.0)	9(5.9)
Urinary tract infection	尿路感染	6(4.0)	4(2.6)
Bronchitis	気管支炎	5(3.3)	4(2.6)
Pneumonia	肺炎	4(2.6)	3(2.0)
Gastroenteritis	胃腸炎	4(2.6)	1(0.7)
Cellulitis	蜂巣炎	3(2.0)	0(0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	1(0.7)	4(2.6)
Herpes zoster	帯状疱疹	1(0.7)	4(2.6)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.3)	8(5.2)
Iron deficiency anaemia	鉄欠乏性貧血	2(1.3)	6(3.9)
Metabolism and nutrition disorders	代謝および栄養障害	22(14.6)	34(22.2)
Hyperuricaemia	高尿酸血症	5(3.3)	4(2.6)
Decreased appetite	食欲減退	3(2.0)	1(0.7)
Metabolic acidosis	代謝性アシドーシス	2(1.3)	6(3.9)
Dehydration	脱水	2(1.3)	4(2.6)
Hyperphosphataemia	高リン酸塩血症	2(1.3)	4(2.6)
Hyperkalaemia	高カリウム血症	1(0.7)	5(3.3)

表 2.7.4.9－72　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Psychiatric disorders	精神障害	7(4.6)	8(5.2)
Insomnia	不眠症	6(4.0)	5(3.3)
Nervous system disorders	神経系障害	11(7.3)	16(10.5)
Headache	頭痛	5(3.3)	7(4.6)
Eye disorders	眼障害	18(11.9)	27(17.6)
Cataract	白内障	4(2.6)	3(2.0)
Dry eye	ドライアイ	4(2.6)	0(0.0)
Blepharitis	眼瞼炎	3(2.0)	2(1.3)
Retinal haemorrhage	網膜出血	2(1.3)	5(3.3)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	4(2.6)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	3(2.0)
Ear and labyrinth disorders	耳および迷路障害	4(2.6)	5(3.3)
Vertigo	回転性めまい	2(1.3)	4(2.6)
Cardiac disorders	心臓障害	11(7.3)	7(4.6)
Cardiac failure chronic	慢性心不全	3(2.0)	0(0.0)
Vascular disorders	血管障害	8(5.3)	16(10.5)
Hypertension	高血圧	2(1.3)	11(7.2)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	12(7.9)	16(10.5)
Cough	咳嗽	4(2.6)	4(2.6)
Pleural effusion	胸水	2(1.3)	3(2.0)
Rhinitis allergic	アレルギー性鼻炎	2(1.3)	3(2.0)

表 2.7.4.9－72　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Gastrointestinal disorders	胃腸障害	59(39.1)	56(36.6)
Diarrhoea	下痢	18(11.9)	8(5.2)
Constipation	便秘	14(9.3)	11(7.2)
Vomiting	嘔吐	10(6.6)	3(2.0)
Nausea	悪心	6(4.0)	5(3.3)
Dental caries	齲歯	4(2.6)	4(2.6)
Abdominal pain upper	上腹部痛	3(2.0)	2(1.3)
Gastrooesophageal reflux disease	胃食道逆流性疾患	3(2.0)	2(1.3)
Abdominal pain	腹痛	3(2.0)	0(0.0)
Abdominal discomfort	腹部不快感	2(1.3)	3(2.0)
Stomatitis	口内炎	2(1.3)	3(2.0)
Periodontal disease	歯周病	1(0.7)	3(2.0)
Large intestine polyp	大腸ポリープ	1(0.7)	3(2.0)
Hepatobiliary disorders	肝胆道系障害	8(5.3)	5(3.3)
Hepatic function abnormal	肝機能異常	3(2.0)	2(1.3)

表 2.7.4.9－72　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	35(23.2)	42(27.5)
Pruritus	そう痒症	7(4.6)	8(5.2)
Eczema	湿疹	5(3.3)	8(5.2)
Dermatitis contact	接触皮膚炎	4(2.6)	4(2.6)
Haemorrhage subcutaneous	皮下出血	3(2.0)	3(2.0)
Rash	発疹	3(2.0)	2(1.3)
Eczema asteatotic	皮脂欠乏性湿疹	3(2.0)	1(0.7)
Skin ulcer	皮膚潰瘍	3(2.0)	1(0.7)
Dry skin	皮膚乾燥	3(2.0)	0(0.0)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	31(20.5)	35(22.9)
Back pain	背部痛	6(4.0)	5(3.3)
Muscle spasms	筋痙縮	4(2.6)	7(4.6)
Arthritis	関節炎	4(2.6)	2(1.3)
Arthralgia	関節痛	3(2.0)	3(2.0)
Osteoporosis	骨粗鬆症	3(2.0)	1(0.7)
Spinal osteoarthritis	変形性脊椎症	3(2.0)	1(0.7)
Myalgia	筋肉痛	3(2.0)	0(0.0)
Musculoskeletal pain	筋骨格痛	1(0.7)	4(2.6)
Osteoarthritis	変形性関節症	1(0.7)	4(2.6)
Renal and urinary disorders	腎および尿路障害	25(16.6)	31(20.3)
Chronic kidney disease	慢性腎臓病	9(6.0)	14(9.2)
Renal impairment	腎機能障害	8(5.3)	8(5.2)
End stage renal disease	末期腎疾患	3(2.0)	1(0.7)

表 2.7.4.9－72　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	5(3.3)	2(1.3)
Benign prostatic hyperplasia	良性前立腺肥大症	3(2.0)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	25(16.6)	16(10.5)
Oedema peripheral	末梢性浮腫	11(7.3)	5(3.3)
Pyrexia	発熱	8(5.3)	1(0.7)
Malaise	倦怠感	5(3.3)	1(0.7)
Investigations	臨床検査	13(8.6)	12(7.8)
Blood creatinine increased	血中クレアチニン増加	3(2.0)	2(1.3)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(1.3)	3(2.0)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	29(19.2)	26(17.0)
Contusion	挫傷	11(7.3)	7(4.6)
Skin abrasion	皮膚擦過傷	5(3.3)	2(1.3)
Spinal compression fracture	脊椎圧迫骨折	3(2.0)	2(1.3)
Heat illness	熱中症	0(0.0)	3(2.0)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Source: t_14_3_1_3_1_1.sas

5.3.5.3—4 表 14.3.1.3.1.1 より引用

表 2.7.4.9－73　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Subjects with at least one adverse event		154(95.1)	158(98.1)
Infections and infestations	感染症および寄生虫症	107(66.0)	111(68.9)
Nasopharyngitis	上咽頭炎	74(45.7)	73(45.3)
Gastroenteritis	胃腸炎	12(7.4)	1(0.6)
Conjunctivitis	結膜炎	11(6.8)	4(2.5)
Influenza	インフルエンザ	9(5.6)	12(7.5)
Upper respiratory tract infection	上気道感染	7(4.3)	8(5.0)
Pneumonia	肺炎	7(4.3)	2(1.2)
Bronchitis	気管支炎	5(3.1)	6(3.7)
Hordeolum	麦粒腫	4(2.5)	1(0.6)
Pharyngitis	咽頭炎	3(1.9)	7(4.3)
Periodontitis	歯周炎	3(1.9)	5(3.1)
Tinea pedis	足部白癬	2(1.2)	6(3.7)
Shunt infection	シャント感染	2(1.2)	5(3.1)
Immune system disorders	免疫系障害	4(2.5)	14(8.7)
Seasonal allergy	季節性アレルギー	4(2.5)	12(7.5)
Metabolism and nutrition disorders	代謝および栄養障害	19(11.7)	21(13.0)
Decreased appetite	食欲減退	9(5.6)	4(2.5)
Hypocarnitinaemia	低カルニチン血症	4(2.5)	2(1.2)
Psychiatric disorders	精神障害	7(4.3)	7(4.3)
Insomnia	不眠症	6(3.7)	6(3.7)

表 2.7.4.9－73　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Nervous system disorders	神経系障害	36(22.2)	24(14.9)
Headache	頭痛	13(8.0)	5(3.1)
Dizziness	浮動性めまい	8(4.9)	5(3.1)
Cerebral infarction	脳梗塞	1(0.6)	5(3.1)
Eye disorders	眼障害	35(21.6)	35(21.7)
Retinal haemorrhage	網膜出血	16(9.9)	10(6.2)
Conjunctival haemorrhage	結膜出血	4(2.5)	3(1.9)
Ear and labyrinth disorders	耳および迷路障害	8(4.9)	6(3.7)
Vertigo	回転性めまい	5(3.1)	2(1.2)
Cardiac disorders	心臓障害	13(8.0)	21(13.0)
Atrial fibrillation	心房細動	0(0.0)	4(2.5)
Vascular disorders	血管障害	20(12.3)	22(13.7)
Hypertension	高血圧	6(3.7)	6(3.7)
Hypotension	低血圧	5(3.1)	3(1.9)
Internal haemorrhage	内出血	3(1.9)	4(2.5)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	21(13.0)	31(19.3)
Rhinitis allergic	アレルギー性鼻炎	5(3.1)	2(1.2)
Epistaxis	鼻出血	4(2.5)	2(1.2)
Upper respiratory tract inflammation	上気道の炎症	4(2.5)	2(1.2)
Hiccups	しゃっくり	1(0.6)	4(2.5)

表 2.7.4.9－73　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Gastrointestinal disorders	胃腸障害	67(41.4)	81(50.3)
Diarrhoea	下痢	25(15.4)	24(14.9)
Vomiting	嘔吐	10(6.2)	17(10.6)
Nausea	悪心	10(6.2)	2(1.2)
Constipation	便秘	7(4.3)	12(7.5)
Gastrooesophageal reflux disease	胃食道逆流性疾患	5(3.1)	6(3.7)
Dental caries	齲歯	5(3.1)	5(3.1)
Haemorrhoids	痔核	4(2.5)	3(1.9)
Abdominal discomfort	腹部不快感	4(2.5)	2(1.2)
Large intestine polyp	大腸ポリープ	3(1.9)	5(3.1)
Stomatitis	口内炎	2(1.2)	4(2.5)
Abdominal pain upper	上腹部痛	0(0.0)	4(2.5)
Periodontal disease	歯周病	0(0.0)	4(2.5)

表 2.7.4.9－73　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	56(34.6)	37(23.0)
Pruritus	そう痒症	12(7.4)	9(5.6)
Eczema	湿疹	10(6.2)	8(5.0)
Haemorrhage subcutaneous	皮下出血	7(4.3)	2(1.2)
Dermatitis contact	接触皮膚炎	5(3.1)	3(1.9)
Skin exfoliation	皮膚剥脱	5(3.1)	2(1.2)
Rash	発疹	5(3.1)	0(0.0)
Drug eruption	薬疹	4(2.5)	0(0.0)
Ingrowing nail	嵌入爪	4(2.5)	0(0.0)
Dermatitis	皮膚炎	3(1.9)	4(2.5)
Xeroderma	乾皮症	3(1.9)	4(2.5)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	66(40.7)	56(34.8)
Back pain	背部痛	15(9.3)	11(6.8)
Pain in extremity	四肢痛	13(8.0)	4(2.5)
Arthralgia	関節痛	10(6.2)	11(6.8)
Myalgia	筋肉痛	9(5.6)	5(3.1)
Musculoskeletal pain	筋骨格痛	7(4.3)	8(5.0)
Periarthritis	関節周囲炎	7(4.3)	5(3.1)
Muscle spasms	筋痙縮	7(4.3)	4(2.5)
Osteoarthritis	変形性関節症	7(4.3)	2(1.2)
Neck pain	頚部痛	4(2.5)	5(3.1)
Spinal osteoarthritis	変形性脊椎症	4(2.5)	3(1.9)
Lumbar spinal stenosis	腰部脊柱管狭窄症	4(2.5)	1(0.6)

表 2.7.4.9－73　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	18(11.1)	18(11.2)
Pyrexia	発熱	5(3.1)	3(1.9)
Oedema peripheral	末梢性浮腫	5(3.1)	0(0.0)
Investigations	臨床検査	14(8.6)	23(14.3)
Blood pressure decreased	血圧低下	5(3.1)	7(4.3)
Blood pressure increased	血圧上昇	3(1.9)	6(3.7)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	75(46.3)	86(53.4)
Shunt stenosis	シャント狭窄	23(14.2)	26(16.1)
Contusion	挫傷	21(13.0)	19(11.8)
Wound	創傷	10(6.2)	7(4.3)
Skin abrasion	皮膚擦過傷	9(5.6)	15(9.3)
Thermal burn	熱傷	7(4.3)	3(1.9)
Procedural hypotension	処置による低血圧	5(3.1)	6(3.7)
Shunt occlusion	シャント閉塞	4(2.5)	4(2.5)
Tooth fracture	歯牙破折	1(0.6)	4(2.5)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Source: t_14_3_1_3_1_2.sas

5.3.5.3—4 表 14.3.1.3.1.2 より引用

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Subjects with at least one adverse event		177(87.6)	218(92.0)	38(90.5)	433(90.0)
Infections and infestations	感染症および寄生虫症	90(44.6)	138(58.2)	22(52.4)	250(52.0)
Nasopharyngitis	上咽頭炎	42(20.8)	91(38.4)	6(14.3)	139(28.9)
Influenza	インフルエンザ	11(5.4)	9(3.8)	0(0.0)	20(4.2)
Conjunctivitis	結膜炎	7(3.5)	12(5.1)	1(2.4)	20(4.2)
Gastroenteritis	胃腸炎	4(2.0)	13(5.5)	0(0.0)	17(3.5)
Pneumonia	肺炎	4(2.0)	10(4.2)	1(2.4)	15(3.1)
Upper respiratory tract infection	上気道感染	3(1.5)	8(3.4)	2(4.8)	13(2.7)
Bronchitis	気管支炎	5(2.5)	6(2.5)	1(2.4)	12(2.5)
Cystitis	膀胱炎	7(3.5)	3(1.3)	0(0.0)	10(2.1)
Catheter site infection	カテーテル留置部位感染	0(0.0)	0(0.0)	10(23.8)	10(2.1)
Urinary tract infection	尿路感染	7(3.5)	0(0.0)	0(0.0)	7(1.5)
Herpes zoster	帯状疱疹	2(1.0)	5(2.1)	0(0.0)	7(1.5)
Cellulitis	蜂巣炎	3(1.5)	1(0.4)	1(2.4)	5(1.0)
Hordeolum	麦粒腫	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Peritonitis	腹膜炎	0(0.0)	0(0.0)	5(11.9)	5(1.0)
Body tinea	体部白癬	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Diverticulitis	憩室炎	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Folliculitis	毛包炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Sepsis	敗血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.0)	10(4.2)	2(4.8)	14(2.9)
Anaemia	貧血	0(0.0)	2(0.8)	1(2.4)	3(0.6)
Nephrogenic anaemia	腎性貧血	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Metabolism and nutrition disorders	代謝および栄養障害	29(14.4)	20(8.4)	5(11.9)	54(11.2)
Decreased appetite	食欲減退	3(1.5)	9(3.8)	3(7.1)	15(3.1)
Hyperkalaemia	高カリウム血症	5(2.5)	1(0.4)	0(0.0)	6(1.2)
Hyperphosphataemia	高リン酸塩血症	3(1.5)	2(0.8)	1(2.4)	6(1.2)
Hyperuricaemia	高尿酸血症	5(2.5)	0(0.0)	0(0.0)	5(1.0)
Dehydration	脱水	3(1.5)	0(0.0)	1(2.4)	4(0.8)
Hypoalbuminaemia	低アルブミン血症	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Psychiatric disorders	精神障害	9(4.5)	10(4.2)	3(7.1)	22(4.6)
Insomnia	不眠症	6(3.0)	8(3.4)	2(4.8)	16(3.3)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Nervous system disorders	神経系障害	13(6.4)	47(19.8)	5(11.9)	65(13.5)
Headache	頭痛	6(3.0)	20(8.4)	0(0.0)	26(5.4)
Dizziness	浮動性めまい	3(1.5)	8(3.4)	1(2.4)	12(2.5)
Neuropathy peripheral	末梢性ニューロパチー	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Cerebral infarction	脳梗塞	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Eye disorders	眼障害	19(9.4)	37(15.6)	6(14.3)	62(12.9)
Retinal haemorrhage	網膜出血	2(1.0)	16(6.8)	2(4.8)	20(4.2)
Dry eye	ドライアイ	4(2.0)	2(0.8)	1(2.4)	7(1.5)
Cataract	白内障	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Retinal vein occlusion	網膜静脈閉塞	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Ear and labyrinth disorders	耳および迷路障害	4(2.0)	9(3.8)	0(0.0)	13(2.7)
Vertigo	回転性めまい	2(1.0)	6(2.5)	0(0.0)	8(1.7)
Cardiac disorders	心臓障害	11(5.4)	17(7.2)	2(4.8)	30(6.2)
Cardiac failure chronic	慢性心不全	3(1.5)	1(0.4)	1(2.4)	5(1.0)
Myocardial ischaemia	心筋虚血	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Vascular disorders	血管障害	14(6.9)	23(9.7)	6(14.3)	43(8.9)
Hypertension	高血圧	7(3.5)	6(2.5)	0(0.0)	13(2.7)
Hypotension	低血圧	1(0.5)	5(2.1)	1(2.4)	7(1.5)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0(0.0)	4(1.7)	2(4.8)	6(1.2)
Orthostatic hypotension	起立性低血圧	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	2(4.8)	2(0.4)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	16(7.9)	28(11.8)	3(7.1)	47(9.8)
Cough	咳嗽	4(2.0)	3(1.3)	2(4.8)	9(1.9)
Rhinitis allergic	アレルギー性鼻炎	2(1.0)	6(2.5)	0(0.0)	8(1.7)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	5(2.1)	1(2.4)	6(1.2)

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Gastrointestinal disorders	胃腸障害	74(36.6)	89(37.6)	18(42.9)	181(37.6)
Diarrhoea	下痢	21(10.4)	36(15.2)	8(19.0)	65(13.5)
Vomiting	嘔吐	11(5.4)	13(5.5)	4(9.5)	28(5.8)
Constipation	便秘	17(8.4)	9(3.8)	1(2.4)	27(5.6)
Nausea	悪心	9(4.5)	12(5.1)	3(7.1)	24(5.0)
Dental caries	齲歯	6(3.0)	5(2.1)	1(2.4)	12(2.5)
Gastrooesophageal reflux disease	胃食道逆流性疾患	4(2.0)	6(2.5)	0(0.0)	10(2.1)
Abdominal pain	腹痛	4(2.0)	4(1.7)	0(0.0)	8(1.7)
Abdominal discomfort	腹部不快感	2(1.0)	4(1.7)	2(4.8)	8(1.7)
Abdominal pain upper	上腹部痛	3(1.5)	0(0.0)	3(7.1)	6(1.2)
Enterocolitis	腸炎	1(0.5)	3(1.3)	2(4.8)	6(1.2)
Gastric polyps	胃ポリープ	0(0.0)	1(0.4)	2(4.8)	3(0.6)
Gingival bleeding	歯肉出血	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Hiatus hernia	裂孔ヘルニア	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hepatobiliary disorders	肝胆道系障害	9(4.5)	6(2.5)	0(0.0)	15(3.1)
Hepatic function abnormal	肝機能異常	4(2.0)	1(0.4)	0(0.0)	5(1.0)

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	37(18.3)	65(27.4)	5(11.9)	107(22.2)
Pruritus	そう痒症	7(3.5)	14(5.9)	0(0.0)	21(4.4)
Eczema	湿疹	6(3.0)	11(4.6)	0(0.0)	17(3.5)
Dermatitis contact	接触皮膚炎	4(2.0)	5(2.1)	2(4.8)	11(2.3)
Haemorrhage subcutaneous	皮下出血	3(1.5)	7(3.0)	0(0.0)	10(2.1)
Rash	発疹	3(1.5)	6(2.5)	1(2.4)	10(2.1)
Eczema asteatotic	皮脂欠乏性湿疹	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Ingrowing nail	嵌入爪	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Skin exfoliation	皮膚剥脱	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Dermatitis	皮膚炎	0(0.0)	3(1.3)	1(2.4)	4(0.8)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	35(17.3)	77(32.5)	4(9.5)	116(24.1)
Back pain	背部痛	9(4.5)	17(7.2)	2(4.8)	28(5.8)
Pain in extremity	四肢痛	3(1.5)	14(5.9)	0(0.0)	17(3.5)
Arthralgia	関節痛	3(1.5)	12(5.1)	1(2.4)	16(3.3)
Muscle spasms	筋痙縮	5(2.5)	10(4.2)	0(0.0)	15(3.1)
Myalgia	筋肉痛	3(1.5)	10(4.2)	0(0.0)	13(2.7)
Musculoskeletal pain	筋骨格痛	1(0.5)	8(3.4)	0(0.0)	9(1.9)
Osteoarthritis	変形性関節症	1(0.5)	7(3.0)	0(0.0)	8(1.7)
Periarthritis	関節周囲炎	0(0.0)	7(3.0)	0(0.0)	7(1.5)
Arthritis	関節炎	4(2.0)	0(0.0)	1(2.4)	5(1.0)

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Renal and urinary disorders	腎および尿路障害	34(16.8)	6(2.5)	3(7.1)	43(8.9)
Renal impairment	腎機能障害	11(5.4)	0(0.0)	1(2.4)	12(2.5)
Chronic kidney disease	慢性腎臓病	10(5.0)	1(0.4)	0(0.0)	11(2.3)
End stage renal disease	末期腎疾患	4(2.0)	0(0.0)	0(0.0)	4(0.8)
Haematuria	血尿	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Reproductive system and breast disorders	生殖系および乳房障害	6(3.0)	5(2.1)	1(2.4)	12(2.5)
Benign prostatic hyperplasia	良性前立腺肥大症	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	1(0.4)	1(2.4)	2(0.4)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	29(14.4)	20(8.4)	6(14.3)	55(11.4)
Oedema peripheral	末梢性浮腫	13(6.4)	5(2.1)	0(0.0)	18(3.7)
Pyrexia	発熱	8(4.0)	7(3.0)	2(4.8)	17(3.5)
Malaise	倦怠感	5(2.5)	0(0.0)	0(0.0)	5(1.0)
Oedema due to renal disease	腎疾患による浮腫	4(2.0)	0(0.0)	1(2.4)	5(1.0)
Chest pain	胸痛	2(1.0)	0(0.0)	1(2.4)	3(0.6)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Investigations	臨床検査	14(6.9)	19(8.0)	3(7.1)	36(7.5)
Blood pressure decreased	血圧低下	0(0.0)	5(2.1)	0(0.0)	5(1.0)
C-reactive protein increased	C－反応性蛋白増加	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Blood potassium decreased	血中カリウム減少	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Weight decreased	体重減少	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－74　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	35(17.3)	99(41.8)	6(14.3)	140(29.1)
Contusion	挫傷	14(6.9)	25(10.5)	1(2.4)	40(8.3)
Shunt stenosis	シャント狭窄	2(1.0)	32(13.5)	0(0.0)	34(7.1)
Skin abrasion	皮膚擦過傷	5(2.5)	14(5.9)	0(0.0)	19(4.0)
Wound	創傷	1(0.5)	11(4.6)	0(0.0)	12(2.5)
Thermal burn	熱傷	1(0.5)	8(3.4)	0(0.0)	9(1.9)
Spinal compression fracture	脊椎圧迫骨折	5(2.5)	1(0.4)	0(0.0)	6(1.2)
Procedural hypotension	処置による低血圧	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Shunt occlusion	シャント閉塞	0(0.0)	4(1.7)	1(2.4)	5(1.0)
Tooth fracture	歯牙破折	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Heat stroke	熱射病	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Traumatic haemothorax	外傷性血胸	0(0.0)	0(0.0)	1(2.4)	1(0.2)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Source: t_14_3_1_3_2.sas

5.3.5.3—4 Table 14.3.1.3.2 より引用

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）

AESI	PT Code	PT Name	SOC
Hypersen i i ity	10081035	Acquired C1 inhibitor de ici ncy	
Hypersen i i ity	10048799	A ute generalised exan hematous pustulo is	
Hypersen i i ity	10069773	Administra i n r lated reac i n	
Hypersen i i ity	10075096	Administra i n ite derma i is	
Hypersen i i ity	10075099	Administra i n ite eczema	
Hypersen i i ity	10075102	Administra i n ite hypersen i i ity	
Hypersen i i ity	10071156	Administra i n ite rash	
Hypersen i i ity	10075964	Administra i n ite recal l reac ion	
Hypersen i i ity	10075109	Administra i n ite ur ic ria	
Hypersen i i ity	10075969	Administra i n ite vasculi is	
Hypersen i i ity	10052613	A ler ic bronchi is	
Hypersen i i ity	10059447	A ler ic co i is	
Hypersen i i ity	10053779	A ler ic cough	
Hypersen i i ity	1005 394	A ler ic cys i is	
Hypersen i i ity	10075185	A ler ic eo in philia	
Hypersen i i ity	1007 308	A ler ic gastro nteri is	
Hypersen i i ity	10071198	A ler ic hepa i is	
Hypersen i i ity	1005 380	A ler ic k ra i is	
Hypersen i i ity	10060934	A ler ic oedema	
Hypersen i i ity	10075072	A ler ic o i is externa	
Hypersen i i ity	10061557	A ler ic o i is media	
Hypersen i i ity	10050839	A ler ic ph ryngi is	
Hypersen i i ity	10078853	A ler ic reaction to excipient	
Hypersen i i ity	10063532	A ler ic respirat ry isease	
Hypersen i i ity	10063527	A ler ic respirat ry symptom	
Hypersen i i ity	10049153	A ler ic inu i is	
Hypersen i i ity	10079554	A ler ic stomati is	
Hypersen i i ity	10066173	A ler ic tr nsfu ion reac i n	
Hypersen i i ity	10075479	A lergy lert test po i ive	
Hypersen i i ity	1005 352	A lergy test po i ive	
Hypersen i i ity	10074079	A lergy to immuno l bu in ther py	
Hypersen i i ity	10077279	A lergy to sur ical utures	
Hypersen i i ity	10055048	A lergy to vaccine	
Hypersen i i ity	10002198	Anaphylac ic reac i n	
Hypersen i i ity	10002199	Anaphylac ic sho k	
Hypersen i i ity	10067113	Anaphylac ic transfusion reac ion	
Hypersen i i ity	10002216	Anaphylact id reaction	
Hypersen i i ity	10063119	Anaphylact id hock	
Hypersen i i ity	10002222	Anaphyla is treatment	
Hypersen i i ity	10002424	Angioedema	
Hypersen i i ity	10064059	An laller ic ther py	
Hypersen i i ity	10065514	An iendomysi l n ibody positive	
Hypersen i i ity	10050894	An i neutr ph l cytopla mic n ibody posi ive vas ulitis	
Hypersen i i ity	10003036	Applica ion site de mati is	
Hypersen i i ity	10050099	Applica ion site ecz ma	
Hypersen i i ity	10063683	Applica ion site hypersensi ivity	
Hypersen i i ity	10003054	Applica ion site ra h	
Hypersen i i ity	10076024	Applica ion site rec ll reac ion	
Hypersen i i ity	10050104	Applica ion site ur icaria	
Hypersen i i ity	10076027	Applica ion site vas ulitis	
Hypersen i i ity	10061430	Ar hri is allergic	
Hypersen i i ity	10075084	A pirin-exac cbated re piratory disease	
Hypersen i i ity	10081492	At pic cou h	
Hypersen i i ity	10003645	At py	
Hypersen i i ity	10005149	Blephari is ll rgic	
Hypersen i i ity	10005589	Blood immunoglobulin E bn rm l	
Hypersen i i ity	10005591	Blood immunoglobulin E increased	
Hypersen i i ity	10006404	Br moderma	
Hypersen i i ity	10006482	Br ncho pasm	
Hypersen i i ity	10073992	Ca heter ite d rma i is	
Hypersen i i ity	10073995	Ca heter ite eczema	
Hypersen i i ity	10073998	Ca heter ite h persensi ivity	
Hypersen i i ity	10052271	Ca heter ite ra h	
Hypersen i i ity	10052272	Ca heter ite ur icaria	
Hypersen i i ity	10074014	Ca heter ite vasculitis	
Hypersen i i ity	1007 399	Chr nic eosinophi ic rhinosinusi is	
Hypersen i i ity	1007 380	Chr nic h perplas ic eo inophi ic inu i is	
Hypersen i i ity	10009192	Cir ulatory collapse	
Hypersen i i ity	10052250	Cir umor l oedema	
Hypersen i i ity	10081703	Cir umor l sw lling	
Hypersen i i ity	10010726	Conjunc ival oedema	
Hypersen i i ity	10010744	Conjunc i i is ller ic	
Hypersen i i ity	10067510	Contact st ma i is	
Hypersen i i ity	10066973	Contrast media a lergy	
Hypersen i i ity	10010836	Contrast media reac i n	
Hypersen i i ity	10011033	Corne l oedema	
Hypersen i i ity	10011686	Cut neous vasculi is	
Hypersen i i ity	10062918	Dennie-Morgan fold	
Hypersen i i ity	10012431	Dermati is	
Hypersen i i ity	10012432	Dermati is aoneiform	
Hypersen i i ity	10012434	Dermati is all rgic	
Hypersen i i ity	10012438	Dermati is atopic	
Hypersen i i ity	10012441	Dermati is bu lous	
Hypersen i i ity	10012442	Dermati is contact	
Hypersen i i ity	10012455	Dermati is exfolia ive	
Hypersen i i ity	10012456	Dermati is exfolia ive generalised	
Hypersen i i ity	10012468	Dermati is herpe if rmis	
Hypersen i i ity	10012470	Dermati is infected	
Hypersen i i ity	10058675	Dermati is ps riasif rm	
Hypersen i i ity	10072867	De ice a lergy	
Hypersen i i ity	10076665	Di ly is membrane reaction	
Hypersen i i ity	10070559	Distribu ive sho k	
Hypersen i i ity	10076470	Do umented hypersen i ivity to administered product	
Hypersen i i ity	10013687	Drug rup i n	
Hypersen i i ity	10013700	Drug hyp rsen i ivity	
Hypersen i i ity	1007 350	Drug provoca ion test	
Hypersen i i ity	10073508	Drug reac i n wi h eosinophi ia nd syst mic symptoms	
Hypersen i i ity	10014184	Ecz ma	
Hypersen i i ity	10014198	Ecz ma infan le	
Hypersen i i ity	10014201	Ecz ma nummular	
Hypersen i i ity	10066042	Ecz ma vaccinatum	
Hypersen i i ity	10058681	Ecz ma vesicular	
Hypersen i i ity	10055182	Ecz ma we ping	
Hypersen i i ity	1005 387	Enc ph li is ll rgic	
Hypersen i i ity	10014627	Enc ph l pa hy a l r ic	
Hypersen i i ity	10078117	Eosin phi ic gr nul mato is wi h polyangi is	
Hypersen i i ity	10059284	Epid rm l necrosis	
Hypersen i i ity	10053177	Epid rm lysis	
Hypersen i i ity	10014989	Epid rm lysis bullosa	
Hypersen i i ity	10015029	Epi lot ic oed ma	
Hypersen i i ity	10015218	Ery h ma mul if rme	
Hypersen i i ity	10015226	Ery h ma nodo um	
Hypersen i i ity	10064579	Exfo iative rash	
Hypersen i i ity	10015907	Eye ll rgy	
Hypersen i i ity	10052139	Eye oed ma	
Hypersen i i ity	10015967	Eye swel ing	
Hypersen i i ity	10015993	Eyelid oedema	
Hypersen i i ity	10016029	Face oedema	
Hypersen i i ity	10016741	Fixed rup ion	
Hypersen i i ity	10018258	Gi nt papll ry c njunctivitis	
Hypersen i i ity	1004 305	Gingival oedema	
Hypersen i i ity	10018291	Gingival sw lling	
Hypersen i i ity	10066837	Gl ich's s ndr me	
Hypersen i i ity	10059499	Ha m rrhagic ur icaria	
Hypersen i i ity	10058898	Hand derma i is	
Hypersen i i ity	10019617	Heno h-S h nl in purpura	
Hypersen i i ity	10069440	Heno h-S h nl in purpura nephri is	
Hypersen i i ity	10062506	Heparin-induced hr mbocytopenia	
Hypersen i i ity	10019860	Hereditary ngioed ma	
Hypersen i i ity	10080955	Hereditary ngioed ma wi h C1 est rase inh bit r deficiency	
Hypersen i i ity	10020751	Hypersen i ivity	
Hypersen i i ity	10081004	Hypersen i ivity myocarditis	
Hypersen i i ity	10081988	Hypersen i ivity pneumoni is	
Hypersen i i ity	10020764	Hypersen i ivity vasculi is	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Hyp rs n i ivity	10021247	I iopa hic ur icaria	
Hyp rs n i ivity	10067142	Immediate post-injec ion reac ion	
Hyp rs n i ivity	10074667	Immune hrombocyt p nic purpura	
Hyp rs n i ivity	10070581	Immune tolerance induc i n	
Hyp rs n i ivity	10077665	Immune-me iated adverse reac ion	
Hyp rs n i ivity	10082452	Immune-me iated pneumoni is	
Hyp rs n i ivity	10063855	Implant ite derma i is	
Hyp rs n i ivity	10063858	Implant ite hypers n i i ity	
Hyp rs n i ivity	10063786	Implant ite ra h	
Hyp rs n i ivity	10063787	Implant ite ur ic ria	
Hyp rs n i ivity	10073168	Inci i n ite derma i is	
Hyp rs n i ivity	10073411	Inci ion ite ra h	
Hyp rs n i ivity	10051792	Infu ion related reac ion	
Hyp rs n i ivity	10065458	Infu ion site d rma i is	
Hyp rs n i ivity	10074850	Infu ion site ecz ma	
Hyp rs n i ivity	10065471	Infu ion site h p rsensi ivity	
Hyp rs n i ivity	10059830	Infu ion site ra h	
Hyp rs n i ivity	10076085	Infu ion site recall reac ion	
Hyp rs n i ivity	10065490	Infu ion site ur icaria	
Hyp rs n i ivity	10074851	Infu ion site vas uli is	
Hyp rs n i ivity	10071152	Injec ion related reaction	
Hyp rs n i ivity	10022056	Injec ion site d rma i is	
Hyp rs n i ivity	10066221	Injec ion site ecz ma	
Hyp rs n i ivity	10022071	Injec ion site h persensitivity	
Hyp rs n i ivity	10022094	Injec ion site ra h	
Hyp rs n i ivity	10066797	Injec ion site recall reac ion	
Hyp rs n i ivity	10022107	Injec ion site ur icaria	
Hyp rs n i ivity	10067995	Injec ion site vas uli is	
Hyp rs n i ivity	10073612	Ins i la ion ite hypersen i i ity	
Hyp rs n i ivity	10073622	Ins i la ion ite rash	
Hyp rs n i ivity	10073627	Ins i la ion ite ur icaria	
Hyp rs n i ivity	10067972	Inters i ial ranul matous derma i is	
Hyp rs n i ivity	10076229	Intes inal angioedema	
Hyp rs n i ivity	10052098	Iodine llergy	
Hyp rs n i ivity	10051891	K po ,l s v ric llform erup ion	
Hyp rs n i ivity	10069167	K unis syndrome	
Hyp rs n i ivity	10023845	L nyrge l oed ma	
Hyp rs n i ivity	10064866	L nyn i is a ler ic	
Hyp rs n i ivity	10023891	L nyngo pasm	
Hyp rs n i ivity	100238 3	L nyngotra he l oed ma	
Hyp rs n i ivity	10070492	Limb l swel ing	
Hyp rs n i ivity	10024558	Lip oedema	
Hyp rs n i ivity	10024570	Lip sw lling	
Hyp rs n i ivity	10076606	Mast ce l degr nula i n gres nt	
Hyp rs n i ivity	10075572	Medic l device ite derma i is	
Hyp rs n i ivity	10075575	Medic l device ite eczema	
Hyp rs n i ivity	10075579	Medic l device ite hyp rs n i ivity	
Hyp rs n i ivity	10075585	Medic l device ite rash	
Hyp rs n i ivity	10076140	Medic l device ite reca l reac ion	
Hyp rs n i ivity	10075588	Medic l device ite urtic ria	
Hyp rs n i ivity	100752 3	Mou h sw lling	
Hyp rs n i ivity	10056671	Mucocut neous ra h	
Hyp rs n i ivity	10028164	Mul iple all rgies	
Hyp rs n i ivity	10029120	Nephri is a ler ic	
Hyp rs n i ivity	10029415	Nikol ky's sign	
Hyp rs n i ivity	10075807	Nodul r ra h	
Hyp rs n i ivity	10030081	Oculomucocut neous syndrome	
Hyp rs n i ivity	1006 317	Oculore piratory syndrome	
Hyp rs n i ivity	10030110	Oed ma mou h	
Hyp rs n i ivity	1006 355	Oral ll rgy syndrome	
Hyp rs n i ivity	10067950	Oropharyngeal blistering	
Hyp rs n i ivity	100787 3	Oropharyngeal oed ma	
Hyp rs n i ivity	10031111	Oropharyngeal pasm	
Hyp rs n i ivity	10031118	Oropharyngeal swel ing	
Hyp rs n i ivity	10056998	P latal oedema	
Hyp rs n i ivity	100744 3	P latal sw lling	
Hyp rs n i ivity	10068809	P lisaded neutroph lic ranul matous derma i is	
Hyp rs n i ivity	10056872	P lpable purpura	
Hyp rs n i ivity	1007 332	Pathergy reac i n	
Hyp rs n i ivity	10034541	P rioral derma itis	
Hyp rs n i ivity	10034545	P riorbit l oed ma	
Hyp rs n i ivity	10056647	P riorbit l swel ing	
Hyp rs n i ivity	10034829	Pharynge l oed ma	
Hyp rs n i ivity	10082270	Pharynge l sw lling	
Hyp rs n i ivity	10060894	Procedural shock	
Hyp rs n i ivity	10063438	Pruritus ll rgic	
Hyp rs n i ivity	10037789	Radio ll rgosorbent test po i ive	
Hyp rs n i ivity	10037844	Rash	
Hyp rs n i ivity	10037855	Rash ry h matous	
Hyp rs n i ivity	10037857	Rash follicular	
Hyp rs n i ivity	10037858	Rash genera ised	
Hyp rs n i ivity	10037867	Rash ma ular	
Hyp rs n i ivity	10037868	Rash ma ulo-papular	
Hyp rs n i ivity	10059004	Rash ma ulovesi ul r	
Hyp rs n i ivity	10037870	Rash morbil iform	
Hyp rs n i ivity	10037871	Rash ne nat l	
Hyp rs n i ivity	10037879	Rash papulosquamous	
Hyp rs n i ivity	10037884	Rash pruri ic	
Hyp rs n i ivity	10037888	Rash pustul r	
Hyp rs n i ivity	10057984	Rash rube lif rm	
Hyp rs n i ivity	10037890	Rash sc rla inif rm	
Hyp rs n i ivity	10037898	Rash ve i ular	
Hyp rs n i ivity	100379 3	Reac i n to azo-dyes	
Hyp rs n i ivity	10037974	Reac i n to colouring	
Hyp rs n i ivity	10079925	Reac i n to ex ipient	
Hyp rs n i ivity	10037977	Reac i n to food addi ive	
Hyp rs n i ivity	10064788	Reac i n to preserva ives	
Hyp rs n i ivity	10038192	Red man syndrome	
Hyp rs n i ivity	10039085	Rhini is ll r ic	
Hyp rs n i ivity	10057431	S leral oedema	
Hyp rs n i ivity	10051126	S leri is a ler ic	
Hyp rs n i ivity	10039755	S rotal oedema	
Hyp rs n i ivity	10040400	S rum si kness	
Hyp rs n i ivity	10040402	S rum si kness- ike reac i n	
Hyp rs n i ivity	10040560	Shock	
Hyp rs n i ivity	10040581	Shock s mptom	
Hyp rs n i ivity	100408 3	Skin necrosis	
Hyp rs n i ivity	10040914	Skin reac i n	
Hyp rs n i ivity	10040934	Skin test po i ive	
Hyp rs n i ivity	1004 307	S lar ur icaria	
Hyp rs n i ivity	1004 316	S lvent s n i i ity	
Hyp rs n i ivity	10042033	Stevens-J hns n syndrome	
Hyp rs n i ivity	10074509	Stoma site hypersen i i ity	
Hyp rs n i ivity	10059071	Stoma site rash	
Hyp rs n i ivity	10042682	Swel ing face	
Hyp rs n i ivity	10042690	Swel ing of ey lid	
Hyp rs n i ivity	10042727	Swollen ton ue	
Hyp rs n i ivity	1007 325	S mmetric l drug-related int rtri inous and le ur l exan hema	
Hyp rs n i ivity	10079645	Therapeu ic product cross reac ivity	
Hyp rs n i ivity	10043967	T ngue oed ma	
Hyp rs n i ivity	100442 3	Toxic epid rmal ne roly is	
Hyp rs n i ivity	10057970	Toxic skin erup ion	
Hyp rs n i ivity	10044296	Tra heal oed ma	
Hyp rs n i ivity	10045240	T pe hypersen i i ity	
Hyp rs n i ivity	10054000	T pe I h persensi ivity	
Hyp rs n i ivity	10053614	T pe II immune c mplex me iated reac i n	
Hyp rs n i ivity	100536 3	T pe V h persen i i ity reaction	
Hyp rs n i ivity	10046735	Ur ic ria	
Hyp rs n i ivity	10046740	Ur ic ria h lin rgic	
Hyp rs n i ivity	10052568	Ur ic ria hronic	
Hyp rs n i ivity	10046742	Ur ic ria contact	
Hyp rs n i ivity	10046750	Ur ic ria papul r	
Hyp rs n i ivity	10046751	Ur ic ria physical	
Hyp rs n i ivity	10046752	Ur ic ria pi m ntosa	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

H persensi ivity	10046755	Ur ic ria ve iculosa	
H persensi ivity	10082290	Ur icarial derma i is	
H persensi ivity	10048820	Ur ic rial vasculi is	
H persensi ivity	10069477	Vaccina i n ite derma i is	
H persensi ivity	10076161	Vaccina i n ite eczema	
H persensi ivity	10069489	Vaccina i n ite exfolia ion	
H persensi ivity	10068880	Vaccina i n ite hypers n i i ity	
H persensi ivity	10069482	Vaccina i n ite rash	
H persensi ivity	10076188	Vaccina i n ite reca l reac i n	
H persensi ivity	10069622	Vaccina i n ite ur ic ria	
H persensi ivity	10076191	Vaccina i n ite vascu i is	
H persensi ivity	10069623	Vaccina i n ite ve icles	
H persensi ivity	10064483	Va in l exf lia ion	
H persensi ivity	10046943	Va in l ulc ra i n	
H persensi ivity	10047111	Vasculi ic ra h	
H persensi ivity	10081000	Vernal keratoc njunc ivi is	
H persensi ivity	10077117	Vess l puncture ite ra h	
H persensi ivity	10077813	Vess l puncture ite ve i les	
H persensi ivity	10047788	Vulval ulcera ion	
H persensi ivity	10071588	Vulvova in l ra h	
H persensi ivity	10050181	Vulvova in l ulcera ion	
H persensi ivity	10080783	Vulvova ini is ll rgic	
H pert n ion	1000 358	Accel rated h pert nsion	
H pert n ion	10005732	Blood pressure ambulat ry increased	
H pert n ion	10005739	Blood pressure diastolic increased	
H pert n ion	10051128	Blood pressure inadequately c ntro led	
H pert n ion	10005750	Blood pressure increased	
H pert n ion	10063926	Blood pressure manag m nt	
H pert n ion	10053355	Blood pressure or hosta ic in reased	
H pert n ion	10005760	Blood pressure systolic increased	
H pert n ion	1008 306	Cardiometabolic syndrome	
H pert n ion	10081751	Cate h lamine crisis	
H pert n ion	10012758	Diasto ic hyp rten i n	
H pert n ion	10014129	E lamp ia	
H pert n ion	10057615	Endo rine hypertension	
H pert n ion	10015488	Ess n i l h pert n ion	
H pert n ion	10070538	Gesta i nal hypert nsion	
H pert n ion	10049058	HELLP syndrome	
H pert n ion	10020571	Hyp raldosteroni m	
H pert n ion	10020772	Hyp rten i n	
H pert n ion	10049781	Hyp rten i n neonatal	
H pert n ion	10059238	Hyp rten ive ngiopa hy	
H pert n ion	10020801	Hyp rten ive cardi megaly	
H pert n ion	10058222	Hyp rten ive cardi myopa hy	
H pert n ion	10077000	Hyp rten ive cerebrovas ul r disease	
H pert n ion	10020802	Hyp rten ive risis	
H pert n ion	10058179	Hyp rten ive m rapnov	
H pert n ion	10020803	Hyp rten ive enc ph lopa hy	
H pert n ion	10079496	Hyp rten ive nd-organ damage	
H pert n ion	10020823	Hyp rten ive heart isease	
H pert n ion	10055171	Hyp rten ive nephropa hy	
H pert n ion	10058181	Hyp rten ive urgency	
H pert n ion	10049079	L bile h pert n ion	
H pert n ion	10025600	Mali nant hyp rten i n	
H pert n ion	10025803	Mali nant hyp rten ive heart disease	
H pert n ion	10026674	Mali nant r nal hypertension	
H pert n ion	10026924	Maternal hyp rten i n affec ing foetus	
H pert n ion	10026985	Mean arterial pressure increased	
H pert n ion	10067598	Neurog nic h pert n ion	
H pert n ion	10065508	Orthosta ic hypert nsion	
H pert n ion	10076704	Page kidney	
H pert n ion	10050631	Postopera ive hyp rten i n	
H pert n ion	10 36485	Pre-eclamp ia	
H pert n ion	10065918	Prehyp rt n i n	
H pert n ion	10062886	Procedural hypertensi n	
H pert n ion	10 39464	Renal hyp rtensi n	
H pert n ion	10074864	Renal sympa hetic nerve abla i n	
H pert n ion	10 38562	Renovas ul r h pert n ion	
H pert n ion	10 38926	Re inopa hy h pert nsive	
H pert n ion	10 39808	Secondary aldost ronism	
H pert n ion	10 39834	Secondary hypertension	
H pert n ion	10078932	Supine hypert nsion	
H pert n ion	10042957	Systo ic h p rten i n	
H pert n ion	10048007	Wi hdrawal hypertensi n	
Hepatotoxicity	10061009	Bi irubin ex re ion disorder	
Hepatotoxicity	10048611	Chola mia	
Hepatotoxicity	10008635	Cholestasis	
Hepatotoxicity	10067989	Cholesta ic liver injury	
Hepatotoxicity	10064190	Cholesta ic pruritus	
Hepatotoxicity	10072268	Drug-induced liver injury	
Hepatotoxicity	10019754	Hepa i is cholestatic	
Hepatotoxicity	10020578	Hyp rbi inubinaemia	
Hepatotoxicity	10021209	Icterus index increased	
Hepatotoxicity	10023126	J un ice	
Hepatotoxicity	10023129	J un ice cholesta ic	
Hepatotoxicity	10023136	J un ice h patoce lular	
Hepatotoxicity	10066758	Mixed iver injury	
Hepatotoxicity	10058117	O ular ict rus	
Hepatotoxicity	10074151	Par nteral nutri ion associated liver disease	
Hepatotoxicity	10071634	De i i ncy of bile secre ion	
Hepatotoxicity	10048245	Ye low kin	
Hepatotoxicity	10080860	Ac uired h patoc r br l deg nera ion	
Hepatotoxicity	10000804	Acute h pa ic f ilure	
Hepatotoxicity	1007 305	Acute on chronic liver f ilure	
Hepatotoxicity	10070815	Acute y llow liver atr phy	
Hepatotoxicity	10003445	Ascites	
Hepatotoxicity	10003547	Ast ri is	
Hepatotoxicity	10068547	Bacterascites	
Hepatotoxicity	10004659	Bi iary cirrhosis	
Hepatotoxicity	10004694	Bi iary ibrosis	
Hepatotoxicity	10082480	Cardioh pa ic syndrome	
Hepatotoxicity	10067989	Cholesta ic liver injury	
Hepatotoxicity	10057573	Chronic hepa ic failure	
Hepatotoxicity	10010075	Coma hepa ic	
Hepatotoxicity	10063075	Cryptog nic cirrho is	
Hepatotoxicity	10071265	Diabe ic h pat pa hy	
Hepatotoxicity	10072268	Drug-induced liver injury	
Hepatotoxicity	10051010	Duodenal varices	
Hepatotoxicity	1007 319	Gal bladd r y rices	
Hepatotoxicity	10076237	Gastric variceal injec ion	
Hepatotoxicity	10076238	Gastric variceal liga i n	
Hepatotoxicity	10051012	Gastric varices	
Hepatotoxicity	10057572	Gastric varices ha m rrhage	
Hepatotoxicity	10061997	Hepatect my	
Hepatotoxicity	10019637	Hepa ic atrophy	
Hepatotoxicity	10065274	Hepa ic calci ica ion	
Hepatotoxicity	10019641	Hepa ic cirrhosis	
Hepatotoxicity	10019660	Hepa ic encephal pa hy	
Hepatotoxicity	10066599	Hepa ic encephal pa hy prophylaxis	
Hepatotoxicity	10019663	Hepa ic failure	
Hepatotoxicity	10019668	Hepa ic ibrosis	
Hepatotoxicity	1006 365	Hepa ic hydro h rax	
Hepatotoxicity	10064668	Hepa ic in ltra i n eosin ph lic	
Hepatotoxicity	10061998	Hepa ic le ion	
Hepatotoxicity	10019692	Hepa ic ne ro is	
Hepatotoxicity	10077215	Hepa ic steato- ibrosis	
Hepatotoxicity	10019708	Hepa ic steato is	
Hepatotoxicity	10019772	Hepa i is fulminant	
Hepatotoxicity	10062000	Hepatobili ry isease	
Hepatotoxicity	10053244	Hepatocellular foamy ce l s ndrome	
Hepatotoxicity	10019837	Hepatocellular injury	
Hepatotoxicity	10052274	Hepatopulmonary syndrome	
Hepatotoxicity	10019845	Hepatorenal failure	
Hepatotoxicity	10019846	Hepatorenal syndr me	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Hepatoto icity	10019851	Hepatotoxicity	
Hepatoto icity	10071502	Intestin l v rices	
Hepatoto icity	10078058	Intestin l v rices haemorrhage	
Hepatoto icity	10076640	Liver ialy is	
Hepatoto icity	10024670	Liver isord r	
Hepatoto icity	10067125	Liver injury	
Hepatoto icity	10062040	Liver pera ion	
Hepatoto icity	10024714	Liver tr n plant	
Hepatoto icity	10025129	Lupoid hepa ic irrhosis	
Hepatoto icity	10076204	Minim l h patic nc ph l pa hy	
Hepatoto icity	10066758	Mixed liv r injury	
Hepatoto icity	10051081	Nodul r regen ra ive h p rplasia	
Hepatoto icity	10082249	Nonalcoh lic fatty liver disease	
Hepatoto icity	10053219	Non-alcoho ic steat hepa i is	
Hepatoto icity	10077259	Non-cirrho ic p rtal hyp rten i n	
Hepatoto icity	10049631	Oedema due to hepa ic disease	
Hepatoto icity	10030210	Oesophage l v rices haemorrhage	
Hepatoto icity	10073215	P rip ncrea ic varices	
Hepatoto icity	10074726	P rt l ibro is	
Hepatoto icity	10036200	P rt l h p rt n ion	
Hepatoto icity	10079446	P rt l h p rt n ive c lopa hy	
Hepatoto icity	100689 3	P rt l h p rt n ive ent ropa hy	
Hepatoto icity	10050897	P rt l h p rt n ive gastr pa hy	
Hepatoto icity	10073979	P rt l v in cavern us tr nsforma ion	
Hepatoto icity	10073209	P rt l v in dilata i n	
Hepatoto icity	10067281	P rt pulm nary h perten ion	
Hepatoto icity	10080429	Primary bi iary ch l ngi is	
Hepatoto icity	10080679	Regenera ive idero ic h pa ic nodule	
Hepatoto icity	10052279	R nal nd liver transplant	
Hepatoto icity	1006 338	Retrograde portal v in low	
Hepatoto icity	10039012	Reye's syndrome	
Hepatoto icity	100709 3	Reynold's syndrome	
Hepatoto icity	10067823	Splenic varices	
Hepatoto icity	10068662	Splenic varices ha m rrhage	
Hepatoto icity	1007 331	Steatoh pa i is	
Hepatoto icity	10056956	Suba ute hepa ic failure	
Hepatoto icity	10056091	V rices oes phageal	
Hepatoto icity	10072284	V ricose veins of abd minal wall	
Hepatoto icity	10078438	White nipple sign	
Hepatoto icity	10068924	Anorect l varices	
Hepatoto icity	10068925	Anorect l varices ha m rrhage	
Hepatoto icity	10010186	Comp ications of tran planted liv r	
Hepatoto icity	10082444	Increased liver s iffness	
Hepatoto icity	10072629	Intrah pa ic p rtal hepa ic venous istula	
Hepatoto icity	100516 3	Liver nd pancreas tr n plant rejec i n	
Hepatoto icity	10024715	Liver tr n plant rejec i n	
Hepatoto icity	10082450	Mul ivisce l tr nsplanta i n	
Hepatoto icity	10081995	P r ial pl nic mb lisa ion	
Hepatoto icity	10052716	P ritoneoven us shunt	
Hepatoto icity	10036204	P rt l hunt	
Hepatoto icity	10077479	P rt l hunt procedure	
Hepatoto icity	1006 380	Small-f r-size liver syndrome	
Hepatoto icity	10041519	Spider naevus	
Hepatoto icity	10041861	Splen ren l hunt	
Hepatoto icity	10077281	Splen ren l hunt procedure	
Hepatoto icity	10076239	Sponti ne us intr hepa ic portosystemic v nous hunt	
Hepatoto icity	10075186	Stom l varices	
Hepatoto icity	100662 3	A ute raft ver us host disease in liv r	
Hepatoto icity	10071198	Allergic hepa i is	
Hepatoto icity	10080576	Aloimmune h pa itis	
Hepatoto icity	10003827	Aut immune hepa i is	
Hepatoto icity	10072160	Chr nic graft v r us host isease in liver	
Hepatoto icity	10008909	Chr nic hepa i is	
Hepatoto icity	10064676	Graft versus host disease in liver	
Hepatoto icity	10019717	Hepa i is	
Hepatoto icity	10019727	Hepa i is a ute	
Hepatoto icity	10019754	Hepa i is cholesta ic	
Hepatoto icity	10019755	Hepa i is chronic ac ive	
Hepatoto icity	10019759	Hepa i is chronic persist nt	
Hepatoto icity	10019772	Hepa i is fulmin nt	
Hepatoto icity	10019795	Hepa i is to ic	
Hepatoto icity	10078962	Immune-me iated hepati is	
Hepatoto icity	10023025	Ischaemic h pa itis	
Hepatoto icity	10067737	Lupus h pa i is	
Hepatoto icity	10053219	Non-alcoho ic steat hepa i is	
Hepatoto icity	10051015	Radia ion hepa i is	
Hepatoto icity	1007 331	Steatoh pa i is	
Hepatoto icity	10018704	Granul matous liver isease	
Hepatoto icity	10068664	Liver sarc idosis	
Hepatoto icity	1007 331	P rt l tract in lamma ion	
Hepatoto icity	10004269	B ni n hepa ic neopla m	
Hepatoto icity	10077922	B ni n hepatob li ry neopla m	
Hepatoto icity	10052285	Focal nodular h pe pla ia	
Hepatoto icity	10018821	Ha m n ioma of liver	
Hepatoto icity	10067796	Ha m rha ic hepa ic cyst	
Hepatoto icity	10019629	Hepa ic aden ma	
Hepatoto icity	10019646	Hepa ic cyst	
Hepatoto icity	100539 3	Hepa ic cyst ruptured	
Hepatoto icity	10054885	Hepa ic haem n ioma rupture	
Hepatoto icity	10079685	Hepa ic h mart ma	
Hepatoto icity	10079889	Hepatobili ry cyst	
Hepatoto icity	10077861	Ch langiosarcoma	
Hepatoto icity	1006 388	Hepa ic angios rcoma	
Hepatoto icity	10073069	Hepa ic c nc r	
Hepatoto icity	10055110	Hepa ic canc r metasta ic	
Hepatoto icity	10073070	Hepa ic canc r recurr nt	
Hepatoto icity	1005 318	Hepa ic canc r stage I	
Hepatoto icity	1005 319	Hepa ic canc r stage I	
Hepatoto icity	1005 324	Hepa ic canc r stage II	
Hepatoto icity	1005 325	Hepa ic canc r stage V	
Hepatoto icity	100730 3	Hepatobili ry cancer	
Hepatoto icity	10073074	Hepatobili ry cancer in itu	
Hepatoto icity	10062001	Hepatoblastoma	
Hepatoto icity	100198 3	Hepatoblastoma recurrent	
Hepatoto icity	10073071	Hepatocellul r car in ma	
Hepatoto icity	10050842	Liver carcinoma ruptured	
Hepatoto icity	10027761	Mixed hepatocellul r ch langioc rcinoma	
Hepatoto icity	10074766	Liver bla ion	
Hepatoto icity	10019695	Hepa ic ne pla m	
Hepatoto icity	100812 3	Hepatobili ry neoplasm	
Hepatoto icity	10001547	Alanine minotr nsf rase bn rm l	
Hepatoto icity	10001551	Alanine minotr nsf rase increased	
Hepatoto icity	10001942	Amm nia abnormal	
Hepatoto icity	10001946	Amm nia increased	
Hepatoto icity	10003445	Ascites	
Hepatoto icity	10003477	A partate aminotransf rase abno mal	
Hepatoto icity	10003481	A partate aminotransf rase increased	
Hepatoto icity	10068547	Bacterascites	
Hepatoto icity	1005 344	Bile output abnormal	
Hepatoto icity	1005 3 3	Bile output de reased	
Hepatoto icity	10074150	B liary ascites	
Hepatoto icity	10067718	Bi irubin conjugated abnormal	
Hepatoto icity	10004685	Bi irubin conjugated in reased	
Hepatoto icity	1007 356	Bi irubin urine pres nt	
Hepatoto icity	10004792	Bi psy liver abnormal	
Hepatoto icity	10058477	Blood bi irubin bn rm l	
Hepatoto icity	1000 364	Blood bi irubin increased	
Hepatoto icity	1000 370	Blood bi irubin unc njugated increased	
Hepatoto icity	10006408	Bromo ulph hal in test bn rm l	
Hepatoto icity	10077020	Ch ld Pugh-Turcotte score bn rm l	
Hepatoto icity	10068287	Ch ld Pugh-Turcotte score increased	
Hepatoto icity	10076215	Computerised t mo r m liv r	
Hepatoto icity	1007 360	Computerised t mo r m liv r abnormal	
Hepatoto icity	10052554	Foetor hepa icus	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

H patoto icity	10059710	Galactose limina i n capacity test abnormal	
H patoto icity	10059712	Galactose limina i n capacity test decreased	
H patoto icity	10017688	Gamma- lut m ltransf rase abn rmal	
H patoto icity	10017693	Gamma- lut m ltransf rase increased	
H patoto icity	1005 333	Gu nase increased	
H patoto icity	10019621	Hepaplastin bn rm l	
H patoto icity	10019622	Hepaplastin decreased	
H patoto icity	10068997	Hepa ic artery low decreased	
H patoto icity	10019645	Hepa ic c nges ion	
H patoto icity	10062685	Hepa ic enzyme abnormal	
H patoto icity	10060794	Hepa ic enzyme de reased	
H patoto icity	10060795	Hepa ic enzyme increased	
H patoto icity	10019670	Hepa ic func ion abnormal	
H patoto icity	1006 365	Hepa ic hydro h rax	
H patoto icity	10076254	Hepa ic hypertrophy	
H patoto icity	10057110	Hepa ic mass	
H patoto icity	10019705	Hepa ic p in	
H patoto icity	10066244	Hepa ic sequestra ion	
H patoto icity	1006 358	Hepa ic vascular resistance in reased	
H patoto icity	10066195	Hepatobili ry sc n abn rmal	
H patoto icity	10019842	Hepatomegaly	
H patoto icity	10019847	Hepato pl n megaly	
H patoto icity	10020575	Hyperammonaemia	
H patoto icity	10020578	Hyperb lirubinaemia	
H patoto icity	10051924	Hypercholia	
H patoto icity	10068237	Hypertransaminasaemia	
H patoto icity	10023321	Kays r−Fl ischer ring	
H t i a	10024690	Li f i t t h l	
H patoto icity	10077677	Liver function test decreased	
H patoto icity	10077692	Liver function test increased	
H patoto icity	10052550	Liver indura ion	
H patoto icity	10075895	Liver palpable	
H patoto icity	10061947	Liver sc n abn rmal	
H patoto icity	10024712	Liver t nd rness	
H patoto icity	10082443	Ma ne ic resonance proton density fat frac ion measurement	
H patoto icity	10064712	Mito hondri l a p rtate minotr nsferase increased	
H patoto icity	10066869	Mol r ra io of total bran hed- hain amino acid to tyrosine	
H patoto icity	10080035	Nu le r magne ic reson nce ima ing liver abn rm l	
H patoto icity	10049631	Oed ma due to hepa ic disease	
H patoto icity	10054125	Per hepa ic disc mfort	
H patoto icity	1006 338	Retrograde portal vein low	
H patoto icity	10064558	Tot l bile acids increased	
H patoto icity	10062688	Trans minases abnormal	
H patoto icity	10054889	Trans minases increased	
H patoto icity	10045428	Ultrasound liv r abnormal	
H patoto icity	10050792	Urine b lirubin in reased	
H patoto icity	10078438	White nipple sign	
H patoto icity	10056536	X-ray hepatob li ry abn rmal	
H patoto icity	10000028	5'nu leo idase increased	
H patoto icity	10059571	Blood lkaline phosphatase abnormal	
H patoto icity	10059570	Blood alka ine phosphatase in reased	
H patoto icity	10005429	Blood h linest rase abn rm l	
H patoto icity	10005430	Blood h linest rase decreased	
H patoto icity	10071634	De ici ncy of bile secre ion	
H patoto icity	10049483	Glut mate dehydrogenase increased	
H patoto icity	10080824	Glyco ho ic acid in reased	
H patoto icity	10059766	Ha m rrha ic ascites	
H patoto icity	10074084	Hepa ic ibrosis marker bno mal	
H patoto icity	10074413	Hepa ic ibrosis marker increased	
H patoto icity	10079686	Hepa ic lymphocy ic in iltra i n	
H patoto icity	10020942	Hypoa bumina mia	
H patoto icity	10024275	L ucine minopeptidase in reased	
H patoto icity	1007 352	Liver iron concentra ion abnormal	
H patoto icity	1007 354	Liver iron concentra ion in reased	
H patoto icity	10077291	Mod l f r end stage liver disease score abnormal	
H patoto icity	10077292	Mod l f r end stage liver disease score in reased	
H patoto icity	10068821	Periport l oed ma	
H patoto icity	10069000	Perit neal fluid protein abnormal	
H patoto icity	10068999	Perit neal fluid protein de reased	
H patoto icity	10068998	Perit neal fluid protein in reased	
H patoto icity	10066004	Pn umobilia	
H patoto icity	1006 337	Port l v in low decreased	
H patoto icity	10064936	Port l v in pressure increased	
H patoto icity	10048473	Re inol binding protein decreased	
H patoto icity	10070480	Urob linogen urine decreased	
H patoto icity	10070479	Urob linogen urine increased	
H patoto icity	10074561	Ac uired n i hr mbin II de ici ncy	
H patoto icity	1006 370	Ac uired protein S de i iency	
H patoto icity	10077670	An i fact r X ac ivity abnormal	
H patoto icity	10077674	An i fact r X ac ivity decreased	
H patoto icity	10077671	An i fact r X ac ivity increased	
H patoto icity	10049547	An ithrombin III decreased	
H patoto icity	10005518	Blood ibrinogen abnormal	
H patoto icity	10005520	Blood ibrinogen de reased	
H patoto icity	10005818	Blood thrombin abnormal	
H patoto icity	10005820	Blood hrombin decreased	
H patoto icity	10005824	Blood thromboplas in abnormal	
H patoto icity	10005826	Blood hromboplas in decreased	
H patoto icity	10009736	Coagula i n factor decreased	
H patoto icity	10061770	Coagula i n factor X level abnormal	
H patoto icity	10009746	Coagula i n factor X level de reased	
H patoto icity	10061771	Coagula i n factor V lev l bn rm l	
H patoto icity	10009754	Coagula i n factor V level decreased	
H patoto icity	10061772	Coagula i n factor V l level abnormal	
H patoto icity	10009761	Coagula i n factor V l level decreased	
H patoto icity	10061774	Coagula i n factor X lev l bn rm l	
H patoto icity	10009775	Coagula i n factor X level decreased	
H patoto icity	10074737	Hyper ibrin ly is	
H patoto icity	10020973	Hypocoa ul ble state	
H patoto icity	10051125	Hypo ibrinog na mia	
H patoto icity	10021085	Hypopro hrombina mia	
H patoto icity	10058517	Hypo hr mbinaemia	
H patoto icity	10058518	Hypo hr mboplastinaemia	
H patoto icity	10022592	Interna ion l normalised ra io abn rm l	
H patoto icity	10022595	Interna ional normalised ra io increased	
H patoto icity	10037005	Prot in C decreased	
H patoto icity	10051736	Prot in S bnormal	
H patoto icity	10051120	Prot in S de reased	
H patoto icity	10037048	Pro hr mbin level bnormal	
H patoto icity	10037050	Pro hr mbin level de reased	
H patoto icity	10037057	Pro hr mbin ime abnormal	
H patoto icity	10037063	Pro hr mbin ime pr longed	
H patoto icity	10061918	Pro hr mbin ime ra io abnormal	
H patoto icity	10037068	Pro hr mbin ime ra io increased	
H patoto icity	1005 319	Thr mbin time abnormal	
H patoto icity	1005 390	Thr mbin time prolonged	
Car iovascular event	10081099	Acute cardiac event	
Car iovascular event	1000 383	An ina pect ris	
Car iovascular event	1000 388	An ina unst ble	
Car iovascular event	10076419	An inal equivalent	
Car iovascular event	10003211	Arterios l rosis coronary rt ry	
Car iovascular event	10003225	Arteriospa m coronary	
Car iovascular event	1005 329	Coronary an i plasty	
Car iovascular event	10052086	Coronary arteri l stent inser i n	
Car iovascular event	10011077	Coronary artery bypass	
Car iovascular event	10079589	Coronary artery compres ion	
Car iovascular event	10011078	Coronary artery disease	
Car iovascular event	10048631	Coronary artery dissec i n	
Car iovascular event	10052895	Coronary artery in uf ici ncy	
Car iovascular event	10056489	Coronary artery rest no is	
Car iovascular event	10011089	Coronary artery steno is	
Car iovascular event	10011090	Coronary artery surgery	
C i l t	10076627	C b h th	
Car iovascular event	10077824	Coronary bypass stenosis	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Cardiovas ul r event	10011101	Coronary ndarterectomy	
Cardiovas ul r event	10068534	Coronary no re low ph n m non	
Cardiovas ul r event	10011105	Coronary ostial steno is	
Cardiovas ul r event	10049887	Coronary revas ularisa ion	
Cardiovas ul r event	1007 334	Coronary vascular raft stenosis	
Cardiovas ul r event	10080788	Diabe ic c ron ry microan i pa hy	
Cardiovas ul r event	10013428	Dissec ing coronary rt ry neury m	
Cardiovas ul r event	1005 317	ECG signs of myocardial is ha mia	
Cardiovas ul r event	10067876	Extem l c unt rpulsa ion	
Cardiovas ul r event	10055803	Haem rrhage c ron ry rtery	
Cardiovas ul r event	10048858	Ischaemic car iomy pa hy	
Cardiovas ul r event	10077864	Ischaemic mitr l re ur itation	
Cardiovas ul r event	10072685	Microvascular coronary rtery isease	
Cardiovas ul r event	10078980	Myocardial hypoxia	
Cardiovas ul r event	10028600	Myocardial is ha mia	
Cardiovas ul r event	10065608	Per utaneous coronary int rvention	
Cardiovas ul r event	10 36759	Prin metal an ina	
Cardiovas ul r event	10066286	Stress cardiomyopa hy	
Cardiovas ul r event	10064994	Subclavi n coronary ste l syndrome	
Cardiovas ul r event	10058145	Subendoc rdi l ischa mia	
Cardiovas ul r event	10080787	W ll ns' syndrome	
Cardiovas ul r event	10003201	Arteriogram coronary abnormal	
Cardiovas ul r event	10055014	Cardiac stress test bn rm l	
Cardiovas ul r event	1007 359	Cardiopulmon ry ex rcise test abn rm l	
Cardiovas ul r event	10084939	Cardiovas ul r event prophylaxis	
Cardiovas ul r event	10060806	Comput rised t mogr m cor nary artery abnormal	
Cardiovas ul r event	10082504	Elas ic vessel rec il complication	
Cardiovas ul r event	10081493	Electrocardio ram PR segment d pression	
Cardiovas ul r event	1001 391	Electrocardio ram ST segment d pression	
Cardiovas ul r event	1005 333	Electrocardio ram ST-T se m nt bn rm l	
Cardiovas ul r event	10049224	Electrocardio ram ST-T se m nt depres ion	
Cardiovas ul r event	1005 380	Electrocardio ram T wave abnormal	
Cardiovas ul r event	1001 395	Electrocardio ram T wave inver ion	
Cardiovas ul r event	10062314	Electrocardio ram U wave inver ion	
Cardiovas ul r event	10015845	Exercise electrocardiogram abnormal	
Cardiovas ul r event	10015853	Exercise test bnormal	
Cardiovas ul r event	10077146	Post angi plasty restenosis	
Cardiovas ul r event	10082493	Restenosis	
Cardiovas ul r event	10070746	Stress echoc r iogram bn rm l	
Cardiovas ul r event	10077144	Vascular stent steno is	
Cardiovas ul r event	10079016	W ll mo ion score index bnormal	
Cardiovas ul r event	1005 375	Ba int's syndrome	
Cardiovas ul r event	10077607	Ba il r artery aneurysm	
Cardiovas ul r event	10007686	Caro id art ry neurysm	
Cardiovas ul r event	10050403	Caro id art ry issec ion	
Cardiovas ul r event	10077079	Cerebral ndovas ul r aneurysm rep ir	
Cardiovas ul r event	10075401	Cerebral r perfusion injury	
Cardiovas ul r event	10075249	Cerebral ventricular rupture	
Cardiovas ul r event	10049165	Cerebrovas ul r ac ident prophylaxis	
Cardiovas ul r event	10054749	Charcot-Bou hard micro n ury ms	
Cardiovas ul r event	1007 359	Cong nital hemiparesis	
Cardiovas ul r event	1007 326	CSF bilirubin posi ive	
Cardiovas ul r event	1007 388	Delayed ischaemic n urological de icit	
Cardiovas ul r event	10077170	Hemi naes hesia	
Cardiovas ul r event	10077171	Hemiasomatogno ia	
Cardiovas ul r event	10081999	Hemiataxia	
Cardiovas ul r event	10080713	Hemihyperaes he ia	
Cardiovas ul r event	10078746	Hemiparaes hesia	
Cardiovas ul r event	10019465	Hemipare is	
Cardiovas ul r event	10019468	Hemiple ia	
Cardiovas ul r event	10022736	Intra-cerebral neury m p ra ion	
Cardiovas ul r event	10022758	Intracranial aneurysm	
Cardiovas ul r event	10081515	Lat ropul ion	
Cardiovas ul r event	10070606	Post str ke depression	
Cardiovas ul r event	10079859	Pos haem rrhagic hydrocephalus	
Cardiovas ul r event	10077889	Vein of G l n aneurysmal m lf rmation	
Cardiovas ul r event	10077498	Vertebral rtery an ury m	
Cardiovas ul r event	10071716	Vertebral rtery dissec i n	
Cardiovas ul r event	10048663	A no ia	
Cardiovas ul r event	10052906	An io ram cerebr l bn rm l	
Cardiovas ul r event	10002948	Apha ia	
Cardiovas ul r event	10067967	Brain injury	
Cardiovas ul r event	10064012	Centr l p in s ndr me	
Cardiovas ul r event	10070728	Cerebral ha mosiderin d po i i n	
Cardiovas ul r event	10075562	CSF red blood ce l count po i ive	
Cardiovas ul r event	10013033	Diple ia	
Cardiovas ul r event	10013887	Dysar hria	
Cardiovas ul r event	1008 308	Intern l c ro id artery deformity	
Cardiovas ul r event	10073565	Intracrani l art ry dissec ion	
Cardiovas ul r event	10072882	Mod ied Rankin score de reased	
Cardiovas ul r event	10072881	Mod ied Rankin score in reased	
Cardiovas ul r event	10027925	Mon paresis	
Cardiovas ul r event	10027926	Mon plegia	
Cardiovas ul r event	10065531	N H str ke scale abnormal	
Cardiovas ul r event	10065529	N H str ke scale score de reased	
Cardiovas ul r event	10065528	N H str ke scale score in reased	
Cardiovas ul r event	10 33799	Par ly is	
Cardiovas ul r event	10 33885	Par paresis	
Cardiovas ul r event	10 33892	Par plegia	
Cardiovas ul r event	10 33985	Paresis	
Cardiovas ul r event	10049680	Quadrip re is	
Cardiovas ul r event	10 37714	Quadriple ia	
Cardiovas ul r event	10075037	Ri ht hemisphere de icit s ndr me	
Cardiovas ul r event	10070564	Super i ial siderosis of c ntral nervous syst m	
Cardiovas ul r event	10077168	Vi ual a nosia	
Cardiovas ul r event	10066856	Vi ual midline shift syndrome	
Cardiovas ul r event	10077031	Basal g n lia ha matoma	
Cardiovas ul r event	10067057	Basal g ng ia ha m rrhage	
Cardiovas ul r event	10071043	Basal g n lia stroke	
Cardiovas ul r event	10075736	Ba il r artery p rbra i n	
Cardiovas ul r event	10073230	Brain st m ha matoma	
Cardiovas ul r event	10006145	Brain st m ha m rrhage	
Cardiovas ul r event	10071205	Brain st m mi rohaemorrhage	
Cardiovas ul r event	10068644	Brain st m stroke	
Cardiovas ul r event	1005 328	Caro id aneury m rupture	
Cardiovas ul r event	10075728	Caro id art ry perforation	
Cardiovas ul r event	10072043	Centr l n rvous system haemorrhage	
Cardiovas ul r event	10061038	Cerebellar haemat ma	
Cardiovas ul r event	10008030	Cerebellar haemorrhage	
Cardiovas ul r event	10071206	Cerebellar micr ha morrhage	
Cardiovas ul r event	10079082	Cerebellar str ke	
Cardiovas ul r event	1007 394	Cerebral n ury m perf ra i n	
Cardiovas ul r event	10008076	Cerebral n ury m ruptured syphi i ic	
Cardiovas ul r event	10008086	Cerebral rteriovenous malforma i n haemorrhagic	
Cardiovas ul r event	10075734	Cerebral rtery perf ra i n	
Cardiovas ul r event	10082099	Cerebral cyst haem rrhage	
Cardiovas ul r event	10053942	Cerebral ha matoma	
Cardiovas ul r event	10008111	Cerebral ha m rrhage	
Cardiovas ul r event	10050157	Cerebral ha m rrhage foetal	
Cardiovas ul r event	10008112	Cerebral ha m rrhage neonatal	
Cardiovas ul r event	10067277	Cerebral mi rohaemorrhage	
Cardiovas ul r event	10008190	Cerebrovas ul r ac ident	
Cardiovas ul r event	10008196	Cerebrovas ul r disorder	
Cardiovas ul r event	10073681	Epidural haemorrhage	
Cardiovas ul r event	10078254	Extra-axi l haemorrhage	
Cardiovas ul r event	10015769	Extradural haemat ma	
Cardiovas ul r event	1008 347	Extr ischaemic ner bral ha matoma	
Cardiovas ul r event	10018985	Haem rrhage intracr ni l	
Cardiovas ul r event	10019005	Haem rrha ic cerebral inf rc i n	
Cardiovas ul r event	10019016	Haem rrha ic stroke	
Cardiovas ul r event	10055677	Haem rrha ic tr nsforma i n str ke	
Cardiovas ul r event	10062025	Intrac r br l haematoma evacua ion	
Cardiovas ul r event	10059491	Intracrani l haematoma	
Cardiovas ul r event	10022775	Intracranial tumour ha m rrhage	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

C rdiovascul r ev nt	10022840	Intraventricular haem rrhage	
C rdiovascul r ev nt	10022841	Intraventricular haem rrhage neonat l	
C rdiovascul r ev nt	10052593	Mening rrha ia	
C rdiovascul r ev nt	10073945	Perinatal str ke	
C rdiovascul r ev nt	10076706	Periventricular haemorrhage neonatal	
C rdiovascul r ev nt	10056447	Pituit ry poplexy	
C rdiovascul r ev nt	10049760	Pituit ry haem rrhage	
C rdiovascul r ev nt	10058940	Putam n haemorrhage	
C rdiovascul r ev nt	10 3 330	Ruptured cer bral aneurysm	
C rdiovascul r ev nt	10078051	Spinal cord ha matoma	
C rdiovascul r ev nt	10048992	Spinal cord ha morrhage	
C rdiovascul r ev nt	10050162	Spinal epidur l haemat ma	
C rdiovascul r ev nt	10049236	Spinal epidur l haemorrhage	
C rdiovascul r ev nt	10082031	Spinal stroke	
C rdiovascul r ev nt	10073564	Spinal subarachnoid haemorrhage	
C rdiovascul r ev nt	10050164	Spinal subdural ha mat ma	
C rdiovascul r ev nt	10073563	Spinal subdural ha m r hage	
C rdiovascul r ev nt	10059613	Stroke in evolu ion	
C rdiovascul r ev nt	10078701	Subara hn id ha matoma	
C rdiovascul r ev nt	10042316	Subara hn id ha m rrhage	
C rdiovascul r ev nt	1004 317	Subara hn id ha m rrhage neonat l	
C rdiovascul r ev nt	1004 361	Subdur l haematoma	
C rdiovascul r ev nt	1004 363	Subdur l haematoma evacua ion	
C rdiovascul r ev nt	1004 364	Subdur l haemorrhage	
C rdiovascul r ev nt	1004 365	Subdur l haemorrhage neonatal	
C rdiovascul r ev nt	10058939	Th lamus haemorrhage	
C rdiovascul r ev nt	10075735	Vertebral rtery perf ra i n	
C rdiovascul r ev nt	10082484	Vertebrobas lar stroke	
C rdiovascul r ev nt	10001903	Am urosis fugax	
C rdiovascul r ev nt	10069020	Basal gang ia inf rc ion	
C rdiovascul r ev nt	10071043	Basal gang ia stroke	
C rdiovascul r ev nt	10048963	Ba il r artery occlu i n	
C rdiovascul r ev nt	10004163	Ba il r artery st no is	
C rdiovascul r ev nt	10063093	Ba il r artery hrombosis	
C rdiovascul r ev nt	10075449	Brachiocepha ic arteries lerosis	
C rdiovascul r ev nt	10069694	Brachiocepha ic artery oc lu ion	
C rdiovascul r ev nt	10075450	Brachiocepha ic artery steno is	
C rdiovascul r ev nt	10006127	Brain h po ia	
C rdiovascul r ev nt	10074422	Brain st m embo ism	
C rdiovascul r ev nt	10006147	Brain st m inf rc ion	
C rdiovascul r ev nt	10006148	Brain st m is haemia	
C rdiovascul r ev nt	10068644	Brain st m stroke	
C rdiovascul r ev nt	10062573	Brain st m thrombo is	
C rdiovascul r ev nt	10080887	Brain st nt jns r ion	
C rdiovascul r ev nt	10065555	CADASIL	
C rdiovascul r ev nt	10067744	C p ular warning s ndr me	
C rdiovascul r ev nt	1008 315	CARASIL syndrome	
C rdiovascul r ev nt	10071260	C ro id angioplasty	
C rdiovascul r ev nt	10007684	C ro id art rial embolus	
C rdiovascul r ev nt	10067116	C ro id art rioscl ro is	
C rdiovascul r ev nt	10053003	C ro id art ry b pass	
C rdiovascul r ev nt	10061744	C ro id art ry disease	
C rdiovascul r ev nt	10064949	C ro id art ry insuf iciency	
C rdiovascul r ev nt	10048864	C ro id art ry occlusion	
C rdiovascul r ev nt	10072558	C ro id art ry restenosis	
C rdiovascul r ev nt	10007687	C ro id art ry stenosis	
C rdiovascul r ev nt	10066102	C ro id art ry stent ins r ion	
C rdiovascul r ev nt	10069952	C ro id art ry stent r moval	
C rdiovascul r ev nt	10007688	C ro id art ry hr mbosis	
C rdiovascul r ev nt	10007692	C ro id endart rect my	
C rdiovascul r ev nt	10072559	C ro id revascularisa i n	
C rdiovascul r ev nt	10053633	C rebellar art ry occlusion	
C rdiovascul r ev nt	10008023	C rebellar art ry hr mbo is	
C rdiovascul r ev nt	10067167	C rebellar emboli m	
C rdiovascul r ev nt	10008034	C rebellar infarction	
C rdiovascul r ev nt	10068821	Cerebellar ischaemia	
C rdiovascul r ev nt	10079062	Cerebellar str ke	
C rdiovascul r ev nt	10065559	C rebral rteriosclero is	
C rdiovascul r ev nt	10008088	C rebral rtery mbolism	
C rdiovascul r ev nt	10008089	C rebral rtery occlu ion	
C rdiovascul r ev nt	10075423	C rebral rtery rest no is	
C rdiovascul r ev nt	10063648	C rebral rtery steno is	
C rdiovascul r ev nt	10081893	C rebral rtery stent inser i n	
C rdiovascul r ev nt	10008092	Cerebral rtery hrombosis	
C rdiovascul r ev nt	10070813	Cerebral gas emb li m	
C rdiovascul r ev nt	10008118	C rebral infarc ion	
C rdiovascul r ev nt	10008119	C rebral infarc ion foetal	
C rdiovascul r ev nt	10008120	C rebral is ha mia	
C rdiovascul r ev nt	1007 311	C rebral mi roemb li m	
C rdiovascul r ev nt	10071508	C rebral revascularisation	
C rdiovascul r ev nt	10070671	C rebral sep ic inf rct	
C rdiovascul r ev nt	10070878	Cerebral mall vessel is ha mic isease	
C rdiovascul r ev nt	10008132	C rebral hrombo is	
C rdiovascul r ev nt	10078895	Cerebral vascular occlu ion	
C rdiovascul r ev nt	10059109	C rebral vasoc nstric i n	
C rdiovascul r ev nt	10008138	C rebral ven us hr mbo is	
C rdiovascul r ev nt	10008190	C rebrovas ul r accident	
C rdiovascul r ev nt	10008196	C rebrovas ul r disorder	
C rdiovascul r ev nt	10058842	C rebrovas ul r in u ficiency	
C rdiovascul r ev nt	10081751	Cerebrovas ul r st no is	
C rdiovascul r ev nt	1007 388	Delayed ischaemic neurological de icit	
C rdiovascul r ev nt	10060839	Embo ic cerebral inf rc i n	
C rdiovascul r ev nt	10014498	Embo ic stroke	
C rdiovascul r ev nt	10070511	H poxic-is ha mic nc ph l pa hy	
C rdiovascul r ev nt	10070754	Inner ear infarction	
C rdiovascul r ev nt	10060840	Is haemic cer bral inf rc i n	
C rdiovascul r ev nt	10061256	Is haemic stroke	
C rdiovascul r ev nt	10081850	Ju ul r v in mbo i m	
C rdiovascul r ev nt	10051078	La un r infarc ion	
C rdiovascul r ev nt	10076994	La unar str ke	
C rdiovascul r ev nt	10024033	Lat r l medullary s ndr me	
C rdiovascul r ev nt	10056237	Migrain us inf rc i n	
C rdiovascul r ev nt	10067462	Mill rd-Gubl r s ndr me	
C rdiovascul r ev nt	10028047	Moyamoya disease	
C rdiovascul r ev nt	10073945	Perinatal str ke	
C rdiovascul r ev nt	10078202	Post c r iac arrest syndrome	
C rdiovascul r ev nt	10066591	Post procedural str ke	
C rdiovascul r ev nt	10077033	Prec rebr l rteriosclero is	
C rdiovascul r ev nt	10 36511	Prec rebr l rtery occlu ion	
C rdiovascul r ev nt	10073240	Revers ble c r br l vasoconstric ion syndrome	
C rdiovascul r ev nt	10050496	Revers ble ischaemic neurological deficit	
C rdiovascul r ev nt	10049440	Spinal artery embo i m	
C rdiovascul r ev nt	1007 316	Spinal artery thrombosis	
C rdiovascul r ev nt	10058571	Spinal cord inf rc i n	
C rdiovascul r ev nt	10050209	Spinal cord ischaemia	
C rdiovascul r ev nt	10082031	Spinal stroke	
C rdiovascul r ev nt	10059613	Stroke in evolu ion	
C rdiovascul r ev nt	1004 335	Subclavi n steal s ndr me	
C rdiovascul r ev nt	10064961	Th lamic inf rc i n	
C rdiovascul r ev nt	1006 347	Thrombo ic cer bral inf rc i n	
C rdiovascul r ev nt	10043647	Thrombo ic stroke	
C rdiovascul r ev nt	1004 390	Tran i nt ischa mic attack	
C rdiovascul r ev nt	10063661	Vascular enc phalopa hy	
C rdiovascul r ev nt	10077143	Vascular stent oc lu ion	
C rdiovascul r ev nt	10077144	Vascular stent steno is	
C rdiovascul r ev nt	10048965	Vertebral rtery oc lu i n	
C rdiovascul r ev nt	1004 330	Vertebral rtery steno is	
C rdiovascul r ev nt	10057777	Vertebral rtery thrombosis	
C rdiovascul r ev nt	1004 334	Vertebrobas lar in uf i i noy	
C rdiovascul r ev nt	10082484	Vertebrobas lar stroke	
Thrombo ic ev nts	1007 337	Acute a r ic syndrome	
Thrombo ic ev nts	10000891	Acute myocar ial inf rc i n	
Thrombo ic ev nts	10001902	Am urosis	
Thrombo ic ev nts	10001903	Am urosis fugax	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Thrombo ic events	10002475	An i plasty	
Thrombo ic events	10057617	Aor ic b pass	
Thrombo ic events	10002897	Aor ic embolus	
Thrombo ic events	10061651	Aor ic urg ry	
Thrombo ic events	10002910	Aor ic hrombo is	
Thrombo ic events	10057794	Aortogram bn rm l	
Thrombo ic events	10071026	Arterectomy	
Thrombo ic events	10003140	Arterectomy wi h graft replacem nt	
Thrombo ic events	10081731	Arteri i n ioplasty	
Thrombo ic events	10077766	Arteri l bypass occlusi n	
Thrombo ic events	10056418	Arteri l bypass opera i n	
Thrombo ic events	10077765	Arteri l bypass hrombo is	
Thrombo ic events	10061655	Arteri l raft	
Thrombo ic events	10062599	Arteri l occlusive disease	
Thrombo ic events	10061657	Arteri l stent inser i n	
Thrombo ic events	10052949	Arteri l h rap u ic procedure	
Thrombo ic events	10003178	Arteri l hr mbo is	
Thrombo ic events	10061659	Arteriogr m bnormal	
Thrombo ic events	10003195	Arteriogr m carotid bn rmal	
Thrombo ic events	10078636	Arteriotomy	
Thrombo ic events	10063025	A h rect my	
Thrombo ic events	10076604	A h rosclero ic pla ue rupture	
Thrombo ic events	10079735	Atrial app ndage closure	
Thrombo ic events	10080843	Atrial appendage resec i n	
Thrombo ic events	10069020	Basal g n lia inf rc i n	
Thrombo ic events	10048963	Ba il r art ry occlusion	
Thrombo ic events	10063093	Ba il r art ry hrombosis	
Thrombo ic events	10005184	Blindness tr n ient	
Thrombo ic events	10069694	Bra hioceph lic artery oc lu i n	
Thrombo ic events	10067744	Capsular warning s ndrome	
Thrombo ic events	10071260	Caro id n ioplasty	
Thrombo ic events	10007684	Caro id rt rial emb lus	
Thrombo ic events	10053003	Caro id rt ry bypass	
Thrombo ic events	10048964	Caro id rt ry occlu ion	
Thrombo ic events	10066102	Caro id rt ry stent inser ion	
Thrombo ic events	10007688	Caro id rt ry hr mbo is	
Thrombo ic events	10007692	Caro id nd rt rect my	
Thrombo ic events	10053633	Cerebe lar rt ry occlu ion	
Thrombo ic events	10008023	Cerebe lar rt ry hr mbo is	
Thrombo ic events	10008088	Cerebral artery embo ism	
Thrombo ic events	10008089	Cerebral artery oc lu ion	
Thrombo ic events	10081893	Cerebral artery stent inser i n	
Thrombo ic events	10008092	Cerebral artery hrombo is	
Thrombo ic events	1006 384	Cerebral hypop rfu ion	
Thrombo ic events	10058842	Cerebrovascul r in uf iciency	
Thrombo ic events	10061751	Cerebrovascul r st no is	
Thrombo ic events	10069696	Co liac art ry occlusion	
Thrombo ic events	1005 329	Coronary an i plasty	
Thrombo ic events	10052086	Coronary arteri l stent inser i n	
Thrombo ic events	10011077	Coronary artery bypass	
Thrombo ic events	10011084	Coronary artery embo ism	
Thrombo ic events	10011086	Coronary artery oc lu i n	
Thrombo ic events	10053261	Coronary artery reocclusion	
Thrombo ic events	10011090	Coronary artery surgery	
Thrombo ic events	10011091	Coronary artery hrombosis	
Thrombo ic events	10011101	Coronary endarterectomy	
Thrombo ic events	10049887	Coronary revas ul risa ion	
Thrombo ic events	10075162	Coronary vascular raft occlu ion	
Thrombo ic events	10058729	Emb lia cutis me ic m ntosa	
Thrombo ic events	10014513	Emb li m rteri l	
Thrombo ic events	10014648	Endart rect my	
Thrombo ic events	1006 365	F m ral rtery mbolism	
Thrombo ic events	10019635	Hepa ic artery embo ism	
Thrombo ic events	10051991	Hepa ic artery oc lu i n	
Thrombo ic events	10019636	Hepa ic artery hrombosis	
Thrombo ic events	10063518	Hypo h nar hamm r s ndr me	
Thrombo ic events	1002 338	Iliac artery emb lism	
Thrombo ic events	10064601	Iliac artery oc lusi n	
Thrombo ic events	10052989	Intra-aor ic ba lo n plac ment	
Thrombo ic events	1005 382	Intraopera ive cerebral rtery oc lu i n	
Thrombo ic events	10060840	Ischaemic c r bral infarc i n	
Thrombo ic events	10061256	Ischaemic stroke	
Thrombo ic events	10051078	Lacunar infarction	
Thrombo ic events	10024242	L niche syndrome	
Thrombo ic events	1002 394	Mesent ric rt rial occlusi n	
Thrombo ic events	10065560	Mesent ric rt riosclero is	
Thrombo ic events	1002 395	Mesent ric rt ry mbolism	
Thrombo ic events	1002 396	Mesent ric rt ry steno is	
Thrombo ic events	10071261	Mesent ric rt ry stent inser i n	
Thrombo ic events	1002 397	Mesent ric rt ry hrombo is	
Thrombo ic events	10028596	Myocardial inf rc ion	
Thrombo ic events	10028602	Myocardial ne rosis	
Thrombo ic events	10081144	Oph halmic artery hrombosis	
Thrombo ic events	10033697	Papillary muscle infarc ion	
Thrombo ic events	10068035	Perile art ry occlu i n	
Thrombo ic events	10065608	Per utane us coronary int rven ion	
Thrombo ic events	10062585	Periph ral rteri l occlusive isease	
Thrombo ic events	1006 379	Periph ral arteri l reocclu ion	
Thrombo ic events	10057518	Periph ral rtery n ioplasty	
Thrombo ic events	10072561	Periph ral rtery bypass	
Thrombo ic events	10057525	Periph ral rtery oc lu ion	
Thrombo ic events	10072562	Periph ral artery stent inser i n	
Thrombo ic events	10082470	Periph ral rtery urgery	
Thrombo ic events	10072564	Periph ral rtery hrombo is	
Thrombo ic events	1006 340	Periph ral embo ism	
Thrombo ic events	10072560	Periph ral nd rterectomy	
Thrombo ic events	10071642	Popliteal rtery ntrapm nt syndrome	
Thrombo ic events	10066592	Post procedur l myocardial infarc ion	
Thrombo ic events	10058144	Pos infarc ion n ina	
Thrombo ic events	10036511	Precerebral rtery occlu ion	
Thrombo ic events	10074717	Precerebral rtery hrombo is	
Thrombo ic events	10078867	Profundaplasty	
Thrombo ic events	10078201	Pulm nary artery occlusion	
Thrombo ic events	10063731	Pulm nary artery h r p u ic procedure	
Thrombo ic events	1003 340	Pulm nary artery hrombosis	
Thrombo ic events	10072893	Pulm nary endarterectomy	
Thrombo ic events	10079988	Pulm nary tumour thrombotic mi roangi pa hy	
Thrombo ic events	10057493	Renal rtery an ioplasty	
Thrombo ic events	10048988	Renal rtery oc lu i n	
Thrombo ic events	1003 380	Renal rtery thrombosis	
Thrombo ic events	10063544	Renal mbo ism	
Thrombo ic events	10038826	Re inal artery embo i m	
Thrombo ic events	10038827	Re inal artery occlu i n	
Thrombo ic events	10038831	Re inal artery hrombosis	
Thrombo ic events	10049768	Silent myoc r i l infarc ion	
Thrombo ic events	10049440	Spiral artery embo i m	
Thrombo ic events	1007 316	Spiral art ry hrombosis	
Thrombo ic events	10074600	Splenic rt ry hr mbo is	
Thrombo ic events	10068677	Splenic mboli m	
Thrombo ic events	10066286	Stress car iomy pa hy	
Thrombo ic events	10042332	Subclavi n rt ry mbolism	
Thrombo ic events	10069895	Subclavi n rt ry occlu ion	
Thrombo ic events	1004 334	Subclavi n rt ry hrombo is	
Thrombo ic events	10064958	Thr mboembolectomy	
Thrombo ic events	10043645	Thr mbo ic micro n iopa hy	
Thrombo ic events	10043648	Thr mbo ic hrombocyt p nic purpura	
Thrombo ic events	1004 390	Transient is ha mic attack	
Thrombo ic events	1006 363	Truncus coe ia us hrombosis	
Thrombo ic events	10078269	Vascular ps udoan urysm hr mbosis	
Thrombo ic events	10046965	Vert bral artery oc lu i n	
Thrombo ic events	10057777	Vert bral artery hrombosis	
Thrombo ic events	10047532	Vi u l a uity reduced transi n ly	
Thrombo ic events	10003880	A ill ry vein hrombosis	
Thrombo ic events	10076837	Bra hioceph lic vein occlusion	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Thrombotic events	100633 3	Bra hioceph lic vein hrombo is	
Thrombotic events	10006537	Budd-Chiari s ndr me	
Thrombotic events	10052898	Ca heterisa ion venous	
Thrombotic events	10007830	Cavern us sinus hr mbo is	
Thrombotic events	10053377	Centr l ven us catheterisation	
Thrombotic events	10008138	Cer bral venous hrombo is	
Thrombotic events	10079209	Compres ion g rm nt appica ion	
Thrombotic events	10051055	De p vein hrombosis	
Thrombotic events	10066881	De p vein hrombosis post p ra ive	
Thrombotic events	10014522	Emb li m venous	
Thrombotic events	10078810	Hepa ic v in mbolism	
Thrombotic events	10058991	Hepa ic v in occlu ion	
Thrombotic events	100197 3	Hepa ic vein hrombo is	
Thrombotic events	10051031	Homans' sign po i ive	
Thrombotic events	10058992	iac v in occlu ion	
Thrombotic events	10070911	Inferi r vena cava s ndr me	
Thrombotic events	10058987	Inferi r vena caval occlu ion	
Thrombotic events	10061251	Intracr ni l v n us inus hrombosis	
Thrombotic events	10081850	Jugular vein emb li m	
Thrombotic events	10076835	Jugular vein occlusi n	
Thrombotic events	10023237	Jugular vein hrombosis	
Thrombotic events	10075428	Mahler ign	
Thrombotic events	10069727	May-Thurner syndrome	
Thrombotic events	10027402	Mesent ric vein hr mbosis	
Thrombotic events	100274 3	Mesent ric venous occlusion	
Thrombotic events	10029925	Obstetric l pulmonary mbo ism	
Thrombotic events	10073708	Obstruc ive hook	
Thrombotic events	1007 349	Ophthalmic v in hr mbo is	
Thrombotic events	10072059	Ov rian vein hr mbo is	
Thrombotic events	10050216	Paget-Schroetter syndrome	
Thrombotic events	10034272	P lvic v nous hrombo is	
Thrombotic events	1003 324	P nile v in hrombosis	
Thrombotic events	10048874	Phlebectomy	
Thrombotic events	10073979	P rt l v in cavern us tr nsforma ion	
Thrombotic events	10082030	P rt l v in embo ism	
Thrombotic events	10058989	P rt l v in oc lu i n	
Thrombotic events	10036206	P rt l v in hrombosis	
Thrombotic events	100776 3	P rtosplenomesent ric ven us hrombosis	
Thrombotic events	10063909	Post procedur l pulmon ry mb lism	
Thrombotic events	10048591	Post hr mbo ic s ndr me	
Thrombotic events	10050902	Postopera ive hrombo is	
Thrombotic events	1003 300	Postp rtum venous hr mbo is	
Thrombotic events	1003 377	Pulm n ry emb li m	
Thrombotic events	10037410	Pulm n ry infarc ion	
Thrombotic events	10037421	Pulm n ry microembol	
Thrombotic events	10037437	Pulm n ry hr mbo is	
Thrombotic events	10068690	Pulm n ry v in oc lu i n	
Thrombotic events	10037458	Pulm n ry v no-occlusive isease	
Thrombotic events	10037459	Pulm n ry v n us hrombo is	
Thrombotic events	10038547	R nal vein mboli m	
Thrombotic events	100562 3	R nal vein occlusion	
Thrombotic events	10038548	R nal vein hr mbo is	
Thrombotic events	10038907	Retin l vein oc lu ion	
Thrombotic events	10038908	Retin l vein hrombo is	
Thrombotic events	10068479	SI QI I TTI pattern	
Thrombotic events	10068122	Splenic vein occlusion	
Thrombotic events	10041659	Splenic vein hrombosis	
Thrombotic events	10079164	Subclavian vein occlusi n	
Thrombotic events	10049446	Subclavian vein hr mbosis	
Thrombotic events	10042567	Superior sagitt l inus hrombo is	
Thrombotic events	10058988	Superior v na cava occlusion	
Thrombotic events	10042569	Superior v na cava syndrome	
Thrombotic events	10043570	Thr mbophl bi is	
Thrombotic events	10043581	Thr mbophl bi is mi r ns	
Thrombotic events	10043586	Thr mbophl bi is neonatal	
Thrombotic events	10043595	Thr mbophl bi is up r icial	
Thrombotic events	10043605	Thr mbosed varicose vein	
Thrombotic events	10067270	Thr mbo is corpora cavernosa	
Thrombotic events	10044457	Transverse inus hrombo is	
Thrombotic events	100471 3	V na cava emb li m	
Thrombotic events	10048932	V na cava ilt r ins r ion	
Thrombotic events	1007 397	V na cava ilt r removal	
Thrombotic events	10047195	V na cava hr mbo is	
Thrombotic events	10047209	V no ram abnormal	
Thrombotic events	100621 3	V noocclu ive disease	
Thrombotic events	10047216	V noocclu ive liver disease	
Thrombotic events	10077826	V nous n ioplasty	
Thrombotic events	10058990	V nous occlu ion	
Thrombotic events	10062175	V nous pera ion	
Thrombotic events	10068605	V nous recanalisation	
Thrombotic events	10052964	V nous repair	
Thrombotic events	10063389	V nous stent inser i n	
Thrombotic events	10047249	V nous hrombo is	
Thrombotic events	10067030	V nous hrombo is in pre n ncy	
Thrombotic events	10061408	V nous hrombo is limb	
Thrombotic events	10064602	V nous hrombo is ne natal	
Thrombotic events	10077829	Visc ral venous hr mbosis	
Thrombotic events	10075968	Administra ion ite hr mbo is	
Thrombotic events	10075178	Adr n l hr mbosis	
Thrombotic events	10060956	Angiogr m bn rm l	
Thrombotic events	10052906	Angiogr m cerebral bn rm l	
Thrombotic events	10057517	Angiogr m peripher l abn rm l	
Thrombotic events	10002817	Antiphosph lipid syndrome	
Thrombotic events	10076026	Applica i n ite thrombosis	
Thrombotic events	10058562	Arteriov nous fistula oc lu ion	
Thrombotic events	10003192	Arteriov nous fistula hr mbo is	
Thrombotic events	10053182	Arteriov nous raft hrombo is	
Thrombotic events	10078895	Ar i ici l blood vessel oc lu i n	
Thrombotic events	10048632	Atri l hrombo is	
Thrombotic events	100710 3	Basal g n lia stroke	
Thrombotic events	10049824	B ne infarc ion	
Thrombotic events	10074422	Brain stem emb li m	
Thrombotic events	10006147	Brain stem inf rc i n	
Thrombotic events	10068644	Brain stem str ke	
Thrombotic events	100625 3	Brain stem hrombosis	
Thrombotic events	10053994	Car iac ventricular hrombo is	
Thrombotic events	100795 3	Ca heter ite hrombo is	
Thrombotic events	10067167	Cer be lar mbolism	
Thrombotic events	10008034	Cer be lar infarc ion	
Thrombotic events	10076929	Cer bral conges i n	
Thrombotic events	10008118	Cer bral inf rc i n	
Thrombotic events	10008119	Cer bral inf rc i n foetal	
Thrombotic events	10008120	Cer bral ischaemia	
Thrombotic events	1007 311	Cer bral micro mbolism	
Thrombotic events	10070671	Cer bral s p ic inf rct	
Thrombotic events	10008132	Cer bral thrombosis	
Thrombotic events	10076895	Cer bral vascular occlu ion	
Thrombotic events	100521 3	Cer bro pinal thrombotic tamponade	
Thrombotic events	10008190	Cer brovascular accident	
Thrombotic events	10049165	Cer brovascular accident prophylaxis	
Thrombotic events	10008196	Cer brovascular dis rder	
Thrombotic events	10051902	Cer brovascular opera ion	
Thrombotic events	100574 3	Ch roidal infarc ion	
Thrombotic events	10069729	Co lat r l irculа i n	
Thrombotic events	10059025	Cor nary b pass hrombo is	
Thrombotic events	10074896	De ice emb lisa i n	
Thrombotic events	10064685	De ice oc lusi n	
Thrombotic events	10077455	De ice related hrombo is	
Thrombotic events	10013033	Diple ia	
Thrombotic events	10013048	Direc ional D ppler low tests bnorm l	
Thrombotic events	10013442	Diss minated intravas ul r coagula ion	
Thrombotic events	100134 3	Diss minated intravas ul r coagula ion in newb rn	
Thrombotic events	10060839	Emb lic c r br l infarc ion	
Thrombotic events	10065680	Emb lic pneumonia	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Thrombotic events	10014498	Emb lic str ke	
Thrombotic events	10061169	Emb li m	
Thrombotic events	10053601	Foetal cer brovascular is rder	
Thrombotic events	10051269	Graft hrombo is	
Thrombotic events	10079902	Ha m rrha ic adr nal infarc i n	
Thrombotic events	10019005	Ha m rrha ic cer bral inf rc i n	
Thrombotic events	100190 3	Ha m rrha ic inf rc i n	
Thrombotic events	10019016	Ha m rrha ic stroke	
Thrombotic events	10055677	Ha m rrha ic transforma i n stroke	
Thrombotic events	100190 3	Ha m rrhoids thrombosed	
Thrombotic events	10019465	Hemipare is	
Thrombotic events	10019468	Hemiple ia	
Thrombotic events	10062506	Heparin-induced hrombocyt penia	
Thrombotic events	10019680	Hepa ic infarc i n	
Thrombotic events	10074494	Hepa ic vascul r hrombo is	
Thrombotic events	10063868	Implant ite hrombosis	
Thrombotic events	10076839	Inci i n ite vess l occlusion	
Thrombotic events	10061216	Infarction	
Thrombotic events	10065489	Infu i n site hr mbo is	
Thrombotic events	10022104	Injec ion site hr mbo is	
Thrombotic events	10070754	Inn r ear infarc ion	
Thrombotic events	10073825	Ins llation site hrombosis	
Thrombotic events	10022657	Intestin l infarc ion	
Thrombotic events	10066087	Intrac rdiac mass	
Thrombotic events	10048620	Intrac rdiac hr mbus	
Thrombotic events	10076145	Me ic l device ite hrombo is	
Thrombotic events	10027401	Mesent ric vascular insuf iciency	
Thrombotic events	100745 3	Mesent ric vascular occlusion	
Thrombotic events	10073734	Microemb li m	
Thrombotic events	10027925	Monop re is	
Thrombotic events	10027926	Monoplegia	
Thrombotic events	10030936	Op ic n rve inf rc ion	
Thrombotic events	10068239	P ncrea ic inf rc ion	
Thrombotic events	10066059	P radoxical embo i m	
Thrombotic events	10079251	P r neoplastic hr mbo is	
Thrombotic events	10033885	P r p resis	
Thrombotic events	10033892	P r plegia	
Thrombotic events	10033985	P resis	
Thrombotic events	10053351	P ripheral revascul risation	
Thrombotic events	10035092	Pituitary inf rc i n	
Thrombotic events	10064820	Placental inf rc i n	
Thrombotic events	10059829	Pneuma ic c mpres i n herapy	
Thrombotic events	10077479	P rt l hunt procedure	
Thrombotic events	10066591	Post procedur l str ke	
Thrombotic events	10077022	Postp rtum hrombosis	
Thrombotic events	10063176	Pros he ic cardiac valve hr mbo is	
Thrombotic events	10068828	Pros he ic vess l impl ntation	
Thrombotic events	10049680	Quadrip re is	
Thrombotic events	10037714	Quadriple ia	
Thrombotic events	10038470	R nal inf rct	
Thrombotic events	10072226	R nal vascular hrombo is	
Thrombotic events	10051742	Retin l inf rc i n	
Thrombotic events	10062108	Retin l vas ular thrombosis	
Thrombotic events	10040621	Shunt occlu ion	
Thrombotic events	10059054	Shunt hr mbo is	
Thrombotic events	10058571	Spinal c rd infarc ion	
Thrombotic events	10082031	Spinal str ke	
Thrombotic events	10041648	Splenic infarc ion	
Thrombotic events	10074601	Splenic hrombo is	
Thrombotic events	10074515	Stoma site hrombosis	
Thrombotic events	100596 3	Stroke in evolu ion	
Thrombotic events	10058408	Sur ical vascular hunt	
Thrombotic events	10043337	Tes i ul r inf rc i n	
Thrombotic events	10064961	Thalamic infarc ion	
Thrombotic events	10043530	Thr mbectomy	
Thrombotic events	10043540	Thr mboan ii is obliter ns	
Thrombotic events	10043568	Thr mbolysis	
Thrombotic events	10043607	Thr mbo is	
Thrombotic events	10062546	Thr mbo is in de ice	
Thrombotic events	10043626	Thr mbo is mes nteric vessel	
Thrombotic events	10043634	Thr mbo is prophyla is	
Thrombotic events	1006 347	Thr mbo ic c rebr l infarc i n	
Thrombotic events	10043647	Thr mbo ic str ke	
Thrombotic events	10043742	Thyroid infarc i n	
Thrombotic events	10045168	Tumour emb li m	
Thrombotic events	10081994	Tumour hr mbect my	
Thrombotic events	10068067	Tumour hr mbosis	
Thrombotic events	10061604	Ultrasonic an iogram abn rm l	
Thrombotic events	100454 3	Ultrasound D ppler bn rm l	
Thrombotic events	10076714	Umbilic l c rd occlusion	
Thrombotic events	10071652	Umbilic l c rd hr mbo is	
Thrombotic events	10076190	Vaccina i n ite thrombosis	
Thrombotic events	10078675	Vascular access ite hr mbo is	
Thrombotic events	100808 3	Vascular de ice oc lu i n	
Thrombotic events	10067740	Vascular raft	
Thrombotic events	10049060	Vascular raft oc lu ion	
Thrombotic events	10069922	Vascular raft hrombo is	
Thrombotic events	10049071	Vascular p ra ion	
Thrombotic events	10063382	Vascular stent inser i n	
Thrombotic events	100771 3	Vascular stent oc lusi n	
Thrombotic events	10063934	Vascular stent hrombosis	
Thrombotic events	10058794	Vaso ila ion procedure	
Thrombotic events	10076838	Vessel puncture site oc lusi n	
Thrombotic events	10070949	Vessel puncture site hrombosis	
Thrombotic events	10066856	Visu l mid ine shift syndrome	
Re inal dis rd r	10054881	Acquired pi m nted re inopa hy	
Re inal dis rd r	1007 367	A ute ma ul r out r re inopa hy	
Re inal dis rd r	10074444	A ute zon l oc ult uter re inopa hy	
Re inal dis rd r	10064930	Age-r lated ma ul r degenera i n	
Re inal dis rd r	10053227	AIDS re in pa hy	
Re inal dis rd r	100019 3	Amaurosis fugax	
Re inal dis rd r	10002444	Angiogr m retina abnormal	
Re inal dis rd r	10063452	Arterios l ro ic re in pathy	
Re inal dis rd r	10071578	Aut immune re in pathy	
Re inal dis rd r	1000 390	B ni n neopla m of re ina	
Re inal dis rd r	100048 3	Biopsy re ina bnormal	
Re inal dis rd r	10072959	Birdshot chori re inopa hy	
Re inal dis rd r	1007 331	Ch lester lo is bu bi	
Re inal dis rd r	10008762	Ch rioretin l atrophy	
Re inal dis rd r	100817 3	Ch rioretin l disorder	
Re inal dis rd r	10008766	Ch rioretin l scar	
Re inal dis rd r	10008769	Ch rioretini is	
Re inal dis rd r	10063118	Ch rioretin pa hy	
Re inal dis rd r	10010050	Colour blindness	
Re inal dis rd r	10010051	Colour blindness acquired	
Re inal dis rd r	10010056	Colour ision tests bn rmal	
Re inal dis rd r	10010057	Colour ision tests bn rmal blue-ye low	
Re inal dis rd r	10010058	Colour ision tests bn rmal red- reen	
Re inal dis rd r	1007 321	Commo io re inae	
Re inal dis rd r	10058202	Cystoid macular oedema	
Re inal dis rd r	10079805	Delayed light adaptation	
Re inal dis rd r	10071004	Detachment of ma ul r re inal pi m nt epi h lium	
Re inal dis rd r	10052501	Detachment of re in l pi ment epi helium	
Re inal dis rd r	10012688	Di be ic re inal oedema	
Re inal dis rd r	10012689	Di be ic re inopa hy	
Re inal dis rd r	10078228	Diffuse uveal m lanocy ic pro iferation	
Re inal dis rd r	10075567	Dry age-related macular degen ra ion	
Re inal dis rd r	10015831	Extraocul r re inoblastoma	
Re inal dis rd r	10015901	E uda ive re inopa hy	
Re inal dis rd r	10051045	Eye nae us	
Re inal dis rd r	10017320	Fundoscopy abnormal	
Re inal dis rd r	10081899	Hypotony ma ul pathy	
Re inal dis rd r	1007 392	Immune recov ry uvei is	
Re inal dis rd r	10073499	Intern l limi ing m mbrane peeling	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Re inal disorder	10073929	IRVAN syndrome	
Re inal disorder	10059239	L ukaemic re inopa hy	
Re inal disorder	10049935	Lipaemia re ina is	
Re inal disorder	10025407	Macular cyst	
Re inal disorder	10025409	Macular degen ra i n	
Re inal disorder	10075873	Macular deta hment	
Re inal disorder	1007 392	Macular bro is	
Re inal disorder	10051058	Macular hole	
Re inal disorder	10065534	Macular is ha mia	
Re inal disorder	10025415	Macular oedema	
Re inal disorder	10025416	Macular pacity	
Re inal disorder	10071041	Macular pi m nta i n	
Re inal disorder	10060815	Macular ps ud h le	
Re inal disorder	10025419	Macular re lex bno mal	
Re inal disorder	1006 319	Macular rupture	
Re inal disorder	10063185	Macular sc r	
Re inal disorder	10081199	Macular t langiecta ia	
Re inal disorder	10025425	Maculopa hy	
Re inal disorder	10026432	Mali nant neopla m of re ina	
Re inal disorder	1007 376	MEK inhibitor-asso iated serous re in pa hy	
Re inal disorder	10063341	Metamorphopsia	
Re inal disorder	10079959	Myopic h rioretin l deg neration	
Re inal disorder	10080534	Myopic trac i n ma ulopa hy	
Re inal disorder	10064997	Necro i ing re ini is	
Re inal disorder	10071129	Neovascular age-related macular deg n ra ion	
Re inal disorder	10062940	Neur pathy, ata ia, re ini is pigmentosa s ndr me	
Re inal disorder	10074696	Noninfec ive chori re ini is	
Re inal disorder	10074699	Noninfec ive re ini is	
Re inal disorder	1008 1568	Non pr lif ra ive re inopa hy	
Re inal disorder	1006 311	Par ne plas ic re inopa hy	
Re inal disorder	10 34962	Photop ia	
Re inal disorder	10 37525	Pupill ry light re lex tests abnormal	
Re inal disorder	10075189	Purtsch r re inopa hy	
Re inal disorder	10064714	Ra ia ion re in pa hy	
Re inal disorder	10064145	Re inal an ury m	
Re inal disorder	10079121	Re inal an ury m nupture	
Re inal disorder	10 38824	Re inal arteriov nous malforma i n	
Re inal disorder	10 38826	Re inal artery emb li m	
Re inal disorder	10 38827	Re inal artery oc lu i n	
Re inal disorder	10 38829	Re inal artery spasm	
Re inal disorder	10 38830	Re inal artery steno is	
Re inal disorder	10 38831	Re inal artery thrombosis	
Re inal disorder	10077911	Re inal colat ral vessels	
Re inal disorder	10052643	Re inal colob ma	
Re inal disorder	10074908	Re inal cryoabla i n	
Re inal disorder	10 38839	Re inal cyst	
Re inal disorder	10 38840	Re inal cyst excisi n	
Re inal disorder	10 38845	Re inal degenera ion	
Re inal disorder	10 38846	Re inal depi m nta ion	
Re inal disorder	10 38847	Re inal depo its	
Re inal disorder	10 38848	Re inal detachment	
Re inal disorder	10 38853	Re inal disord r	
Re inal disorder	10062776	Re inal drusen	
Re inal disorder	10 38857	Re inal dystrophy	
Re inal disorder	10 38862	Re inal exudates	
Re inal disorder	1007 391	Re inal ibrosis	
Re inal disorder	10 38866	Re inal func ion test abnormal	
Re inal disorder	10 38867	Re inal ha m rrhage	
Re inal disorder	10067848	Re inal impl nt	
Re inal disorder	10051742	Re inal inf rc i n	
Re inal disorder	10064833	Re inal in ltrates	
Re inal disorder	10057430	Re inal injury	
Re inal disorder	10 38871	Re inal is haemia	
Re inal disorder	10 38873	Re inal laser coa ula ion	
Re inal disorder	10057428	Re inal m lanocytoma	
Re inal disorder	10 38878	Re inal m lanoma	
Re inal disorder	10052784	Re inal mi raine	
Re inal disorder	10057407	Re inal ne plasm	
Re inal disorder	10055666	Re inal neovas ularisation	
Re inal disorder	10 38886	Re inal oedema	
Re inal disorder	10062107	Re inal op ra i n	
Re inal disorder	10 38891	Re inal pa lor	
Re inal disorder	10071246	Re inal perivascular hea hing	
Re inal disorder	10069652	Re inal phototo i ity	
Re inal disorder	10062971	Re inal pi ment pi heli l tear	
Re inal disorder	10 38893	Re inal pi ment pi heli pa hy	
Re inal disorder	10 38894	Re inal pi mentation	
Re inal disorder	10 38895	Re inal sc r	
Re inal disorder	10 38897	Re inal tear	
Re inal disorder	10 38899	Re inal tel ngiectasia	
Re inal disorder	10077890	Re inal hi kening	
Re inal disorder	10048955	Re inal to icity	
Re inal disorder	10067870	Re inal tr n pl nt	
Re inal disorder	10 38900	Re inal tumour ex i ion	
Re inal disorder	10 38901	Re inal vascular is rd r	
Re inal disorder	10 38903	Re inal vascular oc lu ion	
Re inal disorder	10062108	Re inal vascular hr mbo is	
Re inal disorder	10 38905	Re inal vasculi is	
Re inal disorder	10 38907	Re inal vein occlusion	
Re inal disorder	10 38908	Re inal vein hr mbo is	
Re inal disorder	10081463	Re inal vein v rices	
Re inal disorder	10073562	Re inal vessel avulsion	
Re inal disorder	10079569	Re inal white wi hout pressure	
Re inal disorder	10 38910	Re ini is	
Re inal disorder	10 38914	Re ini is pigmentosa	
Re inal disorder	10 38916	Re inoblastoma	
Re inal disorder	10059663	Re ino ram abnormal	
Re inal disorder	10 38923	Re inopa hy	
Re inal disorder	10051447	Re inopa hy ha morrha ic	
Re inal disorder	10 38926	Re inopa hy h pert nsive	
Re inal disorder	10 38930	Re inopa hy h per isso ity	
Re inal disorder	10 38933	Re inopa hy of prematurity	
Re inal disorder	10 38934	Re inopa hy pr lifera ive	
Re inal disorder	10 38935	Re inopa hy sickle cell	
Re inal disorder	10 38936	Re inopa hy s lar	
Re inal disorder	10066985	Re inopexy	
Re inal disorder	10061492	Re inoschisis	
Re inal disorder	10065569	Rhegmatog nous re inal detachm nt	
Re inal disorder	10 39677	Scin i la ing scotoma	
Re inal disorder	10066785	Scleral bu k ing surg ry	
Re inal disorder	10040114	Ser us re inal deta hment	
Re inal disorder	10081652	Serpi inous ch roi i is	
Re inal disorder	10082958	Subre inal bro is	
Re inal disorder	1006 356	Subre inal luid	
Re inal disorder	10071935	Subre inal haemat ma	
Re inal disorder	10082240	Subre inal hyp rre lec ive exuda ion	
Re inal disorder	1008 316	Tractional retin l detachm nt	
Re inal disorder	10045178	Tunn l vi i n	
Re inal disorder	10065622	Venous sta is re in pa hy	
Re inal disorder	10047567	Vi ual i ld tests abnormal	
Re inal disorder	10066421	Vitre l cells	
Re inal disorder	10047644	Vitrectomy	
Re inal disorder	10071035	Vitre macular interface bnormal	
Re inal disorder	10057435	Vitre us a he i ns	
Re inal disorder	10047650	Vitre us detachm nt	
Re inal disorder	10047651	Vitre us disorder	
Re inal disorder	10047654	Vitre us loaters	
Re inal disorder	10071936	Vitre us haematoma	
Re inal disorder	10047655	Vitre us haemorrhage	
Re inal disorder	10077514	Vitre us haze	
Re inal disorder	10047663	Vitri is	
Gastr intes inal disord rs	10028813	Nausea	
Gastr intes inal disord rs	10012735	Diarrhoea	
Gastr intes inal disord rs	10047700	Vomi ing	

表 2.7.4.9－75　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver22.0）（続き）

Gastrointes inal disord rs	10000081	Abdomin l p in	
Headache	10019211	Headа he	
Blood uric a id increased	10005861	Blood uric acid in reased	
Hyp rkalemia	10020646	Hyperk la mia	
Hyp rkalemia	10005722	Blood potas ium abnormal	
Hyp rkalemia	10005725	Blood potas ium in reased	
Malignancy			Neoplasms beni n, ma ignant nd un peci ied (incl cysts and polyps)
QT pr longa ion	100 3748	Electrocardiogr m QT interv l abnormal	
QT pr longa ion	10014387	Electrocardiogr m QT prolonged	
QT pr longa ion	100248 3	L ng QT syndrome	
QT pr longa ion	10057926	L ng QT syndrome congenital	
QT pr longa ion	10044066	Torsade de pointes	
QT pr longa ion	10047302	Ventricular ta hycardia	
QT pr longa ion	10007515	Cardiac arrest	
QT pr longa ion	100499 3	Cardiac dea h	
QT pr longa ion	10061592	Cardiac ibri la ion	
QT pr longa ion	10007617	Cardio-respiratory arrest	
QT pr longa ion	10052464	Electrocardiogr m r polarisa i n bn rma ity	
QT pr longa ion	10062314	Electrocardiogr m U wave inv r i n	
QT pr longa ion	100579 3	Electrocardiogr m U wave pres nt	
QT pr longa ion	10055032	Electrocardiogr m U-wave abnormality	
QT pr longa ion	10024855	Loss of consci u ness	
QT pr longa ion	10077361	Mul iple org n dysfunc ion syndrome	
QT pr longa ion	10081980	Subacute kidney injury	
QT pr longa ion	10049418	Sudden cardiac dea h	
QT pr longa ion	10042434	Sudden dea h	
QT pr longa ion	10042772	Syncope	
QT pr longa ion	10047281	Ventricular rrhy hmia	
QT pr longa ion	10047290	Ventricular brilla i n	
QT pr longa ion	10047294	Ventricular lutter	
QT pr longa ion	10065341	Ventricular ta hy rrhy hmia	

5.3.5.3—3 統計解析計画書　別添より引用

表 2.7.4.9－76　規定した基準一覧（52 週）

項目	規定した基準
尿酸	いずれかの時点で，治療期間開始日と比較して 25%以上増加かつ 7.0 mg/dL 超を示した被験者
血清 K	いずれかの時点で，6.0 mmol/L 超 7.0 mmol/L 以下を示した被験者
	いずれかの時点で，7.0 mmol/L 超を示した被験者
VEGF	いずれかの時点で，治療期間開始日の 2 倍かつ 200 pg/mL 以上を示した被験者
Hb	NDD-CKD，PD-CKD：いずれかの時点で，13.0 g/dL 以上を示した被験者
	HD-CKD：いずれかの時点で，12.0 g/dL 以上を示した被験者
	NDD-CKD，PD-CKD：いずれかの時点で，14.0 g/dL 以上を示した被験者
	HD-CKD：いずれかの時点で，13.0 g/dL 以上を示した被験者
	（ISS-1 のみ）NDD-CKD，PD-CKD：いずれかの時点で，治療期間開始日からの変化量が 2.0 g/dL 超かつ 13.0 g/dL 以上を示した被験者
	（ISS-1 のみ）HD-CKD：いずれかの時点で，治療期間開始日からの変化量が 2.0 g/dL 超かつ 12.0 g/dL 以上を示した被験者
	（ISS-1 のみ）NDD-CKD，PD-CKD：いずれかの時点で，治療期間開始日からの変化量が 2.0 g/dL 超かつ 14.0 g/dL 以上を示した被験者
	（ISS-1 のみ）HD-CKD：いずれかの時点で，治療期間開始日からの変化量が 2.0 g/dL 超かつ 13.0 g/dL 以上を示した被験者
eGFR	NDD-CKD：いずれかの時点で，治療期間開始日からの変化率が 30%超減少した被験者
AST，ALT	いずれかの時点で，AST が ULN の 3 倍超を示した被験者
	いずれかの時点で，AST が ULN の 5 倍超を示した被験者
	いずれかの時点で，AST が ULN の 8 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 3 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 5 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 8 倍超を示した被験者

表 2.7.4.9－76　規定した基準一覧（52 週）（続き）

項目	規定した基準
AST，ALT（続き）	いずれかの時点で，AST が ULN の 3 倍超かつ総ビリルビンが ULN の 2 倍以下を示した被験者
	いずれかの時点で，ALT が ULN の 3 倍超かつ総ビリルビンが ULN の 2 倍以下を示した被験者
	いずれかの時点で，AST が ULN の 3 倍超かつ総ビリルビンが ULN の 2 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 3 倍超かつ総ビリルビンが ULN の 2 倍超を示した被験者
	いずれかの時点で，AST 又は ALT が ULN の 3 倍超かつ ALP が ULN の 2 倍未満かつ総ビリルビンが ULN の 2 倍超を示した被験者
収縮期血圧	NDD-CKD，PD-CKD：いずれかの時点で，治療期間開始日からの変化量が 20 mmHg 超かつ 180 mmHg 超を示した被験者
	HD-CKD：いずれかの時点で，治療期間開始日からの変化量が 20 mmHg 超かつ 190 mmHg 超を示した被験者
拡張期血圧	いずれかの時点で，治療期間開始日からの変化量が 15 mmHg 超かつ 110 mmHg 超を示した被験者

NDD-CKD：保存期慢性腎臓病；PD-CKD：腹膜透析を実施中の慢性腎臓病；HD-CKD：血液透析を実施中の慢性腎臓病；ULN：基準値上限

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）

Parameter:Ery. Mean Corpuscular Volume (fL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	93.6	5.2	93.0	(82, 119)						
	Week 2	151	94.2	5.3	94.0	(82, 118)	151	93.6 (5.2)	0.6	1.2	1.0	(-2, 4)
	Week 4	149	94.6	5.3	94.0	(83, 120)	149	93.5 (5.3)	1.0	1.6	1.0	(-3, 6)
	Week 6	148	95.2	5.6	95.0	(82, 122)	148	93.5 (5.3)	1.7	1.9	1.0	(-3, 10)
	Week 8	145	95.5	5.4	96.0	(83, 122)	145	93.5 (5.2)	2.0	2.1	2.0	(-3, 9)
	Week 10	145	95.7	5.4	96.0	(82, 124)	145	93.4 (5.2)	2.3	2.2	2.0	(-3, 11)
	Week 12	145	95.9	5.5	96.0	(83, 123)	145	93.5 (5.2)	2.4	2.4	2.0	(-2, 14)
	Week 16	143	95.9	5.8	96.0	(82, 124)	143	93.5 (5.3)	2.4	2.7	2.0	(-4, 17)
	Week 20	140	95.9	6.0	95.0	(82, 128)	140	93.5 (5.2)	2.4	2.9	2.0	(-4, 16)
	Week 24	132	95.8	6.3	95.0	(82, 132)	132	93.6 (5.3)	2.2	3.1	2.0	(-4, 17)
	Week 28	126	96.1	6.4	95.0	(82, 130)	126	93.6 (5.3)	2.5	3.0	2.0	(-4, 16)
	Week 32	121	96.1	6.1	96.0	(82, 128)	121	93.6 (5.3)	2.5	2.7	2.0	(-4, 10)
	Week 36	119	96.4	6.1	96.0	(83, 128)	119	93.7 (5.3)	2.6	2.8	2.0	(-4, 15)
	Week 40	115	96.2	5.6	96.0	(83, 125)	115	93.8 (5.4)	2.4	2.5	2.0	(-4, 10)
	Week 44	114	96.3	5.7	96.0	(84, 127)	114	93.7 (5.3)	2.5	2.7	2.0	(-4, 11)
	Week 48	112	96.5	5.8	96.0	(83, 128)	112	93.7 (5.3)	2.8	2.8	2.0	(-6, 13)
	Week 52	111	96.2	5.9	95.0	(83, 126)	111	93.7 (5.3)	2.5	2.8	2.0	(-4, 15)
darbepoetin	Baseline	153	93.5	5.6	93.0	(79, 110)						
	Week 2	153	94.0	6.3	94.0	(77, 131)	153	93.5 (5.6)	0.5	2.4	0.0	(-3, 27)
	Week 4	153	93.8	5.5	94.0	(78, 109)	153	93.5 (5.6)	0.3	1.5	0.0	(-7, 3)
	Week 6	152	94.0	5.6	94.0	(77, 109)	152	93.5 (5.6)	0.5	2.0	1.0	(-10, 6)
	Week 8	151	93.6	5.7	93.0	(76, 109)	151	93.5 (5.7)	0.0	2.5	0.0	(-12, 7)
	Week 10	150	93.7	5.9	94.0	(76, 112)	150	93.6 (5.6)	0.0	2.7	0.0	(-13, 7)
	Week 12	148	93.3	5.7	93.0	(75, 113)	148	93.7 (5.6)	-0.4	3.2	0.0	(-16, 6)
	Week 16	148	92.9	6.0	92.5	(75, 112)	148	93.6 (5.6)	-0.8	3.6	-1.0	(-18, 7)
	Week 20	144	92.6	5.8	92.5	(76, 112)	144	93.8 (5.5)	-1.2	3.9	-1.0	(-19, 8)
	Week 24	140	92.9	5.5	93.0	(75, 108)	140	93.6 (5.4)	-0.7	3.7	-1.0	(-17, 9)
	Week 28	137	93.6	5.3	94.0	(79, 108)	137	93.7 (5.2)	-0.1	3.8	0.0	(-17, 11)
	Week 32	133	94.1	5.2	94.0	(80, 107)	133	93.9 (5.2)	0.1	4.0	0.0	(-16, 12)
	Week 36	130	94.1	5.2	94.0	(80, 107)	130	93.8 (5.2)	0.3	4.0	0.0	(-17, 11)
	Week 40	128	93.8	5.1	94.0	(81, 108)	128	93.7 (5.2)	0.1	4.1	0.0	(-18, 13)
	Week 44	125	94.1	5.2	94.0	(80, 108)	125	93.8 (5.1)	0.3	3.9	0.0	(-17, 12)
	Week 48	125	94.0	5.2	94.0	(82, 108)	125	93.8 (5.1)	0.2	4.1	1.0	(-16, 12)
	Week 52	123	93.9	5.4	94.0	(81, 109)	123	93.8 (5.1)	0.1	3.9	0.0	(-16, 12)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Ery. Mean Corpuscular Hemoglobin (pg)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	31.07	1.89	31.00	(26.2, 39.7)						
	Week 2	151	31.21	1.94	31.10	(26.7, 40.3)	151	31.07 (1.89)	0.14	0.50	0.20	(-1.1, 1.3)
	Week 4	149	31.41	1.90	31.30	(27.1, 40.3)	149	31.05 (1.89)	0.36	0.59	0.30	(-1.7, 1.9)
	Week 6	148	31.56	1.96	31.40	(27.1, 41.0)	148	31.05 (1.90)	0.51	0.75	0.50	(-1.2, 3.2)
	Week 8	145	31.57	1.89	31.60	(27.1, 40.7)	145	31.03 (1.88)	0.54	0.81	0.40	(-1.3, 3.9)
	Week 10	145	31.68	1.98	31.80	(27.1, 42.3)	145	31.02 (1.88)	0.66	0.94	0.60	(-1.8, 4.9)
	Week 12	145	31.71	1.98	31.80	(26.8, 42.1)	145	31.03 (1.88)	0.67	0.97	0.60	(-1.3, 4.8)
	Week 16	143	31.73	2.06	31.70	(27.0, 42.5)	143	31.02 (1.89)	0.71	1.16	0.60	(-1.7, 7.0)
	Week 20	140	31.80	2.16	31.95	(26.8, 43.6)	140	31.07 (1.89)	0.74	1.30	0.50	(-1.8, 6.2)
	Week 24	132	31.84	2.25	31.60	(27.2, 45.2)	132	31.08 (1.91)	0.75	1.36	0.60	(-1.9, 7.0)
	Week 28	126	31.96	2.26	31.85	(27.4, 44.2)	126	31.09 (1.89)	0.88	1.29	0.60	(-1.6, 6.5)
	Week 32	121	32.03	2.12	32.00	(27.1, 43.7)	121	31.10 (1.91)	0.92	1.11	0.70	(-0.9, 5.2)
	Week 36	119	32.13	2.15	31.90	(27.3, 43.4)	119	31.14 (1.91)	0.99	1.23	0.70	(-1.1, 6.5)
	Week 40	115	32.10	2.02	32.00	(27.6, 43.0)	115	31.18 (1.92)	0.92	1.16	0.70	(-1.5, 6.0)
	Week 44	114	32.14	2.06	31.85	(27.5, 43.3)	114	31.14 (1.91)	1.00	1.22	0.75	(-1.2, 4.6)
	Week 48	112	32.24	2.09	32.10	(27.5, 44.2)	112	31.12 (1.90)	1.11	1.17	1.00	(-1.2, 4.6)
	Week 52	111	32.11	2.03	32.00	(27.3, 44.0)	111	31.11 (1.90)	0.99	1.19	0.70	(-1.3, 4.9)
darbepoetin	Baseline	153	31.10	2.11	31.00	(25.7, 36.9)						
	Week 2	153	31.17	2.38	31.10	(24.9, 46.2)	153	31.10 (2.11)	0.06	0.95	0.00	(-1.9, 9.3)
	Week 4	153	31.01	1.99	31.00	(25.4, 36.8)	153	31.10 (2.11)	-0.09	0.67	-0.10	(-2.7, 1.8)
	Week 6	152	30.97	2.00	30.90	(24.7, 36.2)	152	31.11 (2.11)	-0.14	0.79	-0.10	(-3.8, 1.7)
	Week 8	151	30.87	2.06	30.80	(24.5, 37.8)	151	31.11 (2.12)	-0.25	1.09	-0.20	(-5.5, 2.1)
	Week 10	150	30.75	2.13	30.85	(24.8, 37.1)	150	31.15 (2.10)	-0.40	1.16	-0.30	(-4.8, 2.3)
	Week 12	148	30.65	2.10	30.55	(24.3, 36.9)	148	31.16 (2.11)	-0.51	1.46	-0.40	(-6.6, 3.0)
	Week 16	148	30.55	2.22	30.50	(23.7, 36.9)	148	31.15 (2.10)	-0.61	1.51	-0.55	(-6.2, 3.7)
	Week 20	144	30.56	2.10	30.55	(23.6, 36.8)	144	31.19 (2.07)	-0.63	1.68	-0.60	(-6.9, 4.0)
	Week 24	140	30.77	2.15	30.80	(23.1, 37.9)	140	31.17 (2.04)	-0.40	1.57	-0.40	(-7.0, 4.6)
	Week 28	137	31.06	2.07	31.20	(25.1, 38.8)	137	31.22 (2.00)	-0.17	1.56	-0.20	(-6.8, 4.6)
	Week 32	133	31.26	2.01	31.20	(25.3, 36.9)	133	31.28 (2.00)	-0.02	1.56	0.00	(-6.2, 5.0)
	Week 36	130	31.27	1.95	31.35	(25.4, 36.0)	130	31.25 (2.01)	0.02	1.72	0.00	(-5.9, 5.7)
	Week 40	128	31.21	1.97	31.10	(25.3, 36.4)	128	31.23 (2.01)	-0.02	1.77	-0.05	(-5.9, 6.1)
	Week 44	125	31.36	1.97	31.40	(25.4, 36.0)	125	31.26 (1.98)	0.10	1.66	0.10	(-5.6, 6.3)
	Week 48	125	31.36	1.96	31.50	(26.9, 36.3)	125	31.26 (1.98)	0.10	1.79	0.20	(-7.3, 6.1)
	Week 52	123	31.25	1.96	31.40	(26.0, 36.4)	123	31.26 (2.00)	-0.02	1.61	0.00	(-6.4, 5.7)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Ery. Mean Corpuscular HGB Concentration (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	33.18	0.63	33.20	(31.5, 34.5)						
	Week 2	151	33.13	0.65	33.10	(31.3, 34.8)	151	33.18 (0.63)	-0.05	0.53	0.00	(-1.5, 1.2)
	Week 4	149	33.19	0.59	33.20	(31.5, 34.8)	149	33.18 (0.63)	0.01	0.52	-0.10	(-1.6, 1.4)
	Week 6	148	33.13	0.55	33.15	(31.4, 34.6)	148	33.18 (0.63)	-0.05	0.55	0.00	(-1.5, 1.1)
	Week 8	145	33.07	0.50	33.00	(32.0, 34.6)	145	33.19 (0.63)	-0.12	0.58	-0.20	(-1.3, 1.5)
	Week 10	145	33.08	0.51	33.10	(31.7, 34.3)	145	33.18 (0.63)	-0.11	0.56	-0.10	(-1.3, 1.4)
	Week 12	145	33.05	0.52	33.10	(31.8, 34.7)	145	33.19 (0.63)	-0.14	0.55	-0.20	(-1.4, 1.5)
	Week 16	143	33.08	0.50	33.00	(32.0, 34.8)	143	33.18 (0.63)	-0.10	0.63	-0.20	(-1.8, 2.2)
	Week 20	140	33.17	0.48	33.10	(31.9, 34.6)	140	33.20 (0.63)	-0.03	0.69	-0.10	(-1.5, 1.9)
	Week 24	132	33.22	0.52	33.20	(31.7, 34.7)	132	33.20 (0.62)	0.01	0.73	0.00	(-1.5, 3.2)
	Week 28	126	33.28	0.55	33.30	(31.7, 34.7)	126	33.21 (0.60)	0.07	0.69	0.00	(-1.8, 2.2)
	Week 32	121	33.33	0.58	33.30	(31.8, 34.5)	121	33.22 (0.61)	0.11	0.60	0.10	(-1.3, 2.1)
	Week 36	119	33.33	0.57	33.30	(31.7, 34.8)	119	33.20 (0.61)	0.12	0.65	0.10	(-1.9, 2.2)
	Week 40	115	33.36	0.57	33.30	(31.8, 34.8)	115	33.23 (0.61)	0.13	0.71	0.10	(-2.0, 3.3)
	Week 44	114	33.37	0.57	33.30	(31.3, 35.1)	114	33.21 (0.61)	0.16	0.74	0.10	(-1.6, 2.2)
	Week 48	112	33.41	0.48	33.30	(31.7, 34.7)	112	33.21 (0.61)	0.19	0.64	0.20	(-1.6, 1.7)
	Week 52	111	33.37	0.64	33.30	(31.4, 35.0)	111	33.20 (0.61)	0.16	0.74	0.20	(-1.6, 2.4)
darbepoetin	Baseline	153	33.25	0.72	33.20	(30.5, 35.6)						
	Week 2	153	33.14	0.68	33.20	(31.3, 35.3)	153	33.25 (0.72)	-0.11	0.53	-0.10	(-1.5, 1.1)
	Week 4	153	33.04	0.56	33.10	(31.8, 35.1)	153	33.25 (0.72)	-0.21	0.54	-0.20	(-1.8, 1.4)
	Week 6	152	32.93	0.55	32.90	(31.5, 34.6)	152	33.25 (0.72)	-0.32	0.56	-0.40	(-1.8, 1.8)
	Week 8	151	32.96	0.59	33.00	(31.4, 35.8)	151	33.26 (0.72)	-0.30	0.62	-0.40	(-1.8, 1.1)
	Week 10	150	32.81	0.57	32.90	(31.2, 34.9)	150	33.25 (0.72)	-0.45	0.64	-0.40	(-2.3, 1.5)
	Week 12	148	32.84	0.55	32.90	(31.4, 34.3)	148	33.25 (0.72)	-0.42	0.72	-0.40	(-2.3, 1.4)
	Week 16	148	32.86	0.68	32.80	(31.0, 36.0)	148	33.26 (0.72)	-0.40	0.69	-0.40	(-2.0, 1.7)
	Week 20	144	32.98	0.60	33.05	(30.8, 35.0)	144	33.27 (0.73)	-0.29	0.72	-0.30	(-2.2, 1.6)
	Week 24	140	33.09	0.66	33.20	(30.9, 35.1)	140	33.30 (0.72)	-0.21	0.73	-0.20	(-2.3, 2.0)
	Week 28	137	33.16	0.66	33.20	(31.3, 35.9)	137	33.30 (0.73)	-0.14	0.72	-0.20	(-2.0, 1.9)
	Week 32	133	33.23	0.64	33.20	(31.5, 35.7)	133	33.30 (0.73)	-0.07	0.69	0.00	(-1.8, 1.2)
	Week 36	130	33.22	0.61	33.20	(31.6, 34.8)	130	33.31 (0.74)	-0.09	0.69	-0.10	(-2.0, 2.0)
	Week 40	128	33.27	0.71	33.30	(31.2, 35.2)	128	33.31 (0.74)	-0.04	0.80	0.00	(-2.5, 2.4)
	Week 44	125	33.33	0.63	33.30	(31.8, 35.2)	125	33.32 (0.74)	0.01	0.81	0.00	(-2.5, 2.4)
	Week 48	125	33.34	0.70	33.30	(31.1, 35.0)	125	33.32 (0.74)	0.02	0.88	0.10	(-3.8, 2.2)
	Week 52	123	33.26	0.67	33.30	(31.5, 34.9)	123	33.33 (0.74)	-0.07	0.80	-0.10	(-2.9, 2.6)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Erythrocytes Distribution Width (%)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	14.48	1.56	14.20	(12.4, 22.8)						
	Week 2	151	14.94	1.66	14.60	(12.1, 23.5)	151	14.48 (1.56)	0.46	0.65	0.40	(-0.9, 3.3)
	Week 4	149	15.17	1.79	14.80	(12.0, 23.7)	149	14.49 (1.56)	0.68	0.95	0.60	(-1.5, 5.3)
	Week 6	148	15.26	1.92	14.80	(12.3, 23.7)	148	14.48 (1.56)	0.77	1.15	0.70	(-1.9, 9.1)
	Week 8	145	15.04	1.70	14.60	(12.3, 21.8)	145	14.48 (1.57)	0.55	0.99	0.50	(-2.2, 3.8)
	Week 10	145	14.88	1.61	14.70	(12.4, 20.4)	145	14.49 (1.57)	0.39	1.19	0.30	(-3.3, 4.2)
	Week 12	145	14.62	1.56	14.40	(11.9, 21.3)	145	14.47 (1.57)	0.15	1.27	0.10	(-3.2, 4.1)
	Week 16	143	14.20	1.29	14.00	(11.9, 19.4)	143	14.48 (1.58)	-0.28	1.36	-0.10	(-4.9, 3.1)
	Week 20	140	14.20	1.35	13.90	(11.4, 20.4)	140	14.44 (1.57)	-0.24	1.48	-0.20	(-5.6, 5.9)
	Week 24	132	14.36	1.47	14.10	(11.8, 21.8)	132	14.40 (1.59)	-0.04	1.47	0.00	(-5.4, 4.7)
	Week 28	126	14.33	1.44	14.30	(12.0, 22.4)	126	14.36 (1.53)	-0.04	1.36	0.00	(-5.1, 3.6)
	Week 32	121	14.24	1.21	14.10	(12.0, 19.6)	121	14.28 (1.34)	-0.05	1.23	0.00	(-4.2, 3.2)
	Week 36	119	14.12	1.13	14.10	(12.1, 19.1)	119	14.35 (1.54)	-0.23	1.28	-0.10	(-5.8, 2.8)
	Week 40	115	14.03	1.27	14.00	(11.9, 20.4)	115	14.26 (1.33)	-0.23	1.15	-0.10	(-4.3, 3.0)
	Week 44	114	14.01	1.40	13.90	(11.8, 23.3)	114	14.27 (1.34)	-0.26	1.22	-0.20	(-4.1, 4.5)
	Week 48	112	14.11	1.32	13.90	(12.1, 22.2)	112	14.27 (1.35)	-0.17	1.23	-0.10	(-4.6, 3.4)
	Week 52	111	14.07	1.25	13.90	(12.2, 20.2)	111	14.24 (1.34)	-0.17	1.28	-0.10	(-4.0, 4.5)
darbepoetin	Baseline	153	14.56	1.73	14.20	(11.9, 22.7)						
	Week 2	153	14.84	1.69	14.40	(12.4, 22.7)	153	14.56 (1.73)	0.28	0.58	0.30	(-1.5, 2.1)
	Week 4	153	14.84	1.66	14.50	(12.5, 22.2)	153	14.56 (1.73)	0.28	0.78	0.20	(-2.4, 3.2)
	Week 6	152	15.03	1.70	14.70	(12.1, 22.7)	152	14.55 (1.73)	0.47	0.92	0.50	(-2.8, 2.7)
	Week 8	151	14.85	1.62	14.50	(12.0, 22.9)	151	14.55 (1.74)	0.30	0.98	0.30	(-3.5, 3.3)
	Week 10	150	15.00	1.75	14.70	(12.1, 23.4)	150	14.55 (1.73)	0.45	1.18	0.40	(-3.3, 6.7)
	Week 12	148	14.94	1.76	14.60	(12.2, 24.7)	148	14.54 (1.73)	0.40	1.29	0.40	(-4.0, 5.7)
	Week 16	148	15.02	1.84	14.40	(12.4, 24.8)	148	14.52 (1.72)	0.49	1.58	0.30	(-4.3, 5.8)
	Week 20	144	15.26	1.87	14.90	(12.2, 24.9)	144	14.50 (1.72)	0.76	1.75	0.60	(-4.1, 6.7)
	Week 24	140	15.32	1.90	15.00	(12.5, 23.8)	140	14.44 (1.71)	0.88	1.89	0.80	(-4.9, 8.6)
	Week 28	137	15.00	1.74	14.50	(11.8, 22.3)	137	14.39 (1.57)	0.61	1.91	0.50	(-5.0, 7.4)
	Week 32	133	14.78	1.71	14.20	(11.4, 22.0)	133	14.38 (1.59)	0.40	1.70	0.40	(-5.8, 6.9)
	Week 36	130	14.63	1.71	14.25	(11.9, 22.2)	130	14.36 (1.58)	0.27	1.69	0.30	(-6.2, 7.1)
	Week 40	128	14.51	1.63	14.20	(12.4, 22.0)	128	14.39 (1.58)	0.12	1.67	0.20	(-6.2, 6.9)
	Week 44	125	14.58	1.86	14.10	(12.3, 25.3)	125	14.32 (1.54)	0.26	1.88	0.20	(-6.7, 9.4)
	Week 48	125	14.61	1.81	14.10	(12.2, 23.5)	125	14.32 (1.54)	0.29	1.89	0.30	(-6.9, 8.2)
	Week 52	123	14.58	1.61	14.10	(12.2, 22.2)	123	14.31 (1.55)	0.27	1.74	0.30	(-6.7, 6.9)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Leukocytes (/uL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	5709.3	1836.8	5300.0	(2400, 13700)						
	Week 2	151	5823.2	2127.9	5400.0	(2500, 19700)	151	5709.3 (1836.8)	113.9	1424.7	100.0	(-3100, 11500)
	Week 4	149	5586.6	1757.6	5200.0	(2400, 12000)	149	5739.6 (1826.1)	-153.0	1051.6	-100.0	(-3700, 2900)
	Week 6	148	5753.4	1589.9	5500.0	(2800, 10900)	148	5745.3 (1831.0)	8.1	1266.9	100.0	(-7000, 3600)
	Week 8	145	5912.4	1766.9	5500.0	(2600, 11600)	145	5730.3 (1787.7)	182.1	1166.1	200.0	(-2900, 6300)
	Week 10	145	5952.4	1852.0	5600.0	(2800, 17600)	145	5725.5 (1790.1)	226.9	1400.9	200.0	(-3700, 11400)
	Week 12	145	5569.0	1480.7	5500.0	(2800, 10400)	145	5726.9 (1788.6)	-157.9	1128.0	0.0	(-4900, 2700)
	Week 16	143	5839.2	1735.7	5500.0	(2800, 14500)	143	5722.4 (1801.7)	116.8	1356.7	100.0	(-3400, 7400)
	Week 20	140	5862.9	1767.5	5600.0	(3100, 12700)	140	5701.4 (1775.7)	161.4	1624.4	100.0	(-5100, 8000)
	Week 24	132	5845.5	1856.7	5550.0	(2500, 14900)	132	5725.0 (1810.8)	120.5	1428.9	50.0	(-3600, 7800)
	Week 28	126	5964.3	1635.5	5700.0	(2800, 12800)	126	5744.4 (1794.3)	219.8	1211.0	200.0	(-3800, 5400)
	Week 32	121	5825.6	1475.7	5700.0	(2900, 12300)	121	5688.4 (1669.1)	137.2	1305.1	100.0	(-4800, 5200)
	Week 36	119	5663.0	1614.5	5600.0	(2700, 11900)	119	5758.0 (1836.0)	-95.0	1285.6	0.0	(-6400, 3200)
	Week 40	115	5570.4	1369.9	5500.0	(3300, 12000)	115	5652.2 (1685.0)	-81.7	1351.0	-100.0	(-5200, 4900)
	Week 44	114	5501.8	1489.1	5300.0	(2500, 9900)	114	5664.9 (1680.8)	-163.2	1211.7	-150.0	(-4200, 3300)
	Week 48	112	5715.2	1569.7	5500.0	(2600, 12000)	112	5642.9 (1687.1)	72.3	1401.0	100.0	(-4600, 4900)
	Week 52	111	5467.6	1410.0	5200.0	(2800, 9800)	111	5668.5 (1690.9)	-200.9	1220.0	-100.0	(-6000, 2700)
darbepoetin	Baseline	153	5578.4	1591.2	5400.0	(2800, 11400)						
	Week 2	153	5515.7	1633.1	5200.0	(2800, 12400)	153	5578.4 (1591.2)	-62.7	1165.3	-100.0	(-4300, 6900)
	Week 4	153	5520.3	1611.2	5400.0	(2700, 13000)	153	5578.4 (1591.2)	-58.2	1187.1	0.0	(-3600, 6500)
	Week 6	152	5474.3	1668.6	5300.0	(2500, 13800)	152	5578.3 (1596.5)	-103.9	1121.8	0.0	(-5200, 5100)
	Week 8	151	5414.6	1422.9	5200.0	(2300, 9300)	151	5577.5 (1601.8)	-162.9	994.0	-100.0	(-4200, 2500)
	Week 10	150	5545.3	1575.3	5300.0	(2800, 10700)	150	5560.7 (1597.1)	-15.3	1146.0	-100.0	(-4700, 5500)
	Week 12	148	5600.0	1641.3	5400.0	(2700, 10500)	148	5581.8 (1614.9)	18.2	1174.6	0.0	(-3100, 4700)
	Week 16	148	5538.5	1532.3	5500.0	(3100, 10800)	148	5558.1 (1602.9)	-19.6	1143.1	0.0	(-4800, 3000)
	Week 20	144	5685.4	1467.4	5600.0	(3300, 10000)	144	5550.0 (1590.5)	135.4	1178.7	100.0	(-4400, 4200)
	Week 24	140	5630.7	1633.0	5300.0	(2900, 11300)	140	5555.7 (1615.3)	75.0	1319.4	0.0	(-4900, 5600)
	Week 28	137	5672.3	1693.4	5400.0	(3100, 11700)	137	5546.7 (1616.4)	125.5	1211.2	100.0	(-4900, 3500)
	Week 32	133	5640.6	1687.5	5300.0	(2600, 12800)	133	5507.5 (1603.9)	133.1	1153.6	100.0	(-4300, 3700)
	Week 36	130	5597.7	1649.8	5300.0	(2400, 12200)	130	5507.7 (1599.9)	90.0	1210.1	0.0	(-4400, 4700)
	Week 40	128	5821.9	2218.7	5500.0	(2900, 22200)	128	5518.8 (1597.4)	303.1	1980.8	200.0	(-4500, 18300)
	Week 44	125	5586.4	1551.2	5500.0	(2900, 11500)	125	5468.8 (1559.3)	117.6	1167.0	200.0	(-4900, 4400)
	Week 48	125	5632.8	1553.9	5400.0	(3200, 9700)	125	5468.8 (1559.3)	164.0	1273.7	0.0	(-4400, 3700)
	Week 52	123	5461.8	1500.5	5300.0	(2700, 10700)	123	5464.2 (1571.6)	-2.4	1149.5	0.0	(-5600, 3000)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Neutrophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	64.05	9.51	63.90	(35.5, 89.0)						
	Week 2	150	63.64	9.48	63.40	(37.0, 91.5)	150	64.05 (9.51)	-0.42	6.90	0.25	(-22.9, 20.0)
	Week 4	148	63.21	9.44	63.15	(36.8, 91.1)	148	64.10 (9.53)	-0.89	6.90	-0.25	(-21.0, 20.4)
	Week 6	148	64.34	8.92	64.45	(41.0, 88.5)	147	64.10 (9.56)	0.29	6.69	0.90	(-16.7, 20.4)
	Week 8	144	64.10	9.34	64.25	(38.5, 91.0)	144	63.96 (9.59)	0.13	7.23	-0.30	(-18.6, 22.1)
	Week 10	145	64.29	8.92	64.10	(39.9, 87.5)	144	64.02 (9.58)	0.29	7.74	0.55	(-28.6, 17.3)
	Week 12	144	64.15	9.42	64.15	(37.2, 89.0)	144	63.98 (9.59)	0.16	6.75	0.20	(-21.1, 18.0)
	Week 16	141	64.64	9.03	64.90	(43.1, 88.0)	141	64.04 (9.69)	0.60	6.97	0.70	(-15.9, 24.5)
	Week 20	139	65.62	9.93	65.50	(36.3, 90.0)	139	63.85 (9.70)	1.77	8.05	1.90	(-19.0, 27.6)
	Week 24	131	65.47	9.16	64.90	(35.9, 92.5)	131	63.74 (9.73)	1.73	8.01	1.30	(-18.6, 28.0)
	Week 28	125	66.33	9.61	66.40	(38.4, 90.0)	124	63.96 (9.89)	2.35	7.61	2.55	(-19.2, 19.5)
	Week 32	119	65.15	9.02	66.00	(42.2, 87.0)	118	63.66 (9.60)	1.45	8.31	2.20	(-23.2, 21.3)
	Week 36	118	65.25	9.22	66.30	(43.7, 85.0)	117	63.84 (9.94)	1.39	7.29	2.00	(-19.8, 19.0)
	Week 40	113	65.74	8.17	65.00	(42.5, 92.0)	113	63.74 (9.71)	1.99	7.73	1.10	(-14.7, 25.9)
	Week 44	114	64.55	9.14	65.05	(37.8, 89.0)	114	63.47 (9.90)	1.08	7.89	1.55	(-26.1, 19.9)
	Week 48	112	65.76	8.81	65.20	(41.4, 89.9)	112	63.37 (9.93)	2.39	8.10	1.70	(-17.5, 22.0)
	Week 52	110	65.59	8.65	65.65	(36.0, 93.0)	110	63.35 (9.95)	2.23	7.55	2.15	(-19.3, 21.0)
darbepoetin	Baseline	153	64.30	8.16	64.00	(42.9, 92.0)						
	Week 2	153	63.55	8.72	64.00	(39.5, 87.5)	153	64.30 (8.16)	-0.75	7.68	0.20	(-33.5, 31.5)
	Week 4	153	63.64	8.92	64.00	(42.0, 93.5)	153	64.30 (8.16)	-0.67	7.24	-0.60	(-28.0, 28.2)
	Week 6	152	64.34	8.15	65.45	(43.1, 83.0)	152	64.31 (8.19)	0.03	6.56	0.35	(-22.0, 15.4)
	Week 8	151	63.28	8.77	64.00	(35.6, 84.5)	151	64.26 (8.19)	-0.98	7.61	-0.40	(-31.0, 25.5)
	Week 10	150	64.78	8.34	65.60	(40.0, 82.5)	150	64.21 (8.19)	0.57	7.21	0.95	(-23.5, 25.0)
	Week 12	148	63.67	9.45	63.95	(32.7, 96.0)	148	64.15 (8.24)	-0.48	7.58	0.30	(-25.5, 18.5)
	Week 16	148	63.63	8.94	65.00	(32.1, 82.0)	148	64.14 (8.16)	-0.51	7.52	-0.40	(-36.4, 20.1)
	Week 20	144	64.50	8.97	65.35	(41.3, 89.0)	144	63.96 (8.19)	0.54	7.85	0.80	(-26.5, 21.2)
	Week 24	140	64.75	9.11	65.45	(39.7, 91.5)	140	64.17 (8.19)	0.58	7.72	0.65	(-23.5, 22.2)
	Week 28	136	65.10	9.71	65.30	(39.0, 90.9)	136	64.09 (8.23)	1.01	7.73	0.50	(-37.0, 23.0)
	Week 32	133	64.36	9.62	65.00	(25.0, 91.5)	133	64.05 (8.11)	0.32	7.75	0.80	(-32.0, 20.8)
	Week 36	130	64.29	9.24	65.00	(38.5, 92.0)	130	64.01 (8.17)	0.28	7.83	0.60	(-27.5, 20.2)
	Week 40	128	64.22	10.15	65.80	(25.0, 94.0)	128	63.93 (8.19)	0.28	8.73	1.35	(-30.0, 22.1)
	Week 44	125	63.50	9.63	64.00	(35.5, 89.5)	125	63.69 (8.10)	-0.20	7.68	1.20	(-23.7, 14.9)
	Week 48	125	63.66	8.46	65.40	(37.6, 84.3)	125	63.69 (8.10)	-0.03	6.83	0.40	(-21.2, 16.5)
	Week 52	123	63.48	7.69	63.60	(45.8, 85.0)	123	63.59 (8.12)	-0.10	6.62	0.00	(-18.5, 15.0)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Eosinophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	3.72	2.94	3.00	(0.0, 23.0)						
	Week 2	150	3.98	3.05	3.50	(0.0, 19.2)	150	3.72 (2.94)	0.25	1.85	0.10	(-3.9, 13.0)
	Week 4	149	3.94	3.16	3.05	(0.0, 23.5)	148	3.73 (2.96)	0.21	2.46	0.10	(-6.8, 17.5)
	Week 6	148	3.85	2.68	3.40	(0.1, 19.1)	147	3.74 (2.96)	0.13	2.01	0.10	(-6.4, 9.8)
	Week 8	144	3.92	2.93	3.05	(0.0, 18.5)	144	3.76 (2.99)	0.16	2.12	0.00	(-5.1, 7.5)
	Week 10	145	4.01	3.41	3.00	(0.0, 22.0)	144	3.76 (2.99)	0.28	2.72	-0.05	(-7.0, 16.0)
	Week 12	144	3.97	2.94	3.35	(0.0, 17.2)	144	3.78 (2.98)	0.19	2.19	0.10	(-5.8, 8.1)
	Week 16	141	3.62	2.68	2.90	(0.0, 15.2)	141	3.68 (2.89)	-0.05	2.04	0.00	(-7.8, 7.0)
	Week 20	139	3.63	2.98	3.00	(0.0, 23.0)	139	3.76 (3.02)	-0.13	2.36	-0.10	(-7.5, 17.0)
	Week 24	131	3.69	3.21	3.00	(0.0, 25.0)	131	3.73 (2.98)	-0.04	2.90	0.10	(-9.5, 18.7)
	Week 28	125	3.32	2.74	2.40	(0.0, 15.0)	124	3.72 (2.99)	-0.38	2.04	-0.25	(-8.0, 9.0)
	Week 32	119	3.64	2.80	3.00	(0.1, 16.2)	118	3.69 (2.95)	-0.02	2.18	0.00	(-6.8, 8.5)
	Week 36	118	3.57	2.67	2.95	(0.0, 17.3)	117	3.62 (2.94)	-0.02	1.87	0.00	(-5.7, 5.5)
	Week 40	113	3.60	2.75	3.00	(0.0, 15.7)	113	3.58 (2.87)	0.02	2.38	0.00	(-8.9, 12.1)
	Week 44	114	3.46	2.35	2.95	(0.0, 13.9)	114	3.68 (2.97)	-0.21	1.91	0.00	(-9.1, 5.0)
	Week 48	112	3.59	2.81	3.00	(0.0, 18.8)	112	3.61 (2.95)	-0.03	1.83	0.00	(-5.8, 4.4)
	Week 52	110	3.66	2.65	3.05	(0.0, 19.3)	110	3.71 (3.00)	-0.05	2.03	0.15	(-5.6, 5.3)
darbepoetin	Baseline	153	3.72	2.81	3.00	(0.0, 15.2)						
	Week 2	153	3.74	3.04	2.90	(0.0, 20.5)	153	3.72 (2.81)	0.02	2.21	0.00	(-8.1, 15.5)
	Week 4	153	3.63	3.11	3.00	(0.0, 26.0)	153	3.72 (2.81)	-0.09	2.20	0.00	(-7.7, 10.8)
	Week 6	152	3.46	2.41	2.85	(0.0, 13.7)	152	3.70 (2.80)	-0.24	2.06	0.00	(-9.1, 6.9)
	Week 8	151	3.59	2.85	3.00	(0.0, 20.0)	151	3.69 (2.81)	-0.10	2.06	0.00	(-10.5, 5.8)
	Week 10	150	3.48	2.68	2.95	(0.5, 16.4)	150	3.72 (2.82)	-0.24	2.19	-0.20	(-10.8, 8.7)
	Week 12	148	3.64	2.85	3.05	(0.0, 18.8)	148	3.72 (2.83)	-0.08	2.08	-0.10	(-10.5, 6.2)
	Week 16	148	3.70	3.06	3.00	(0.0, 23.0)	148	3.74 (2.83)	-0.04	2.30	0.00	(-9.8, 9.5)
	Week 20	144	3.65	3.11	3.00	(0.0, 18.8)	144	3.74 (2.83)	-0.09	2.45	0.00	(-10.8, 9.4)
	Week 24	140	3.55	2.89	3.00	(0.0, 19.6)	140	3.67 (2.74)	-0.12	2.39	-0.20	(-11.1, 7.5)
	Week 28	136	3.51	3.07	2.60	(0.0, 18.0)	136	3.71 (2.77)	-0.20	2.40	-0.10	(-10.5, 13.0)
	Week 32	133	3.77	5.03	2.80	(0.0, 54.5)	133	3.62 (2.72)	0.15	4.88	0.10	(-10.1, 49.5)
	Week 36	130	3.84	3.97	2.70	(0.0, 36.5)	130	3.58 (2.66)	0.26	3.47	0.00	(-10.1, 31.5)
	Week 40	128	4.14	5.60	2.90	(0.0, 55.5)	128	3.56 (2.66)	0.58	5.19	-0.10	(-10.5, 50.5)
	Week 44	125	4.16	4.96	3.00	(0.0, 48.0)	125	3.61 (2.70)	0.55	4.58	0.00	(-9.8, 43.0)
	Week 48	125	3.97	4.01	3.00	(0.5, 31.5)	125	3.61 (2.70)	0.36	3.65	0.00	(-9.7, 26.5)
	Week 52	123	3.83	3.43	3.00	(0.4, 24.0)	123	3.61 (2.72)	0.23	2.91	0.00	(-7.0, 21.8)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Monocytes/Leukocytes (%)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	6.31	2.13	6.25	(0.9, 12.5)						
	Week 2	150	6.95	1.99	7.00	(3.0, 12.8)	150	6.31 (2.13)	0.63	1.86	0.45	(-4.4, 6.8)
	Week 4	148	7.10	2.27	7.00	(2.0, 12.5)	148	6.30 (2.10)	0.80	1.97	0.70	(-6.0, 6.0)
	Week 6	148	6.86	2.10	6.85	(1.1, 12.1)	147	6.30 (2.10)	0.55	2.08	0.50	(-5.8, 5.6)
	Week 8	144	7.07	2.15	7.00	(3.0, 12.6)	144	6.30 (2.12)	0.76	1.98	0.60	(-5.9, 10.4)
	Week 10	145	6.87	2.05	6.60	(2.5, 11.9)	144	6.29 (2.12)	0.57	1.87	0.60	(-7.1, 5.5)
	Week 12	144	6.87	2.25	7.00	(1.5, 13.0)	144	6.29 (2.12)	0.58	2.12	0.80	(-5.4, 4.7)
	Week 16	141	7.27	2.22	7.00	(1.5, 15.0)	141	6.28 (2.13)	0.99	1.96	0.90	(-6.2, 6.5)
	Week 20	139	7.00	2.26	7.00	(2.0, 15.0)	139	6.36 (2.12)	0.64	2.13	0.70	(-4.9, 5.3)
	Week 24	131	6.97	2.18	6.90	(2.5, 14.5)	131	6.40 (2.10)	0.56	2.37	0.60	(-8.5, 5.7)
	Week 28	125	6.68	2.02	6.50	(2.0, 12.8)	124	6.29 (2.10)	0.38	1.98	0.40	(-5.5, 7.7)
	Week 32	119	7.01	2.36	6.70	(2.9, 13.5)	118	6.36 (2.08)	0.65	2.31	0.70	(-6.6, 6.5)
	Week 36	118	6.94	2.26	6.90	(2.6, 16.0)	117	6.31 (2.04)	0.64	2.17	0.40	(-5.6, 11.0)
	Week 40	113	6.83	2.47	6.80	(1.9, 18.0)	113	6.34 (2.02)	0.50	2.38	0.20	(-5.0, 7.5)
	Week 44	114	6.93	2.16	7.00	(2.2, 16.5)	114	6.30 (1.98)	0.63	2.14	0.60	(-7.7, 6.2)
	Week 48	112	6.96	2.22	6.90	(1.3, 16.0)	112	6.33 (1.99)	0.62	2.06	0.75	(-6.1, 5.2)
	Week 52	110	6.81	2.19	6.65	(1.9, 17.0)	110	6.31 (1.99)	0.50	2.15	0.80	(-6.5, 6.1)
darbepoetin	Baseline	153	6.47	2.04	6.20	(2.5, 13.5)						
	Week 2	153	6.82	2.11	6.50	(2.0, 14.0)	153	6.47 (2.04)	0.34	2.09	0.30	(-7.5, 7.5)
	Week 4	153	6.70	1.98	6.50	(1.0, 12.9)	153	6.47 (2.04)	0.23	2.02	0.20	(-5.0, 7.4)
	Week 6	152	6.74	2.14	6.60	(2.1, 13.5)	152	6.48 (2.04)	0.26	1.98	0.30	(-6.0, 5.4)
	Week 8	151	6.82	2.01	6.70	(2.0, 12.3)	151	6.48 (2.05)	0.34	2.15	0.40	(-7.0, 6.5)
	Week 10	150	6.80	1.94	6.70	(3.0, 14.5)	150	6.49 (2.04)	0.30	2.14	0.55	(-8.5, 6.6)
	Week 12	148	6.78	2.12	6.55	(1.0, 15.0)	148	6.52 (2.03)	0.26	2.11	0.25	(-5.7, 6.6)
	Week 16	148	6.49	1.97	6.45	(2.0, 12.9)	148	6.50 (2.04)	-0.02	2.12	0.00	(-4.8, 7.5)
	Week 20	144	6.45	1.97	6.30	(2.1, 12.5)	144	6.52 (2.06)	-0.07	1.95	-0.05	(-5.1, 5.2)
	Week 24	140	6.59	2.14	6.35	(0.7, 12.8)	140	6.45 (1.97)	0.15	2.00	0.20	(-6.3, 6.0)
	Week 28	136	6.61	2.30	6.35	(0.2, 13.5)	136	6.45 (1.98)	0.16	1.91	0.20	(-5.9, 4.6)
	Week 32	133	6.68	2.33	6.50	(1.8, 14.0)	133	6.50 (1.97)	0.18	2.10	0.30	(-5.1, 6.0)
	Week 36	130	6.20	2.20	5.70	(1.4, 15.5)	130	6.54 (1.98)	-0.34	2.16	-0.50	(-6.8, 8.0)
	Week 40	128	6.32	2.02	6.10	(2.3, 12.2)	128	6.53 (1.97)	-0.21	2.08	-0.10	(-5.1, 6.5)
	Week 44	125	6.31	2.41	6.10	(1.1, 16.5)	125	6.59 (1.95)	-0.28	2.32	-0.30	(-9.5, 6.5)
	Week 48	125	6.50	2.05	6.10	(1.2, 14.5)	125	6.59 (1.95)	-0.09	2.01	-0.10	(-6.0, 5.1)
	Week 52	123	6.64	1.99	6.60	(1.8, 14.5)	123	6.59 (1.96)	0.05	2.06	0.00	(-5.1, 8.1)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Lymphocytes/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	25.54	8.20	24.90	(7.5, 51.2)						
	Week 2	150	25.06	8.28	24.65	(5.0, 54.5)	150	25.54 (8.20)	-0.48	5.47	-0.95	(-19.9, 13.7)
	Week 4	148	25.39	8.50	24.50	(5.7, 51.4)	148	25.49 (8.22)	-0.10	5.31	0.00	(-13.3, 16.2)
	Week 6	148	24.55	8.00	24.10	(7.5, 48.0)	147	25.49 (8.25)	-1.01	5.15	-0.60	(-20.0, 12.7)
	Week 8	144	24.51	8.28	24.05	(4.0, 49.4)	144	25.60 (8.29)	-1.09	5.91	-0.65	(-17.4, 14.1)
	Week 10	145	24.47	7.86	24.00	(7.0, 46.8)	144	25.56 (8.28)	-1.13	5.90	-1.00	(-15.6, 22.8)
	Week 12	144	24.62	8.56	23.65	(7.0, 53.1)	144	25.57 (8.29)	-0.95	5.35	-1.00	(-15.4, 19.9)
	Week 16	141	24.09	7.99	23.00	(6.5, 47.0)	141	25.63 (8.35)	-1.55	5.90	-1.70	(-25.4, 12.3)
	Week 20	139	23.45	8.69	22.60	(6.0, 56.5)	139	25.67 (8.37)	-2.22	6.71	-1.50	(-24.5, 11.7)
	Week 24	131	23.52	8.20	22.50	(2.0, 59.3)	131	25.76 (8.43)	-2.24	6.66	-1.50	(-20.4, 15.2)
	Week 28	125	23.33	8.42	23.40	(7.0, 56.2)	124	25.66 (8.50)	-2.33	6.26	-2.25	(-18.2, 15.6)
	Week 32	119	23.60	8.16	22.80	(7.0, 49.5)	118	25.93 (8.34)	-2.13	6.64	-2.55	(-20.0, 16.3)
	Week 36	118	23.86	8.03	23.05	(9.0, 51.6)	117	25.87 (8.57)	-2.02	5.94	-1.80	(-21.0, 16.9)
	Week 40	113	23.50	7.72	23.30	(4.5, 50.0)	113	25.97 (8.47)	-2.48	6.32	-1.40	(-28.4, 12.7)
	Week 44	114	24.66	8.04	23.30	(5.5, 48.2)	114	26.17 (8.56)	-1.51	6.22	-1.60	(-18.4, 24.2)
	Week 48	112	23.33	7.62	22.70	(6.0, 52.8)	112	26.31 (8.56)	-2.97	6.52	-2.30	(-17.7, 12.6)
	Week 52	110	23.60	7.50	23.35	(4.5, 57.5)	110	26.24 (8.58)	-2.64	6.06	-2.95	(-18.2, 13.2)
darbepoetin	Baseline	153	25.14	6.91	25.00	(4.0, 44.7)						
	Week 2	153	25.53	7.54	25.10	(7.5, 43.1)	153	25.14 (6.91)	0.39	5.89	0.80	(-22.0, 28.0)
	Week 4	153	25.70	7.90	25.00	(5.5, 47.2)	153	25.14 (6.91)	0.55	5.72	0.80	(-25.1, 23.0)
	Week 6	152	25.15	7.41	24.70	(10.1, 44.9)	152	25.15 (6.93)	-0.01	5.03	-0.35	(-13.2, 16.5)
	Week 8	151	25.96	7.82	24.90	(8.4, 50.9)	151	25.21 (6.92)	0.75	5.86	0.80	(-16.0, 23.4)
	Week 10	150	24.58	7.37	23.50	(9.9, 44.5)	150	25.22 (6.94)	-0.64	5.72	-0.25	(-22.5, 15.4)
	Week 12	148	25.53	8.27	24.40	(3.0, 53.5)	148	25.25 (6.97)	0.28	5.95	0.00	(-14.0, 20.0)
	Week 16	148	25.83	8.12	25.00	(9.0, 56.7)	148	25.26 (6.90)	0.57	6.05	0.30	(-17.3, 23.2)
	Week 20	144	25.04	8.09	24.25	(8.0, 48.0)	144	25.42 (6.90)	-0.38	6.20	-0.65	(-17.8, 20.5)
	Week 24	140	24.73	7.77	23.40	(3.5, 45.4)	140	25.36 (6.90)	-0.63	5.86	-0.65	(-16.6, 14.1)
	Week 28	136	24.43	8.32	23.65	(7.9, 52.0)	136	25.40 (6.93)	-0.96	6.30	-1.00	(-20.8, 27.5)
	Week 32	133	24.82	7.95	24.40	(5.5, 49.8)	133	25.48 (6.87)	-0.66	5.82	-1.00	(-15.3, 25.0)
	Week 36	130	25.31	7.96	25.00	(4.0, 47.8)	130	25.53 (6.86)	-0.21	6.38	0.00	(-17.4, 16.5)
	Week 40	128	25.01	8.53	24.10	(2.5, 58.0)	128	25.64 (6.83)	-0.63	6.66	-0.60	(-18.0, 21.5)
	Week 44	125	25.64	7.91	25.00	(8.0, 51.2)	125	25.76 (6.81)	-0.13	5.92	-0.50	(-20.0, 14.0)
	Week 48	125	25.52	7.91	25.00	(9.0, 52.0)	125	25.76 (6.81)	-0.24	5.92	-0.20	(-18.5, 14.0)
	Week 52	123	25.69	7.17	25.70	(7.0, 42.9)	123	25.87 (6.81)	-0.18	5.84	-0.20	(-13.2, 15.9)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Basophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	0.37	0.31	0.30	(0.0, 2.0)						
	Week 2	150	0.38	0.33	0.30	(0.0, 1.2)	150	0.37 (0.31)	0.01	0.44	0.00	(-2.0, 1.2)
	Week 4	148	0.36	0.30	0.30	(0.0, 1.4)	148	0.37 (0.32)	-0.01	0.42	0.00	(-1.3, 1.2)
	Week 6	148	0.40	0.37	0.40	(0.0, 2.2)	147	0.37 (0.32)	0.03	0.48	0.00	(-1.7, 2.0)
	Week 8	144	0.40	0.33	0.40	(0.0, 1.7)	144	0.37 (0.32)	0.03	0.45	0.00	(-2.0, 1.7)
	Week 10	145	0.36	0.34	0.30	(0.0, 2.0)	144	0.37 (0.32)	-0.01	0.43	0.00	(-1.9, 1.7)
	Week 12	144	0.39	0.31	0.40	(0.0, 1.6)	144	0.37 (0.31)	0.02	0.37	0.00	(-1.5, 0.9)
	Week 16	141	0.38	0.38	0.30	(0.0, 2.5)	141	0.37 (0.31)	0.01	0.49	0.00	(-2.0, 2.3)
	Week 20	139	0.30	0.27	0.30	(0.0, 1.1)	139	0.36 (0.28)	-0.06	0.34	0.00	(-1.4, 0.9)
	Week 24	131	0.34	0.35	0.30	(0.0, 1.8)	131	0.37 (0.29)	-0.02	0.43	0.00	(-1.3, 1.4)
	Week 28	125	0.33	0.33	0.30	(0.0, 2.0)	124	0.36 (0.28)	-0.03	0.44	-0.10	(-1.5, 1.8)
	Week 32	119	0.41	0.39	0.40	(0.0, 2.7)	118	0.36 (0.28)	0.05	0.47	0.00	(-1.4, 1.8)
	Week 36	118	0.37	0.31	0.30	(0.0, 1.6)	117	0.37 (0.28)	0.01	0.44	0.00	(-1.4, 1.6)
	Week 40	113	0.33	0.31	0.30	(0.0, 1.5)	113	0.37 (0.28)	-0.04	0.37	0.00	(-1.4, 1.1)
	Week 44	114	0.39	0.31	0.40	(0.0, 1.8)	114	0.38 (0.28)	0.01	0.39	0.00	(-1.0, 1.6)
	Week 48	112	0.36	0.36	0.30	(0.0, 2.0)	112	0.38 (0.28)	-0.01	0.43	0.00	(-0.9, 2.0)
	Week 52	110	0.34	0.25	0.30	(0.0, 1.0)	110	0.38 (0.28)	-0.04	0.36	0.00	(-1.4, 1.0)
darbepoetin	Baseline	153	0.36	0.32	0.30	(0.0, 2.0)						
	Week 2	153	0.36	0.34	0.30	(0.0, 2.0)	153	0.36 (0.32)	0.00	0.49	0.00	(-2.0, 2.0)
	Week 4	153	0.33	0.30	0.30	(0.0, 1.5)	153	0.36 (0.32)	-0.03	0.38	0.00	(-1.7, 1.3)
	Week 6	152	0.31	0.27	0.30	(0.0, 1.1)	152	0.36 (0.32)	-0.05	0.37	0.00	(-1.7, 1.0)
	Week 8	151	0.35	0.32	0.30	(0.0, 1.5)	151	0.36 (0.32)	-0.01	0.45	0.00	(-1.7, 1.4)
	Week 10	150	0.37	0.33	0.30	(0.0, 1.6)	150	0.36 (0.32)	0.01	0.43	0.00	(-1.5, 1.3)
	Week 12	148	0.39	0.31	0.40	(0.0, 1.5)	148	0.37 (0.32)	0.02	0.43	0.00	(-1.7, 1.2)
	Week 16	148	0.35	0.34	0.30	(0.0, 2.0)	148	0.36 (0.32)	-0.01	0.43	0.00	(-1.5, 2.0)
	Week 20	144	0.36	0.33	0.30	(0.0, 2.0)	144	0.36 (0.32)	0.00	0.47	0.00	(-1.8, 2.0)
	Week 24	140	0.38	0.34	0.30	(0.0, 2.0)	140	0.36 (0.29)	0.02	0.42	0.00	(-1.0, 1.7)
	Week 28	136	0.35	0.32	0.30	(0.0, 1.8)	136	0.35 (0.29)	0.00	0.40	0.00	(-1.0, 1.8)
	Week 32	133	0.37	0.34	0.30	(0.0, 2.0)	133	0.35 (0.27)	0.02	0.38	0.00	(-1.0, 1.0)
	Week 36	130	0.36	0.36	0.30	(0.0, 2.1)	130	0.34 (0.27)	0.01	0.39	0.00	(-1.0, 1.5)
	Week 40	128	0.32	0.25	0.30	(0.0, 1.1)	128	0.34 (0.27)	-0.02	0.36	0.00	(-1.0, 1.1)
	Week 44	125	0.40	0.36	0.30	(0.0, 2.0)	125	0.34 (0.27)	0.06	0.42	0.00	(-0.8, 1.8)
	Week 48	125	0.35	0.27	0.30	(0.0, 1.3)	125	0.34 (0.27)	0.00	0.33	0.00	(-0.8, 1.1)
	Week 52	123	0.35	0.27	0.30	(0.0, 1.1)	123	0.35 (0.27)	0.01	0.37	0.00	(-1.0, 1.0)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Platelets (10^4/uL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	19.74	6.32	18.60	(7.4, 41.5)						
	Week 2	151	20.39	6.46	19.50	(6.9, 39.4)	151	19.74 (6.32)	0.65	3.00	0.80	(-13.9, 9.5)
	Week 4	148	20.01	6.84	18.80	(8.1, 59.1)	148	19.77 (6.38)	0.23	3.62	0.00	(-10.7, 32.6)
	Week 6	147	20.16	6.28	19.10	(7.9, 38.7)	147	19.83 (6.37)	0.33	3.05	0.60	(-12.7, 12.2)
	Week 8	144	20.16	6.20	19.40	(6.9, 46.4)	144	19.84 (6.40)	0.32	2.95	0.15	(-8.6, 15.9)
	Week 10	145	19.97	6.18	19.10	(4.7, 40.4)	145	19.81 (6.40)	0.15	3.28	0.20	(-12.9, 11.7)
	Week 12	144	20.08	6.10	19.00	(9.0, 38.1)	144	19.72 (6.38)	0.36	3.20	0.50	(-13.4, 8.4)
	Week 16	143	19.93	5.80	19.20	(6.6, 39.5)	143	19.74 (6.39)	0.19	3.31	0.30	(-13.0, 8.7)
	Week 20	138	20.08	5.91	19.50	(8.2, 40.8)	138	19.83 (6.39)	0.25	3.56	0.30	(-16.5, 9.8)
	Week 24	131	20.37	6.30	19.30	(5.2, 42.1)	131	20.05 (6.38)	0.32	3.71	0.30	(-14.5, 13.5)
	Week 28	126	20.96	6.25	20.45	(9.2, 42.0)	126	20.15 (6.40)	0.81	3.90	0.90	(-14.7, 23.0)
	Week 32	121	20.82	6.08	20.80	(7.4, 42.8)	121	20.11 (6.37)	0.71	3.31	0.80	(-13.8, 7.8)
	Week 36	114	20.68	6.08	20.10	(9.2, 45.0)	114	20.33 (6.57)	0.35	3.64	0.65	(-14.3, 10.0)
	Week 40	112	20.16	5.78	18.95	(8.0, 40.2)	112	20.23 (6.48)	-0.08	3.82	0.00	(-14.0, 9.2)
	Week 44	112	20.10	5.76	19.15	(8.3, 38.0)	112	20.11 (6.54)	-0.01	3.56	0.20	(-12.6, 7.1)
	Week 48	110	19.73	5.35	18.85	(5.7, 38.4)	110	20.09 (6.54)	-0.36	3.52	0.10	(-12.2, 7.4)
	Week 52	109	20.46	6.07	19.80	(6.5, 40.9)	109	20.15 (6.56)	0.31	3.72	0.50	(-13.5, 10.3)
darbepoetin	Baseline	152	19.72	5.37	18.85	(6.6, 35.7)						
	Week 2	150	20.05	5.49	19.60	(9.1, 38.9)	150	19.65 (5.37)	0.40	2.73	0.55	(-10.1, 12.1)
	Week 4	149	20.83	6.60	20.00	(7.0, 55.1)	149	19.75 (5.36)	1.08	3.68	0.50	(-8.5, 29.5)
	Week 6	149	20.73	5.98	20.30	(7.6, 43.8)	149	19.74 (5.36)	0.99	3.41	0.90	(-7.7, 18.2)
	Week 8	147	20.71	5.66	20.50	(8.5, 46.1)	147	19.81 (5.37)	0.90	3.32	0.60	(-6.4, 10.4)
	Week 10	147	20.93	5.94	20.60	(7.6, 40.4)	147	19.71 (5.39)	1.23	3.40	1.00	(-7.0, 13.8)
	Week 12	146	20.12	5.72	19.80	(7.8, 37.3)	146	19.72 (5.44)	0.41	3.16	0.15	(-8.1, 10.6)
	Week 16	146	19.09	5.57	19.20	(2.5, 46.3)	146	19.63 (5.39)	-0.54	3.37	-0.60	(-10.6, 16.2)
	Week 20	141	19.36	5.16	19.80	(7.4, 38.9)	141	19.61 (5.41)	-0.25	3.15	-0.20	(-10.2, 9.5)
	Week 24	138	19.37	5.39	18.95	(4.1, 36.5)	138	19.70 (5.34)	-0.33	3.15	-0.30	(-9.0, 9.6)
	Week 28	134	19.49	5.59	18.70	(9.1, 46.8)	134	19.76 (5.33)	-0.27	3.58	-0.30	(-11.3, 16.9)
	Week 32	131	20.00	5.83	19.40	(8.4, 37.2)	131	19.71 (5.25)	0.29	3.66	0.00	(-8.6, 17.3)
	Week 36	128	20.04	5.68	19.40	(9.9, 42.4)	128	19.84 (5.22)	0.20	4.24	0.10	(-9.4, 29.3)
	Week 40	126	20.05	5.78	19.70	(8.6, 41.0)	126	19.78 (5.23)	0.27	4.09	-0.30	(-8.1, 19.5)
	Week 44	123	20.33	5.72	19.60	(8.9, 43.4)	122	19.93 (5.26)	0.42	3.75	0.10	(-8.5, 18.1)
	Week 48	121	19.77	5.36	18.90	(9.5, 40.3)	121	19.86 (5.29)	-0.09	3.27	-0.10	(-10.7, 8.2)
	Week 52	120	19.53	5.60	18.60	(6.4, 41.7)	120	19.76 (5.22)	-0.23	3.35	-0.20	(-9.8, 10.2)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Protein (g/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	6.79	0.56	6.80	(5.1, 8.4)						
	Week 2	151	6.81	0.55	6.80	(5.3, 8.8)	151	6.79 (0.56)	0.01	0.31	0.00	(-0.8, 0.8)
	Week 4	149	6.76	0.59	6.80	(5.4, 8.8)	149	6.79 (0.57)	-0.03	0.32	-0.10	(-1.1, 0.7)
	Week 6	148	6.75	0.60	6.80	(5.0, 8.7)	148	6.79 (0.57)	-0.03	0.33	0.00	(-1.2, 0.8)
	Week 8	145	6.77	0.60	6.80	(5.2, 8.4)	145	6.78 (0.57)	-0.01	0.33	0.00	(-1.1, 0.8)
	Week 10	145	6.77	0.60	6.80	(5.3, 9.1)	145	6.78 (0.57)	-0.01	0.36	0.00	(-1.2, 0.9)
	Week 12	145	6.82	0.59	6.80	(5.1, 8.5)	145	6.78 (0.57)	0.04	0.39	0.00	(-1.2, 0.9)
	Week 16	143	6.76	0.65	6.80	(4.8, 9.1)	143	6.79 (0.56)	-0.04	0.44	0.00	(-1.6, 0.9)
	Week 20	140	6.78	0.62	6.85	(4.9, 9.0)	140	6.78 (0.57)	-0.01	0.41	0.00	(-1.3, 1.0)
	Week 24	132	6.84	0.64	6.90	(5.0, 9.2)	132	6.81 (0.57)	0.03	0.44	0.00	(-1.1, 1.7)
	Week 28	126	6.87	0.60	6.90	(5.1, 9.1)	126	6.80 (0.57)	0.07	0.38	0.10	(-1.0, 1.0)
	Week 32	121	6.92	0.55	6.90	(5.1, 8.6)	121	6.81 (0.54)	0.10	0.44	0.00	(-1.2, 1.5)
	Week 36	119	6.94	0.56	7.00	(4.9, 8.7)	119	6.80 (0.55)	0.13	0.42	0.10	(-0.9, 1.3)
	Week 40	115	6.89	0.55	7.00	(4.8, 8.3)	115	6.82 (0.55)	0.07	0.41	0.10	(-1.0, 1.1)
	Week 44	114	6.86	0.56	6.90	(5.1, 7.9)	114	6.81 (0.55)	0.05	0.42	0.10	(-1.3, 1.1)
	Week 48	112	6.86	0.55	6.90	(5.2, 8.1)	112	6.83 (0.55)	0.04	0.40	0.10	(-1.5, 1.0)
	Week 52	111	6.89	0.57	6.90	(5.3, 8.1)	111	6.82 (0.55)	0.06	0.42	0.10	(-1.3, 1.1)
darbepoetin	Baseline	153	6.74	0.60	6.80	(4.1, 8.2)						
	Week 2	153	6.71	0.58	6.80	(4.1, 7.8)	153	6.74 (0.60)	-0.02	0.31	0.00	(-0.9, 0.9)
	Week 4	153	6.71	0.63	6.80	(4.2, 8.3)	153	6.74 (0.60)	-0.02	0.35	0.00	(-1.4, 1.1)
	Week 6	152	6.68	0.62	6.70	(4.2, 8.2)	152	6.73 (0.60)	-0.05	0.35	-0.10	(-1.2, 0.8)
	Week 8	151	6.71	0.60	6.80	(4.4, 8.1)	151	6.73 (0.60)	-0.03	0.33	0.00	(-1.1, 0.9)
	Week 10	150	6.70	0.58	6.70	(4.3, 7.9)	150	6.73 (0.60)	-0.03	0.37	0.00	(-1.0, 1.0)
	Week 12	148	6.75	0.61	6.75	(4.2, 8.0)	148	6.72 (0.60)	0.03	0.34	0.00	(-1.1, 0.8)
	Week 16	148	6.73	0.63	6.80	(4.3, 8.6)	148	6.74 (0.60)	-0.01	0.43	0.00	(-1.0, 1.3)
	Week 20	144	6.74	0.63	6.80	(3.9, 7.9)	144	6.74 (0.61)	0.00	0.39	0.00	(-1.0, 1.2)
	Week 24	140	6.80	0.66	6.85	(3.9, 8.4)	140	6.75 (0.61)	0.05	0.48	0.05	(-1.5, 1.6)
	Week 28	137	6.81	0.65	6.90	(3.9, 8.3)	137	6.74 (0.61)	0.07	0.44	0.00	(-1.3, 1.4)
	Week 32	133	6.84	0.67	6.90	(4.2, 8.2)	133	6.75 (0.60)	0.09	0.46	0.10	(-1.5, 1.5)
	Week 36	130	6.91	0.63	7.00	(4.0, 8.2)	130	6.75 (0.60)	0.16	0.43	0.15	(-0.9, 1.5)
	Week 40	128	6.85	0.60	6.90	(4.8, 8.3)	128	6.75 (0.60)	0.09	0.45	0.10	(-1.6, 1.7)
	Week 44	125	6.86	0.59	6.90	(4.6, 8.2)	125	6.74 (0.60)	0.12	0.44	0.10	(-1.5, 1.7)
	Week 48	125	6.87	0.60	6.90	(4.2, 8.1)	125	6.74 (0.60)	0.12	0.40	0.10	(-1.6, 1.5)
	Week 52	123	6.82	0.57	6.80	(4.4, 8.0)	123	6.73 (0.60)	0.09	0.42	0.10	(-1.1, 1.6)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Albumin (g/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	3.77	0.42	3.80	(2.4, 4.7)						
	Week 2	151	3.73	0.38	3.80	(2.4, 4.5)	151	3.77 (0.42)	-0.04	0.20	0.00	(-0.8, 0.4)
	Week 4	149	3.70	0.41	3.70	(1.7, 4.5)	149	3.77 (0.42)	-0.07	0.27	-0.10	(-2.1, 0.5)
	Week 6	148	3.68	0.40	3.70	(2.0, 4.5)	148	3.76 (0.42)	-0.08	0.24	-0.10	(-1.1, 0.8)
	Week 8	145	3.70	0.38	3.70	(2.4, 4.6)	145	3.76 (0.43)	-0.06	0.23	0.00	(-1.0, 0.8)
	Week 10	145	3.67	0.37	3.70	(2.4, 4.4)	145	3.76 (0.43)	-0.09	0.25	-0.10	(-1.0, 0.8)
	Week 12	145	3.68	0.38	3.70	(2.1, 4.4)	145	3.76 (0.43)	-0.08	0.27	-0.10	(-1.0, 0.9)
	Week 16	143	3.66	0.43	3.70	(2.0, 4.6)	143	3.76 (0.43)	-0.10	0.31	-0.10	(-1.2, 0.9)
	Week 20	140	3.67	0.45	3.80	(1.7, 4.5)	140	3.75 (0.43)	-0.09	0.32	-0.10	(-1.2, 0.9)
	Week 24	132	3.75	0.39	3.80	(2.5, 4.7)	132	3.78 (0.42)	-0.03	0.33	0.00	(-1.1, 1.2)
	Week 28	126	3.76	0.37	3.80	(2.6, 4.5)	126	3.80 (0.42)	-0.03	0.29	0.00	(-1.0, 1.1)
	Week 32	121	3.78	0.38	3.80	(2.6, 4.5)	121	3.80 (0.42)	-0.02	0.34	0.00	(-1.2, 1.4)
	Week 36	119	3.82	0.37	3.80	(2.6, 4.5)	119	3.80 (0.43)	0.02	0.31	0.00	(-1.1, 1.2)
	Week 40	115	3.79	0.38	3.80	(2.5, 4.7)	115	3.81 (0.43)	-0.02	0.31	0.00	(-1.3, 0.8)
	Week 44	114	3.79	0.36	3.80	(2.6, 4.9)	114	3.81 (0.43)	-0.02	0.30	0.00	(-1.1, 1.1)
	Week 48	112	3.79	0.37	3.80	(2.8, 4.5)	112	3.82 (0.41)	-0.03	0.30	0.00	(-1.3, 0.7)
	Week 52	111	3.78	0.37	3.80	(2.7, 4.5)	111	3.82 (0.41)	-0.04	0.32	0.00	(-1.2, 0.8)
darbepoetin	Baseline	153	3.79	0.44	3.80	(1.8, 4.6)						
	Week 2	153	3.76	0.44	3.80	(1.7, 5.0)	153	3.79 (0.44)	-0.03	0.21	0.00	(-1.0, 0.5)
	Week 4	153	3.73	0.46	3.80	(1.7, 5.3)	153	3.79 (0.44)	-0.05	0.27	0.00	(-1.7, 0.7)
	Week 6	152	3.75	0.45	3.80	(1.9, 4.8)	152	3.78 (0.44)	-0.03	0.24	0.00	(-1.2, 0.6)
	Week 8	151	3.75	0.44	3.80	(1.8, 4.5)	151	3.78 (0.44)	-0.04	0.23	0.00	(-0.9, 0.7)
	Week 10	150	3.72	0.43	3.80	(1.9, 4.7)	150	3.78 (0.44)	-0.06	0.27	0.00	(-1.0, 0.7)
	Week 12	148	3.74	0.46	3.80	(1.7, 4.6)	148	3.77 (0.44)	-0.03	0.25	0.00	(-1.1, 0.8)
	Week 16	148	3.70	0.46	3.80	(1.9, 4.8)	148	3.78 (0.44)	-0.08	0.30	-0.10	(-1.3, 0.7)
	Week 20	144	3.72	0.50	3.80	(1.6, 4.9)	144	3.78 (0.44)	-0.06	0.29	0.00	(-0.9, 0.7)
	Week 24	140	3.79	0.49	3.90	(1.7, 4.8)	140	3.79 (0.45)	0.00	0.32	0.00	(-0.8, 0.9)
	Week 28	137	3.78	0.48	3.80	(1.6, 4.6)	137	3.79 (0.45)	-0.01	0.31	0.00	(-0.8, 0.9)
	Week 32	133	3.78	0.49	3.80	(1.6, 4.8)	133	3.80 (0.43)	-0.02	0.32	0.00	(-0.9, 0.9)
	Week 36	130	3.85	0.45	3.90	(1.6, 4.7)	130	3.80 (0.44)	0.04	0.30	0.00	(-0.8, 1.3)
	Week 40	128	3.80	0.45	3.90	(1.8, 4.6)	128	3.80 (0.44)	0.00	0.35	0.00	(-1.7, 1.7)
	Week 44	125	3.83	0.44	3.90	(1.7, 4.6)	125	3.81 (0.43)	0.02	0.36	0.00	(-1.2, 1.7)
	Week 48	125	3.84	0.42	3.90	(1.6, 4.7)	125	3.81 (0.43)	0.03	0.32	0.00	(-1.1, 1.6)
	Week 52	123	3.84	0.43	3.90	(1.6, 4.6)	123	3.81 (0.43)	0.03	0.33	0.00	(-1.0, 1.7)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Glucose (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	120.2	38.9	108.0	(72, 308)						
	Week 2	151	116.8	40.6	105.0	(64, 377)	151	120.2 (38.9)	-3.4	40.3	-2.0	(-197, 201)
	Week 4	149	119.1	38.6	106.0	(53, 278)	149	120.3 (39.1)	-1.2	33.3	-1.0	(-136, 104)
	Week 6	148	119.3	37.4	107.5	(54, 262)	148	120.5 (39.2)	-1.2	31.1	-2.0	(-139, 116)
	Week 8	145	119.3	40.0	107.0	(64, 312)	145	120.2 (39.1)	-0.9	34.9	1.0	(-135, 121)
	Week 10	145	119.6	37.1	107.0	(66, 228)	145	120.3 (39.2)	-0.7	32.4	-3.0	(-148, 116)
	Week 12	145	122.4	45.0	109.0	(73, 426)	145	120.8 (39.4)	1.6	36.6	-1.0	(-122, 250)
	Week 16	143	120.1	40.1	106.0	(71, 313)	143	121.0 (39.5)	-0.9	39.6	-1.0	(-213, 104)
	Week 20	140	121.2	41.9	105.0	(57, 284)	140	121.0 (40.0)	0.2	40.0	-1.5	(-115, 198)
	Week 24	132	110.9	31.2	102.0	(38, 275)	132	119.0 (38.0)	-8.0	36.8	-5.5	(-210, 198)
	Week 28	126	118.7	40.5	105.0	(68, 333)	126	119.9 (39.1)	-1.3	37.2	-3.0	(-143, 256)
	Week 32	121	116.9	35.5	106.0	(49, 254)	121	119.6 (39.6)	-2.7	30.2	-3.0	(-109, 138)
	Week 36	119	114.2	33.5	105.0	(54, 256)	119	118.2 (35.9)	-4.0	30.5	-2.0	(-125, 85)
	Week 40	115	111.7	30.2	106.0	(64, 224)	115	117.5 (34.5)	-5.8	33.2	-4.0	(-140, 117)
	Week 44	114	115.5	36.5	105.5	(55, 276)	114	118.7 (36.2)	-3.1	36.7	-3.0	(-135, 131)
	Week 48	112	116.1	40.0	104.0	(40, 283)	112	119.2 (36.3)	-3.1	39.6	-4.5	(-114, 206)
	Week 52	111	110.6	30.8	102.0	(51, 206)	111	118.1 (35.6)	-7.6	37.2	-6.0	(-159, 101)
darbepoetin	Baseline	153	122.0	33.2	114.0	(68, 230)						
	Week 2	153	121.3	34.5	111.0	(73, 291)	153	122.0 (33.2)	-0.8	26.7	-1.0	(-72, 87)
	Week 4	153	125.6	44.2	112.0	(66, 294)	153	122.0 (33.2)	3.5	36.4	2.0	(-106, 122)
	Week 6	152	124.9	42.3	114.0	(57, 371)	152	121.9 (33.3)	3.0	36.3	-2.0	(-105, 159)
	Week 8	151	129.0	41.0	116.0	(64, 329)	151	122.0 (33.4)	6.9	30.6	5.0	(-95, 117)
	Week 10	150	126.3	42.7	115.0	(70, 313)	150	122.0 (33.5)	4.3	33.6	0.0	(-111, 163)
	Week 12	148	125.4	44.5	113.0	(67, 390)	148	121.4 (32.8)	4.0	35.7	-1.0	(-109, 178)
	Week 16	148	126.3	46.0	109.5	(70, 422)	148	121.0 (32.3)	5.3	36.6	-2.0	(-104, 192)
	Week 20	144	123.7	45.0	111.5	(63, 395)	144	121.5 (32.5)	2.1	34.6	-0.5	(-104, 165)
	Week 24	140	115.9	38.3	105.0	(73, 283)	140	121.5 (32.9)	-5.6	33.1	-5.0	(-114, 138)
	Week 28	137	121.8	40.2	112.0	(69, 354)	137	121.2 (32.7)	0.6	33.5	-2.0	(-82, 163)
	Week 32	133	121.0	38.8	113.0	(61, 323)	133	121.3 (33.0)	-0.2	33.8	2.0	(-116, 109)
	Week 36	130	121.8	40.7	109.0	(76, 287)	130	121.5 (33.2)	0.3	35.6	-1.0	(-110, 126)
	Week 40	128	126.1	51.1	111.5	(63, 459)	128	121.8 (33.2)	4.3	43.1	1.0	(-102, 240)
	Week 44	125	119.8	40.5	104.0	(63, 282)	125	121.1 (32.5)	-1.4	36.1	-1.0	(-120, 140)
	Week 48	125	122.8	48.7	110.0	(72, 438)	125	121.1 (32.5)	1.7	41.2	0.0	(-116, 226)
	Week 52	123	117.2	39.5	104.0	(58, 316)	123	120.7 (32.0)	-3.5	35.8	-3.0	(-120, 106)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Urea Nitrogen (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	44.08	19.99	39.80	(14.5, 162.4)						
	Week 2	151	43.66	17.78	40.90	(16.9, 122.7)	151	44.08 (19.99)	-0.42	7.96	0.20	(-39.7, 21.9)
	Week 4	149	42.19	17.85	40.00	(7.9, 114.4)	149	44.18 (20.08)	-1.99	8.89	-1.50	(-48.0, 16.8)
	Week 6	148	41.51	16.65	39.05	(12.7, 107.4)	148	43.95 (19.95)	-2.44	8.86	-1.90	(-55.0, 15.9)
	Week 8	145	41.32	16.13	40.00	(15.3, 109.9)	145	43.63 (19.34)	-2.31	9.11	-1.80	(-52.5, 18.6)
	Week 10	145	42.08	16.76	39.30	(15.3, 127.3)	145	43.83 (19.36)	-1.74	8.56	-0.80	(-35.1, 12.5)
	Week 12	145	41.71	16.71	38.20	(13.1, 126.6)	145	43.83 (19.36)	-2.12	8.66	-2.00	(-35.8, 20.5)
	Week 16	143	43.14	17.82	40.60	(15.9, 132.2)	143	43.65 (19.44)	-0.51	9.75	0.40	(-30.2, 40.4)
	Week 20	140	43.36	17.61	40.95	(11.2, 121.9)	140	43.09 (18.93)	0.27	9.91	0.35	(-40.5, 39.9)
	Week 24	132	42.43	18.55	39.85	(12.0, 112.2)	132	42.29 (16.29)	0.14	9.60	0.00	(-20.6, 56.0)
	Week 28	126	43.09	19.61	39.80	(11.8, 115.0)	126	41.52 (16.23)	1.57	9.96	0.50	(-24.3, 48.6)
	Week 32	121	42.82	17.74	39.90	(14.0, 98.9)	121	41.25 (15.63)	1.57	10.45	1.40	(-23.6, 48.3)
	Week 36	119	43.23	17.72	41.50	(12.1, 97.9)	119	40.79 (15.01)	2.44	10.01	2.30	(-19.5, 47.3)
	Week 40	115	44.99	19.34	42.60	(13.7, 127.7)	115	41.08 (15.13)	3.91	12.30	2.30	(-25.2, 77.1)
	Week 44	114	45.17	19.15	41.45	(15.9, 104.0)	114	40.87 (15.27)	4.30	10.74	2.55	(-17.1, 43.9)
	Week 48	112	44.49	17.78	43.30	(8.1, 85.4)	112	40.63 (15.28)	3.86	9.94	2.95	(-27.2, 25.8)
	Week 52	111	44.95	19.22	41.60	(16.4, 106.5)	111	40.44 (15.12)	4.51	10.66	2.90	(-17.4, 44.8)
darbepoetin	Baseline	153	40.95	17.40	38.40	(10.0, 98.0)						
	Week 2	153	40.12	16.34	38.60	(9.9, 88.7)	153	40.95 (17.40)	-0.84	7.67	-0.10	(-22.1, 30.5)
	Week 4	153	39.93	16.54	37.90	(9.8, 90.6)	153	40.95 (17.40)	-1.02	7.90	-0.40	(-29.0, 22.4)
	Week 6	152	39.46	16.39	36.45	(10.9, 89.9)	152	40.78 (17.33)	-1.32	7.71	-0.75	(-25.7, 16.3)
	Week 8	151	39.69	17.30	37.00	(8.1, 101.4)	151	40.73 (17.37)	-1.04	9.04	-1.00	(-30.5, 59.9)
	Week 10	150	39.63	17.31	37.85	(13.2, 96.4)	150	40.83 (17.42)	-1.20	7.48	-0.30	(-24.5, 17.0)
	Week 12	148	40.55	17.26	39.70	(11.6, 99.9)	148	40.60 (17.03)	-0.05	7.40	0.20	(-16.0, 22.7)
	Week 16	148	40.83	18.02	37.45	(11.3, 96.2)	148	40.65 (17.28)	0.18	9.34	0.70	(-37.1, 34.7)
	Week 20	144	42.43	20.65	36.75	(12.7, 112.4)	144	40.63 (17.48)	1.80	9.61	1.40	(-18.9, 45.2)
	Week 24	140	42.07	19.79	37.20	(13.7, 121.0)	140	39.69 (16.72)	2.38	10.02	1.80	(-26.2, 59.4)
	Week 28	137	42.59	20.27	36.60	(12.9, 107.3)	137	39.28 (15.96)	3.31	11.30	2.20	(-25.0, 39.9)
	Week 32	133	41.11	18.36	36.40	(13.2, 96.7)	133	38.65 (15.49)	2.45	10.43	1.20	(-23.8, 38.4)
	Week 36	130	41.69	17.94	36.35	(11.1, 117.3)	130	38.19 (15.35)	3.49	10.63	2.65	(-50.1, 40.9)
	Week 40	128	42.06	19.80	38.00	(12.8, 138.8)	128	37.98 (15.37)	4.08	12.34	2.45	(-25.9, 62.4)
	Week 44	125	40.79	17.38	37.70	(12.6, 94.0)	125	37.72 (15.04)	3.07	11.06	2.40	(-28.6, 44.3)
	Week 48	125	43.90	19.79	41.10	(12.3, 111.1)	125	37.72 (15.04)	6.18	12.74	4.20	(-25.8, 63.5)
	Week 52	123	42.98	19.12	39.40	(12.6, 98.8)	123	37.41 (14.91)	5.57	12.20	2.80	(-32.3, 43.1)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Creatinine (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	2.830	1.492	2.630	(0.82, 9.09)						
	Week 2	151	2.975	1.542	2.570	(0.89, 8.84)	151	2.830 (1.492)	0.144	0.346	0.120	(-1.48, 2.06)
	Week 4	149	2.941	1.528	2.570	(0.76, 8.47)	149	2.839 (1.494)	0.102	0.335	0.100	(-1.11, 1.13)
	Week 6	148	2.967	1.511	2.650	(0.88, 7.85)	148	2.833 (1.498)	0.134	0.363	0.135	(-1.24, 1.04)
	Week 8	145	2.982	1.523	2.810	(0.91, 7.94)	145	2.820 (1.497)	0.162	0.416	0.140	(-1.75, 1.31)
	Week 10	145	3.008	1.544	2.830	(0.93, 8.30)	145	2.837 (1.505)	0.171	0.432	0.170	(-2.33, 1.64)
	Week 12	145	3.000	1.535	2.870	(0.90, 8.30)	145	2.841 (1.504)	0.159	0.447	0.150	(-2.11, 1.97)
	Week 16	143	3.092	1.701	2.770	(0.91, 9.07)	143	2.830 (1.510)	0.262	0.498	0.170	(-1.31, 2.32)
	Week 20	140	3.114	1.802	2.830	(0.84, 9.49)	140	2.798 (1.504)	0.315	0.731	0.160	(-1.56, 4.52)
	Week 24	132	3.015	1.720	2.515	(0.89, 8.60)	132	2.723 (1.407)	0.292	0.648	0.150	(-1.25, 3.73)
	Week 28	126	2.972	1.750	2.530	(0.81, 10.29)	126	2.647 (1.393)	0.324	0.752	0.150	(-1.91, 5.42)
	Week 32	121	3.000	1.687	2.490	(0.83, 9.67)	121	2.644 (1.372)	0.356	0.682	0.170	(-1.32, 4.28)
	Week 36	119	3.025	1.761	2.460	(0.84, 9.84)	119	2.621 (1.361)	0.404	0.750	0.160	(-1.04, 4.45)
	Week 40	115	3.178	1.920	2.570	(0.88, 12.91)	115	2.637 (1.366)	0.541	0.979	0.290	(-1.69, 7.52)
	Week 44	114	3.143	1.826	2.585	(0.92, 9.50)	114	2.587 (1.349)	0.556	0.866	0.330	(-1.62, 4.15)
	Week 48	112	3.144	1.761	2.675	(0.83, 9.02)	112	2.544 (1.320)	0.600	0.795	0.385	(-1.04, 4.36)
	Week 52	111	3.204	1.902	2.680	(0.79, 10.24)	111	2.544 (1.330)	0.660	0.971	0.380	(-1.70, 5.58)
darbepoetin	Baseline	153	2.616	1.441	2.400	(0.70, 7.60)						
	Week 2	153	2.633	1.484	2.300	(0.75, 8.77)	153	2.616 (1.441)	0.017	0.404	0.020	(-1.32, 3.40)
	Week 4	153	2.628	1.437	2.270	(0.71, 7.46)	153	2.616 (1.441)	0.011	0.349	0.010	(-2.32, 0.99)
	Week 6	152	2.625	1.452	2.260	(0.66, 7.93)	152	2.598 (1.428)	0.027	0.340	0.040	(-2.26, 0.96)
	Week 8	151	2.642	1.500	2.190	(0.55, 8.13)	151	2.596 (1.432)	0.046	0.379	0.040	(-2.42, 1.14)
	Week 10	150	2.684	1.567	2.315	(0.59, 8.10)	150	2.590 (1.433)	0.094	0.399	0.050	(-1.83, 2.17)
	Week 12	148	2.729	1.626	2.305	(0.60, 8.94)	148	2.577 (1.413)	0.152	0.445	0.100	(-1.61, 1.79)
	Week 16	148	2.795	1.772	2.315	(0.75, 9.23)	148	2.582 (1.413)	0.213	0.611	0.080	(-0.85, 2.67)
	Week 20	144	2.866	1.938	2.325	(0.73, 11.03)	144	2.583 (1.430)	0.283	0.692	0.090	(-0.72, 3.53)
	Week 24	140	2.802	1.825	2.225	(0.75, 11.04)	140	2.497 (1.323)	0.306	0.725	0.100	(-1.07, 4.84)
	Week 28	137	2.804	1.886	2.320	(0.76, 11.55)	137	2.453 (1.244)	0.351	0.894	0.080	(-0.66, 5.35)
	Week 32	133	2.675	1.658	2.240	(0.71, 10.82)	133	2.367 (1.136)	0.308	0.826	0.050	(-1.06, 5.42)
	Week 36	130	2.609	1.461	2.215	(0.74, 8.30)	130	2.310 (1.077)	0.298	0.715	0.115	(-1.25, 4.20)
	Week 40	128	2.650	1.528	2.215	(0.67, 8.93)	128	2.287 (1.063)	0.363	0.768	0.125	(-0.99, 4.83)
	Week 44	125	2.659	1.460	2.240	(0.72, 8.45)	125	2.277 (1.064)	0.382	0.652	0.160	(-0.92, 2.69)
	Week 48	125	2.769	1.591	2.360	(0.69, 9.02)	125	2.277 (1.064)	0.491	0.778	0.250	(-0.77, 4.15)
	Week 52	123	2.774	1.598	2.430	(0.70, 9.01)	123	2.251 (1.045)	0.523	0.843	0.240	(-0.74, 4.67)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Estimated GFR (mL/min/1.73m^2)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	21.28	11.66	18.10	(4.9, 53.1)						
	Week 2	151	19.97	10.81	16.90	(5.1, 48.5)	151	21.28 (11.66)	-1.31	2.61	-1.00	(-13.4, 10.1)
	Week 4	149	20.60	11.76	17.20	(5.3, 57.7)	149	21.22 (11.60)	-0.62	3.68	-0.70	(-9.0, 26.7)
	Week 6	148	20.09	11.05	16.60	(5.6, 50.7)	148	21.28 (11.63)	-1.18	3.23	-1.00	(-10.2, 16.4)
	Week 8	145	19.94	10.83	16.60	(5.3, 47.4)	145	21.34 (11.59)	-1.40	2.75	-1.10	(-8.4, 7.2)
	Week 10	145	19.70	10.60	17.00	(4.9, 44.8)	145	21.25 (11.63)	-1.55	3.19	-1.20	(-10.5, 9.8)
	Week 12	145	19.76	10.70	16.50	(4.7, 47.9)	145	21.25 (11.63)	-1.49	2.92	-1.30	(-10.9, 8.2)
	Week 16	143	19.69	10.97	16.50	(4.4, 46.5)	143	21.35 (11.68)	-1.66	3.49	-1.40	(-11.3, 13.2)
	Week 20	140	20.00	11.46	16.40	(3.8, 51.7)	140	21.58 (11.67)	-1.58	3.45	-1.45	(-10.2, 13.7)
	Week 24	132	20.41	11.33	17.40	(5.7, 48.5)	132	21.96 (11.69)	-1.56	3.19	-1.45	(-10.9, 13.3)
	Week 28	126	20.89	11.84	17.60	(4.7, 53.8)	126	22.54 (11.82)	-1.64	3.28	-1.35	(-11.2, 12.1)
	Week 32	121	20.37	11.44	17.30	(4.8, 52.4)	121	22.39 (11.63)	-2.02	3.52	-2.00	(-10.8, 13.7)
	Week 36	119	20.37	11.41	18.00	(4.7, 50.1)	119	22.47 (11.61)	-2.10	3.51	-2.40	(-9.5, 11.3)
	Week 40	115	19.75	11.88	16.10	(3.5, 49.9)	115	22.41 (11.69)	-2.67	4.57	-2.50	(-19.4, 20.1)
	Week 44	114	19.80	11.68	16.75	(4.7, 47.7)	114	22.75 (11.72)	-2.95	4.25	-2.75	(-17.0, 17.4)
	Week 48	112	19.60	11.55	15.60	(5.5, 50.7)	112	22.98 (11.70)	-3.37	4.24	-3.15	(-15.0, 14.9)
	Week 52	111	19.42	11.38	16.00	(4.4, 53.5)	111	23.06 (11.72)	-3.64	3.92	-3.80	(-14.0, 16.8)
darbepoetin	Baseline	153	22.60	11.60	20.10	(6.0, 61.3)						
	Week 2	153	22.54	11.60	20.10	(5.2, 59.0)	153	22.60 (11.60)	-0.06	2.35	-0.20	(-9.5, 9.2)
	Week 4	153	22.60	11.77	20.50	(6.0, 60.4)	153	22.60 (11.60)	0.00	3.09	-0.20	(-13.9, 10.6)
	Week 6	152	22.48	11.64	19.95	(5.9, 62.5)	152	22.69 (11.58)	-0.21	3.25	-0.30	(-10.1, 16.3)
	Week 8	151	22.79	12.48	19.80	(5.3, 76.3)	151	22.73 (11.61)	0.07	3.92	-0.50	(-10.2, 30.1)
	Week 10	150	22.75	12.70	20.35	(5.2, 70.6)	150	22.79 (11.63)	-0.03	3.95	-0.40	(-9.0, 24.4)
	Week 12	148	22.33	12.38	19.10	(5.0, 69.4)	148	22.75 (11.44)	-0.42	4.33	-0.95	(-12.9, 23.2)
	Week 16	148	22.41	12.55	20.30	(5.0, 58.4)	148	22.68 (11.50)	-0.27	3.86	-0.65	(-10.0, 12.8)
	Week 20	144	22.20	12.52	19.95	(4.2, 58.8)	144	22.72 (11.62)	-0.53	3.41	-0.95	(-9.8, 13.7)
	Week 24	140	22.17	12.13	19.75	(4.3, 56.9)	140	23.16 (11.52)	-0.99	3.48	-1.50	(-10.0, 12.3)
	Week 28	137	22.47	12.38	18.90	(4.0, 56.3)	137	23.17 (11.16)	-0.70	3.80	-0.70	(-10.6, 12.6)
	Week 32	133	22.85	12.41	19.40	(4.4, 60.6)	133	23.58 (11.05)	-0.73	3.97	-0.90	(-13.5, 12.7)
	Week 36	130	22.75	12.14	19.15	(3.9, 57.9)	130	23.90 (10.97)	-1.15	4.11	-1.30	(-12.9, 12.1)
	Week 40	128	22.47	12.17	19.60	(3.6, 64.4)	128	24.02 (10.99)	-1.55	3.95	-1.35	(-11.6, 14.5)
	Week 44	125	22.29	12.06	19.30	(4.9, 59.5)	125	24.24 (11.00)	-1.95	4.20	-1.90	(-12.8, 13.0)
	Week 48	125	21.80	12.33	17.70	(4.0, 62.3)	125	24.24 (11.00)	-2.44	4.05	-2.60	(-12.3, 11.0)
	Week 52	123	21.70	12.08	17.70	(5.0, 61.6)	123	24.48 (10.97)	-2.73	3.87	-2.30	(-13.5, 13.7)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Urate (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	6.08	1.39	5.90	(3.1, 12.4)						
	Week 2	151	6.02	1.67	5.90	(2.3, 12.3)	151	6.08 (1.39)	-0.06	1.17	0.00	(-6.7, 3.4)
	Week 4	149	5.89	1.69	5.80	(2.0, 12.9)	149	6.10 (1.39)	-0.21	1.27	-0.10	(-7.0, 3.7)
	Week 6	148	5.88	1.73	5.65	(2.0, 11.8)	148	6.08 (1.37)	-0.20	1.42	0.00	(-7.1, 2.9)
	Week 8	145	5.92	1.81	5.70	(1.6, 12.4)	145	6.04 (1.27)	-0.12	1.40	-0.10	(-7.4, 6.6)
	Week 10	145	5.86	1.81	5.60	(1.7, 11.5)	145	6.04 (1.27)	-0.18	1.37	-0.10	(-7.3, 3.4)
	Week 12	145	5.85	1.76	5.80	(1.4, 11.7)	145	6.05 (1.28)	-0.20	1.40	-0.10	(-7.6, 4.6)
	Week 16	143	5.79	1.67	5.80	(1.7, 10.8)	143	6.06 (1.28)	-0.26	1.26	-0.10	(-7.3, 2.0)
	Week 20	140	5.88	1.68	5.80	(1.8, 12.2)	140	6.06 (1.28)	-0.18	1.37	-0.10	(-7.2, 4.0)
	Week 24	132	5.82	1.72	5.65	(2.1, 11.2)	132	6.05 (1.25)	-0.23	1.33	-0.10	(-6.9, 3.5)
	Week 28	126	5.68	1.75	5.50	(2.0, 11.9)	126	6.03 (1.29)	-0.35	1.40	-0.40	(-7.0, 3.1)
	Week 32	121	5.58	1.63	5.50	(2.1, 10.2)	121	6.00 (1.28)	-0.42	1.42	-0.30	(-6.9, 3.3)
	Week 36	119	5.66	1.61	5.60	(2.0, 11.0)	119	5.96 (1.24)	-0.30	1.39	-0.30	(-7.0, 4.0)
	Week 40	115	5.73	1.54	5.70	(2.4, 10.0)	115	5.99 (1.23)	-0.25	1.42	-0.20	(-6.6, 4.6)
	Week 44	114	5.71	1.64	5.65	(2.4, 10.4)	114	5.98 (1.25)	-0.26	1.44	-0.10	(-6.6, 4.0)
	Week 48	112	5.66	1.53	5.60	(1.6, 10.4)	112	5.95 (1.25)	-0.29	1.36	-0.30	(-7.4, 2.8)
	Week 52	111	5.80	1.64	5.80	(1.3, 11.8)	111	5.95 (1.25)	-0.15	1.51	-0.10	(-7.7, 3.8)
darbepoetin	Baseline	153	6.18	1.38	6.20	(3.2, 11.1)						
	Week 2	153	6.24	1.37	6.10	(2.6, 10.7)	153	6.18 (1.38)	0.05	0.66	0.10	(-2.1, 2.8)
	Week 4	153	6.21	1.41	6.10	(2.8, 10.7)	153	6.18 (1.38)	0.03	0.89	0.00	(-3.5, 5.8)
	Week 6	152	6.30	1.49	6.15	(2.8, 10.6)	152	6.18 (1.39)	0.12	0.97	0.20	(-3.3, 5.9)
	Week 8	151	6.16	1.34	6.10	(2.6, 9.9)	151	6.18 (1.39)	-0.02	1.02	0.00	(-4.0, 6.1)
	Week 10	150	6.20	1.29	6.10	(2.3, 10.6)	150	6.16 (1.38)	0.04	0.95	0.15	(-3.7, 2.5)
	Week 12	148	6.13	1.36	6.05	(2.3, 10.6)	148	6.16 (1.39)	-0.03	0.91	0.00	(-3.9, 2.6)
	Week 16	148	6.03	1.36	5.90	(3.0, 12.3)	148	6.17 (1.40)	-0.14	1.06	0.00	(-4.2, 4.3)
	Week 20	144	5.96	1.29	6.00	(2.1, 9.8)	144	6.15 (1.39)	-0.20	1.02	0.00	(-4.1, 2.4)
	Week 24	140	6.01	1.43	5.80	(2.0, 10.8)	140	6.15 (1.40)	-0.14	1.21	0.00	(-4.6, 4.3)
	Week 28	137	5.98	1.43	5.80	(2.8, 10.4)	137	6.14 (1.41)	-0.17	1.22	-0.10	(-5.2, 3.0)
	Week 32	133	5.99	1.38	5.90	(2.5, 10.2)	133	6.13 (1.40)	-0.15	1.31	-0.10	(-5.5, 3.9)
	Week 36	130	5.93	1.45	5.80	(2.6, 13.6)	130	6.12 (1.41)	-0.19	1.26	-0.20	(-5.4, 4.6)
	Week 40	128	5.93	1.35	5.85	(3.1, 12.4)	128	6.15 (1.39)	-0.22	1.14	-0.10	(-4.9, 3.4)
	Week 44	125	5.84	1.25	5.80	(3.0, 9.7)	125	6.09 (1.36)	-0.25	1.13	-0.10	(-5.0, 2.6)
	Week 48	125	5.86	1.35	5.70	(3.7, 9.3)	125	6.09 (1.36)	-0.23	1.07	-0.20	(-4.0, 2.8)
	Week 52	123	5.87	1.33	5.80	(2.7, 9.9)	123	6.10 (1.36)	-0.23	1.13	0.00	(-5.3, 2.8)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Creatine Kinase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	125.0	79.0	101.0	(24, 516)						
	Week 2	151	129.0	84.3	109.0	(18, 790)	151	125.0 (79.0)	4.1	66.8	3.0	(-194, 499)
	Week 4	149	134.5	88.3	108.0	(17, 563)	149	124.3 (79.0)	10.2	72.8	6.0	(-255, 412)
	Week 6	148	132.6	80.9	119.0	(24, 587)	148	124.6 (79.3)	8.1	68.6	9.0	(-269, 464)
	Week 8	145	145.6	122.3	109.0	(24, 922)	145	125.8 (79.5)	19.8	115.0	8.0	(-343, 847)
	Week 10	145	131.8	82.5	110.0	(21, 547)	145	124.2 (78.6)	7.6	79.6	7.0	(-318, 420)
	Week 12	145	144.3	152.5	112.0	(29, 1528)	145	125.4 (79.7)	18.9	142.5	10.0	(-272, 1271)
	Week 16	143	138.5	97.2	117.0	(24, 848)	143	124.8 (79.7)	13.7	93.7	7.0	(-258, 622)
	Week 20	140	143.2	106.5	121.0	(24, 929)	140	125.9 (80.9)	17.4	106.8	7.0	(-318, 770)
	Week 24	132	147.1	132.0	106.5	(23, 1184)	132	124.0 (80.6)	23.2	128.7	6.5	(-262, 1009)
	Week 28	126	133.9	88.5	107.5	(29, 581)	126	123.5 (80.5)	10.4	96.3	2.0	(-252, 475)
	Week 32	121	137.7	93.1	111.0	(26, 616)	121	124.1 (81.0)	13.7	101.1	3.0	(-289, 492)
	Week 36	119	126.4	67.2	110.0	(26, 531)	119	124.7 (82.2)	1.7	74.6	2.0	(-277, 294)
	Week 40	115	137.3	90.5	122.0	(27, 765)	115	125.9 (83.0)	11.4	92.0	6.0	(-264, 474)
	Week 44	114	135.2	84.1	116.0	(27, 628)	114	127.2 (83.1)	8.0	92.0	3.0	(-253, 399)
	Week 48	112	138.4	75.5	124.5	(31, 519)	112	126.4 (83.3)	12.0	90.8	11.5	(-263, 436)
	Week 52	111	136.7	105.2	112.0	(22, 714)	111	126.0 (82.9)	10.7	102.1	8.0	(-302, 603)
darbepoetin	Baseline	153	128.6	100.1	98.0	(29, 742)						
	Week 2	153	131.4	99.8	97.0	(31, 658)	153	128.6 (100.1)	2.8	65.4	0.0	(-475, 311)
	Week 4	153	132.7	119.9	98.0	(30, 942)	153	128.6 (100.1)	4.1	71.9	-3.0	(-427, 449)
	Week 6	152	132.0	126.0	93.0	(25, 1026)	152	128.9 (100.4)	3.1	77.8	-3.0	(-303, 533)
	Week 8	151	139.0	154.6	94.0	(27, 1240)	151	129.5 (100.5)	9.5	109.9	-4.0	(-509, 747)
	Week 10	150	134.4	157.6	86.0	(27, 1395)	150	129.2 (101.0)	5.2	110.4	-4.5	(-327, 948)
	Week 12	148	135.4	149.5	89.0	(26, 1308)	148	128.1 (99.7)	7.3	106.4	-2.5	(-438, 861)
	Week 16	148	141.9	183.6	87.0	(21, 1652)	148	129.0 (101.4)	12.9	141.4	-3.0	(-522, 1230)
	Week 20	144	127.7	120.2	91.5	(26, 900)	144	128.2 (102.3)	-0.5	75.0	-6.0	(-246, 416)
	Week 24	140	149.5	170.0	104.5	(25, 1378)	140	129.0 (101.9)	20.5	117.6	0.0	(-214, 897)
	Week 28	137	320.4	2210.9	91.0	(29, 25946)	137	127.8 (101.4)	192.6	2210.9	-7.0	(-277, 25858)
	Week 32	133	145.4	189.1	98.0	(31, 1679)	133	127.2 (101.6)	18.2	149.0	-1.0	(-350, 1378)
	Week 36	130	133.5	147.0	90.0	(30, 960)	130	124.5 (98.4)	9.0	111.2	-4.0	(-493, 729)
	Week 40	128	125.7	102.2	93.5	(32, 624)	128	123.8 (98.8)	1.8	83.1	-2.0	(-511, 383)
	Week 44	125	128.4	126.2	89.0	(27, 999)	125	123.4 (98.9)	5.0	95.2	-2.0	(-427, 635)
	Week 48	125	124.4	105.8	95.0	(34, 770)	125	123.4 (98.9)	1.0	77.2	-3.0	(-480, 399)
	Week 52	123	126.8	118.7	100.0	(30, 1147)	123	124.6 (99.2)	2.1	94.0	0.0	(-537, 654)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Bilirubin (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	0.55	0.19	0.50	(0.2, 1.2)						
	Week 2	151	0.53	0.19	0.50	(0.2, 1.5)	151	0.55 (0.19)	-0.02	0.13	0.00	(-0.5, 0.6)
	Week 4	149	0.53	0.16	0.50	(0.2, 1.1)	149	0.55 (0.19)	-0.02	0.14	0.00	(-0.4, 0.3)
	Week 6	148	0.53	0.19	0.50	(0.2, 1.2)	148	0.55 (0.19)	-0.02	0.14	0.00	(-0.4, 0.3)
	Week 8	145	0.53	0.17	0.50	(0.3, 1.1)	145	0.54 (0.19)	-0.01	0.14	0.00	(-0.5, 0.3)
	Week 10	145	0.54	0.20	0.50	(0.3, 1.5)	145	0.55 (0.19)	-0.01	0.17	0.00	(-0.7, 0.6)
	Week 12	145	0.54	0.18	0.50	(0.2, 1.0)	145	0.55 (0.19)	0.00	0.14	0.00	(-0.5, 0.4)
	Week 16	143	0.54	0.19	0.50	(0.3, 1.2)	143	0.55 (0.19)	0.00	0.16	0.00	(-0.7, 0.5)
	Week 20	140	0.57	0.20	0.50	(0.2, 1.6)	140	0.55 (0.19)	0.02	0.18	0.00	(-0.6, 0.7)
	Week 24	132	0.57	0.19	0.50	(0.2, 1.3)	132	0.55 (0.19)	0.02	0.16	0.00	(-0.5, 0.4)
	Week 28	126	0.58	0.19	0.50	(0.2, 1.2)	126	0.55 (0.19)	0.03	0.16	0.00	(-0.6, 0.3)
	Week 32	121	0.59	0.19	0.60	(0.2, 1.4)	121	0.55 (0.19)	0.04	0.18	0.00	(-0.5, 0.7)
	Week 36	119	0.59	0.19	0.60	(0.2, 1.2)	119	0.55 (0.20)	0.03	0.18	0.00	(-0.4, 0.4)
	Week 40	115	0.57	0.18	0.60	(0.3, 1.2)	115	0.55 (0.20)	0.02	0.16	0.00	(-0.4, 0.4)
	Week 44	114	0.56	0.18	0.50	(0.2, 1.1)	114	0.56 (0.20)	0.01	0.17	0.00	(-0.5, 0.4)
	Week 48	112	0.56	0.18	0.55	(0.3, 1.2)	112	0.56 (0.20)	0.00	0.15	0.00	(-0.5, 0.4)
	Week 52	111	0.58	0.20	0.50	(0.2, 1.3)	111	0.56 (0.20)	0.02	0.15	0.00	(-0.5, 0.4)
darbepoetin	Baseline	153	0.53	0.18	0.50	(0.2, 1.4)						
	Week 2	153	0.57	0.20	0.50	(0.2, 1.5)	153	0.53 (0.18)	0.04	0.13	0.00	(-0.4, 0.5)
	Week 4	153	0.58	0.24	0.50	(0.2, 1.8)	153	0.53 (0.18)	0.05	0.13	0.00	(-0.2, 0.5)
	Week 6	152	0.60	0.25	0.50	(0.3, 1.7)	152	0.53 (0.18)	0.07	0.15	0.00	(-0.3, 1.1)
	Week 8	151	0.58	0.23	0.50	(0.3, 1.7)	151	0.53 (0.18)	0.05	0.14	0.00	(-0.3, 0.8)
	Week 10	150	0.59	0.23	0.50	(0.3, 1.5)	150	0.53 (0.18)	0.05	0.14	0.00	(-0.2, 0.5)
	Week 12	148	0.59	0.23	0.50	(0.3, 1.5)	148	0.53 (0.18)	0.06	0.15	0.10	(-0.2, 0.7)
	Week 16	148	0.58	0.23	0.50	(0.2, 1.7)	148	0.54 (0.18)	0.04	0.15	0.00	(-0.4, 0.6)
	Week 20	144	0.61	0.24	0.60	(0.2, 1.8)	144	0.54 (0.19)	0.07	0.15	0.10	(-0.2, 0.7)
	Week 24	140	0.66	0.38	0.60	(0.3, 4.0)	140	0.54 (0.19)	0.12	0.35	0.10	(-0.3, 3.6)
	Week 28	137	0.62	0.26	0.60	(0.3, 1.6)	137	0.54 (0.19)	0.08	0.20	0.00	(-0.3, 1.1)
	Week 32	133	0.58	0.21	0.50	(0.2, 1.7)	133	0.54 (0.19)	0.04	0.14	0.00	(-0.3, 0.6)
	Week 36	130	0.58	0.23	0.55	(0.2, 2.0)	130	0.54 (0.19)	0.04	0.14	0.00	(-0.4, 0.6)
	Week 40	128	0.59	0.22	0.50	(0.2, 1.6)	128	0.54 (0.19)	0.04	0.15	0.00	(-0.4, 0.5)
	Week 44	125	0.58	0.20	0.50	(0.2, 1.5)	125	0.54 (0.19)	0.04	0.14	0.00	(-0.4, 0.4)
	Week 48	125	0.58	0.21	0.50	(0.3, 1.6)	125	0.54 (0.19)	0.04	0.13	0.00	(-0.4, 0.4)
	Week 52	123	0.59	0.20	0.50	(0.3, 1.3)	123	0.54 (0.19)	0.04	0.14	0.00	(-0.3, 0.5)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Aspartate Aminotransferase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	19.6	9.6	17.0	(5, 86)						
	Week 2	151	18.0	8.8	16.0	(5, 84)	151	19.6 (9.6)	-1.5	8.7	-1.0	(-65, 65)
	Week 4	149	17.5	6.7	17.0	(4, 48)	149	19.4 (9.6)	-1.9	6.6	-1.0	(-65, 10)
	Week 6	148	17.8	7.9	17.0	(4, 64)	148	19.5 (9.6)	-1.7	6.8	-1.0	(-64, 16)
	Week 8	145	17.3	7.6	16.0	(4, 79)	145	19.4 (9.5)	-2.1	7.5	-1.0	(-66, 27)
	Week 10	145	17.0	6.2	16.0	(4, 43)	145	19.1 (9.1)	-2.1	7.3	-1.0	(-68, 14)
	Week 12	145	18.6	9.8	17.0	(4, 82)	145	19.4 (9.5)	-0.8	9.3	-1.0	(-69, 35)
	Week 16	143	18.5	7.6	17.0	(4, 59)	143	19.3 (9.5)	-0.8	8.4	-1.0	(-66, 27)
	Week 20	140	18.7	7.9	18.0	(3, 71)	140	19.4 (9.6)	-0.7	8.6	0.0	(-68, 19)
	Week 24	132	19.0	7.2	18.0	(6, 50)	132	19.4 (9.8)	-0.5	8.6	-0.5	(-63, 26)
	Week 28	126	18.7	6.9	18.0	(4, 45)	126	19.5 (9.9)	-0.8	8.4	0.0	(-66, 16)
	Week 32	121	21.6	23.4	19.0	(5, 255)	121	19.2 (9.8)	2.4	24.5	0.0	(-68, 244)
	Week 36	119	18.8	7.0	18.0	(6, 66)	119	19.4 (9.9)	-0.6	8.2	1.0	(-70, 14)
	Week 40	115	19.3	9.3	18.0	(5, 67)	115	19.4 (9.9)	-0.2	9.7	0.0	(-66, 37)
	Week 44	114	19.2	11.7	17.0	(5, 125)	114	19.5 (9.9)	-0.4	10.5	0.0	(-66, 73)
	Week 48	112	18.5	9.6	17.0	(5, 94)	112	19.6 (10.0)	-1.0	9.2	-1.0	(-68, 42)
	Week 52	111	17.8	6.9	16.0	(5, 47)	111	19.7 (10.0)	-1.9	7.7	-1.0	(-66, 13)
darbepoetin	Baseline	153	20.0	8.7	18.0	(8, 86)						
	Week 2	153	19.8	8.2	18.0	(7, 68)	153	20.0 (8.7)	-0.3	4.5	0.0	(-20, 24)
	Week 4	153	20.8	10.7	18.0	(8, 85)	153	20.0 (8.7)	0.7	7.8	0.0	(-18, 71)
	Week 6	152	20.0	9.6	18.0	(7, 83)	152	20.1 (8.7)	-0.1	5.3	0.0	(-13, 24)
	Week 8	151	20.4	9.1	19.0	(7, 75)	151	20.2 (8.7)	0.3	5.2	0.0	(-19, 23)
	Week 10	150	21.5	14.2	18.0	(7, 134)	150	20.2 (8.8)	1.3	11.5	0.0	(-17, 116)
	Week 12	148	21.4	12.5	19.0	(8, 107)	148	20.2 (8.8)	1.3	7.6	0.0	(-13, 68)
	Week 16	148	20.9	8.9	19.0	(8, 68)	148	20.1 (8.8)	0.8	6.4	1.0	(-39, 29)
	Week 20	144	21.0	9.0	20.0	(8, 79)	144	20.1 (8.9)	1.0	6.5	1.0	(-41, 40)
	Week 24	140	24.6	29.2	20.0	(6, 344)	140	20.4 (8.9)	4.3	27.5	2.0	(-14, 320)
	Week 28	137	23.9	29.8	20.0	(5, 350)	137	19.9 (8.8)	4.0	28.9	1.0	(-15, 330)
	Week 32	133	22.6	13.5	20.0	(7, 139)	133	20.1 (8.8)	2.6	11.1	1.0	(-17, 100)
	Week 36	130	22.7	10.8	21.0	(6, 71)	130	20.2 (8.8)	2.5	7.9	1.0	(-17, 35)
	Week 40	128	22.1	10.9	20.5	(7, 96)	128	20.2 (8.8)	1.9	8.3	1.0	(-18, 57)
	Week 44	125	21.7	8.2	20.0	(7, 51)	125	20.0 (8.7)	1.6	6.2	1.0	(-20, 25)
	Week 48	125	20.8	7.3	19.0	(9, 43)	125	20.0 (8.7)	0.8	4.9	0.0	(-21, 13)
	Week 52	123	20.2	6.9	19.0	(9, 41)	123	20.2 (8.6)	0.0	4.9	0.0	(-20, 13)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Alanine Aminotransferase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	13.2	7.2	12.0	(4, 59)						
	Week 2	151	10.8	7.4	9.0	(4, 77)	151	13.2 (7.2)	-2.4	5.4	-2.0	(-26, 25)
	Week 4	149	10.5	5.2	9.0	(2, 33)	149	13.2 (7.2)	-2.7	5.3	-2.0	(-26, 18)
	Week 6	148	10.1	5.0	9.0	(3, 34)	148	13.2 (7.2)	-3.1	5.3	-2.0	(-38, 15)
	Week 8	145	10.0	5.0	9.0	(3, 37)	145	13.2 (7.3)	-3.3	5.9	-2.0	(-48, 10)
	Week 10	145	10.0	5.4	9.0	(3, 34)	145	13.1 (7.2)	-3.1	6.1	-2.0	(-45, 15)
	Week 12	145	10.8	6.7	9.0	(4, 57)	145	13.2 (7.3)	-2.5	7.3	-2.0	(-46, 30)
	Week 16	143	11.0	6.7	10.0	(3, 51)	143	13.1 (7.3)	-2.1	7.7	-2.0	(-47, 37)
	Week 20	140	11.0	6.1	10.0	(2, 38)	140	13.1 (7.3)	-2.2	7.3	-2.0	(-46, 27)
	Week 24	132	11.0	5.5	9.5	(3, 34)	132	13.1 (7.4)	-2.0	7.3	-1.0	(-45, 28)
	Week 28	126	11.0	5.5	10.0	(4, 42)	126	13.0 (7.5)	-2.1	6.8	-2.0	(-45, 14)
	Week 32	121	12.9	18.0	10.0	(1, 177)	121	12.6 (7.1)	0.3	18.3	-1.0	(-44, 164)
	Week 36	119	10.8	5.1	10.0	(3, 35)	119	12.8 (7.4)	-2.0	6.7	-1.0	(-46, 11)
	Week 40	115	11.3	7.7	10.0	(3, 53)	115	12.7 (7.4)	-1.5	7.8	-1.0	(-46, 26)
	Week 44	114	10.9	7.4	9.0	(3, 65)	114	12.8 (7.4)	-1.9	7.7	-1.0	(-50, 38)
	Week 48	112	10.5	6.9	9.0	(2, 59)	112	12.7 (7.4)	-2.2	7.1	-2.0	(-52, 32)
	Week 52	111	9.9	5.7	8.0	(1, 40)	111	12.8 (7.5)	-2.9	6.0	-2.0	(-47, 11)
darbepoetin	Baseline	153	14.0	7.6	12.0	(4, 49)						
	Week 2	153	14.0	8.6	12.0	(4, 70)	153	14.0 (7.6)	0.0	5.3	0.0	(-12, 41)
	Week 4	153	14.7	11.1	12.0	(4, 100)	153	14.0 (7.6)	0.6	8.9	0.0	(-19, 84)
	Week 6	152	13.5	7.8	11.0	(4, 51)	152	14.0 (7.6)	-0.6	4.8	0.0	(-19, 22)
	Week 8	151	14.2	7.6	12.0	(4, 49)	151	14.1 (7.6)	0.1	5.6	0.0	(-26, 24)
	Week 10	150	16.4	24.8	12.0	(4, 290)	150	14.1 (7.7)	2.3	23.5	0.0	(-23, 272)
	Week 12	148	15.0	10.3	12.0	(4, 74)	148	14.1 (7.7)	1.0	7.4	0.0	(-22, 56)
	Week 16	148	15.1	9.2	13.0	(4, 66)	148	14.0 (7.7)	1.0	6.9	0.0	(-25, 41)
	Week 20	144	15.0	8.2	12.0	(4, 55)	144	14.1 (7.8)	0.9	6.4	1.0	(-31, 19)
	Week 24	140	16.4	15.2	13.0	(4, 162)	140	14.2 (7.9)	2.3	13.5	1.0	(-19, 146)
	Week 28	137	15.9	11.4	13.0	(4, 91)	137	13.9 (7.3)	2.0	10.1	1.0	(-28, 73)
	Week 32	133	14.8	8.0	13.0	(5, 58)	133	13.9 (7.3)	0.9	6.6	1.0	(-24, 23)
	Week 36	130	16.3	12.9	13.0	(5, 108)	130	14.0 (7.4)	2.3	11.4	1.0	(-21, 93)
	Week 40	128	16.2	13.9	13.0	(4, 131)	128	14.1 (7.4)	2.1	12.3	1.0	(-18, 116)
	Week 44	125	15.3	8.4	12.0	(5, 53)	125	13.9 (7.2)	1.4	6.9	1.0	(-20, 25)
	Week 48	125	14.9	7.9	13.0	(5, 49)	125	13.9 (7.2)	1.0	6.4	0.0	(-25, 37)
	Week 52	123	13.8	6.7	12.0	(4, 42)	123	14.0 (7.2)	-0.3	5.3	0.0	(-27, 20)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Alkaline Phosphatase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	255.7	99.2	235.0	(98, 802)						
	Week 2	151	255.3	98.0	236.0	(112, 718)	151	255.7 (99.2)	-0.4	34.4	0.0	(-120, 209)
	Week 4	149	254.2	99.2	232.0	(99, 602)	149	255.4 (99.4)	-1.3	43.6	-4.0	(-218, 288)
	Week 6	148	254.2	101.2	230.5	(101, 749)	148	255.6 (99.7)	-1.4	36.1	-1.5	(-72, 170)
	Week 8	145	254.7	105.0	228.0	(87, 787)	145	255.4 (100.1)	-0.8	36.9	-6.0	(-87, 196)
	Week 10	145	254.5	99.7	237.0	(99, 743)	145	255.8 (99.8)	-1.3	40.4	-4.0	(-159, 123)
	Week 12	145	255.5	102.5	237.0	(92, 761)	145	255.4 (100.1)	0.1	45.7	-3.0	(-159, 193)
	Week 16	143	257.3	105.7	230.0	(81, 849)	143	255.4 (100.7)	1.9	49.4	1.0	(-158, 143)
	Week 20	140	269.4	119.4	235.5	(99, 870)	140	255.3 (101.6)	14.1	60.0	11.0	(-162, 232)
	Week 24	132	267.1	109.1	245.0	(98, 761)	132	255.3 (102.4)	11.8	60.0	9.0	(-165, 309)
	Week 28	126	274.1	108.7	252.0	(90, 660)	126	257.8 (105.5)	16.4	61.1	18.0	(-197, 211)
	Week 32	121	283.1	117.4	255.0	(95, 738)	121	258.4 (105.9)	24.7	70.4	21.0	(-238, 351)
	Week 36	119	279.5	105.9	259.0	(94, 618)	119	257.6 (105.8)	21.9	70.3	20.0	(-225, 340)
	Week 40	115	278.6	106.2	251.0	(93, 683)	115	257.6 (105.5)	21.0	74.6	21.0	(-270, 407)
	Week 44	114	280.2	110.4	242.5	(86, 640)	114	259.6 (107.2)	20.6	81.1	18.5	(-261, 323)
	Week 48	112	277.5	101.8	251.5	(102, 632)	112	258.1 (106.6)	19.4	82.6	23.5	(-354, 262)
	Week 52	111	266.3	94.8	241.0	(101, 550)	111	255.5 (102.2)	10.7	69.7	16.0	(-365, 140)
darbepoetin	Baseline	153	236.1	81.4	221.0	(75, 523)						
	Week 2	153	233.5	78.2	220.0	(71, 524)	153	236.1 (81.4)	-2.6	28.0	-2.0	(-145, 64)
	Week 4	153	235.2	79.3	224.0	(77, 548)	153	236.1 (81.4)	-0.9	31.1	1.0	(-128, 96)
	Week 6	152	235.3	83.3	220.5	(76, 550)	152	235.6 (81.5)	-0.3	29.7	1.5	(-108, 87)
	Week 8	151	240.1	86.2	224.0	(83, 551)	151	235.8 (81.7)	4.3	31.5	3.0	(-71, 92)
	Week 10	150	241.3	89.8	221.0	(77, 546)	150	235.5 (81.9)	5.8	39.4	4.0	(-108, 147)
	Week 12	148	242.3	86.1	224.0	(77, 549)	148	236.5 (82.1)	5.8	38.1	4.5	(-138, 148)
	Week 16	148	245.9	87.2	228.0	(79, 677)	148	237.1 (81.5)	8.9	50.6	6.5	(-169, 256)
	Week 20	144	245.3	78.5	228.5	(86, 501)	144	236.9 (81.5)	8.4	42.7	10.5	(-129, 128)
	Week 24	140	251.8	86.3	238.5	(86, 567)	140	235.6 (82.0)	16.2	55.5	10.5	(-139, 298)
	Week 28	137	253.9	91.8	231.0	(88, 558)	137	236.7 (82.4)	17.1	51.7	13.0	(-180, 205)
	Week 32	133	255.0	97.4	230.0	(95, 565)	133	234.0 (81.8)	21.0	67.4	15.0	(-157, 414)
	Week 36	130	264.9	119.0	235.0	(97, 890)	130	233.5 (82.6)	31.4	76.8	17.5	(-150, 543)
	Week 40	128	265.2	123.3	237.5	(84, 1120)	128	234.4 (82.8)	30.8	93.4	16.0	(-144, 773)
	Week 44	125	252.4	88.7	237.0	(99, 598)	125	232.4 (83.3)	20.0	58.5	19.0	(-151, 256)
	Week 48	125	254.5	86.6	242.0	(89, 541)	125	232.4 (83.3)	22.1	54.3	16.0	(-136, 316)
	Week 52	123	253.8	85.7	238.0	(87, 487)	123	233.0 (83.8)	20.7	56.9	15.0	(-158, 256)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Lactate Dehydrogenase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	200.6	33.4	199.0	(124, 303)						
	Week 2	151	205.3	36.2	202.0	(133, 334)	151	200.6 (33.4)	4.7	18.2	3.0	(-35, 76)
	Week 4	149	204.7	37.7	201.0	(130, 354)	149	200.3 (33.5)	4.4	18.4	4.0	(-43, 77)
	Week 6	148	207.5	38.6	204.0	(137, 373)	148	200.4 (33.6)	7.2	21.8	6.0	(-42, 96)
	Week 8	145	209.8	39.2	206.0	(131, 396)	145	200.7 (33.7)	9.1	25.0	4.0	(-49, 119)
	Week 10	145	210.7	41.7	204.0	(135, 380)	145	200.3 (33.7)	10.4	26.4	11.0	(-57, 114)
	Week 12	145	212.8	40.6	203.0	(128, 383)	145	200.4 (33.8)	12.4	30.1	11.0	(-59, 114)
	Week 16	143	211.4	38.4	203.0	(131, 411)	143	199.7 (33.3)	11.8	32.4	11.0	(-85, 200)
	Week 20	140	216.3	44.8	208.0	(142, 377)	140	200.0 (33.9)	16.3	34.5	13.0	(-96, 174)
	Week 24	132	216.2	42.5	211.0	(142, 402)	132	199.3 (34.4)	16.9	33.8	14.5	(-86, 207)
	Week 28	126	210.8	39.2	204.5	(140, 327)	126	198.7 (33.8)	12.1	32.2	11.5	(-93, 129)
	Week 32	121	212.2	39.0	208.0	(144, 434)	121	198.0 (33.9)	14.2	36.0	11.0	(-93, 253)
	Week 36	119	212.3	35.0	207.0	(138, 317)	119	198.4 (34.4)	13.9	27.1	14.0	(-77, 79)
	Week 40	115	214.9	42.5	211.0	(116, 342)	115	198.1 (34.1)	16.9	34.5	15.0	(-101, 147)
	Week 44	114	211.1	42.6	206.0	(126, 444)	114	198.9 (34.0)	12.2	31.4	11.0	(-110, 141)
	Week 48	112	211.2	36.1	209.5	(137, 313)	112	197.9 (32.8)	13.3	28.7	12.0	(-103, 121)
	Week 52	111	210.8	40.0	205.0	(139, 360)	111	198.0 (32.8)	12.8	32.8	12.0	(-105, 168)
darbepoetin	Baseline	153	204.2	55.4	190.0	(116, 495)						
	Week 2	153	203.4	55.3	188.0	(112, 457)	153	204.2 (55.4)	-0.8	18.8	-2.0	(-93, 63)
	Week 4	153	205.5	59.9	193.0	(97, 495)	153	204.2 (55.4)	1.2	23.9	-2.0	(-84, 104)
	Week 6	152	205.9	60.9	193.5	(115, 544)	152	204.3 (55.6)	1.7	29.0	-1.0	(-150, 156)
	Week 8	151	208.2	60.8	196.0	(126, 507)	151	204.6 (55.6)	3.6	30.1	2.0	(-137, 202)
	Week 10	150	211.3	67.9	194.0	(104, 558)	150	204.4 (55.9)	6.9	36.0	2.0	(-84, 259)
	Week 12	148	211.8	65.1	197.0	(122, 524)	148	203.8 (55.8)	8.0	32.0	7.5	(-108, 225)
	Week 16	148	212.2	62.7	199.0	(128, 537)	148	203.6 (55.5)	8.6	31.0	6.5	(-96, 177)
	Week 20	144	214.1	66.2	197.5	(114, 559)	144	201.6 (52.8)	12.5	37.6	7.0	(-76, 345)
	Week 24	140	218.2	64.0	203.0	(120, 548)	140	202.3 (53.2)	15.9	31.8	11.0	(-92, 178)
	Week 28	137	214.5	65.8	200.0	(114, 525)	137	201.7 (53.3)	12.8	40.3	8.0	(-117, 340)
	Week 32	133	218.1	77.8	201.0	(123, 731)	133	201.5 (53.2)	16.6	46.2	10.0	(-66, 406)
	Week 36	130	215.7	68.8	203.0	(118, 575)	130	200.2 (52.9)	15.5	38.2	10.0	(-75, 224)
	Week 40	128	213.0	67.0	200.5	(126, 604)	128	200.5 (53.2)	12.5	33.3	8.5	(-71, 192)
	Week 44	125	211.0	57.0	205.0	(116, 509)	125	199.4 (52.6)	11.7	28.5	7.0	(-59, 100)
	Week 48	125	208.8	57.5	198.0	(122, 546)	125	199.4 (52.6)	9.4	29.1	7.0	(-89, 120)
	Week 52	123	208.3	57.7	197.0	(124, 572)	123	200.3 (52.5)	8.0	32.7	5.0	(-102, 150)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Gamma Glutamyl Transferase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	29.6	39.0	19.0	(7, 400)						
	Week 2	151	26.8	32.3	18.0	(6, 355)	151	29.6 (39.0)	-2.8	10.9	-1.0	(-104, 10)
	Week 4	149	25.9	31.9	18.0	(7, 326)	149	29.6 (39.2)	-3.7	15.1	-2.0	(-135, 59)
	Week 6	148	24.2	26.8	17.0	(6, 248)	148	29.4 (39.2)	-5.2	17.3	-2.0	(-152, 58)
	Week 8	145	22.5	20.4	16.0	(6, 140)	145	26.9 (24.7)	-4.5	12.3	-3.0	(-90, 71)
	Week 10	145	21.6	19.4	16.0	(5, 131)	145	26.5 (24.2)	-4.8	14.1	-2.0	(-124, 62)
	Week 12	145	22.1	19.9	16.0	(6, 123)	145	26.9 (24.7)	-4.9	14.7	-2.0	(-123, 54)
	Week 16	143	21.7	19.4	16.0	(5, 116)	143	26.8 (24.9)	-5.1	16.0	-2.0	(-120, 31)
	Week 20	140	21.4	18.6	16.0	(6, 117)	140	26.6 (24.7)	-5.2	18.3	-2.0	(-143, 45)
	Week 24	132	22.0	19.9	16.0	(6, 125)	132	26.7 (25.1)	-4.7	18.2	-2.0	(-141, 49)
	Week 28	126	21.6	18.6	16.0	(5, 130)	126	26.4 (25.4)	-4.8	18.4	-2.0	(-142, 43)
	Week 32	121	23.8	28.2	16.0	(6, 233)	121	24.9 (21.5)	-1.0	23.8	-2.0	(-98, 217)
	Week 36	119	22.2	20.6	16.0	(6, 148)	119	25.3 (21.9)	-3.1	15.0	-2.0	(-109, 63)
	Week 40	115	22.2	23.1	15.0	(6, 187)	115	25.4 (22.0)	-3.2	16.7	-2.0	(-108, 102)
	Week 44	114	22.1	25.0	15.0	(6, 186)	114	24.9 (21.3)	-2.8	18.1	-2.0	(-83, 117)
	Week 48	112	21.6	24.1	16.0	(6, 177)	112	25.0 (21.5)	-3.3	17.9	-2.0	(-97, 91)
	Week 52	111	21.3	20.3	16.0	(6, 153)	111	25.1 (21.6)	-3.8	12.6	-3.0	(-69, 66)
darbepoetin	Baseline	153	26.0	22.8	19.0	(8, 174)						
	Week 2	153	25.4	22.5	20.0	(8, 177)	153	26.0 (22.8)	-0.5	5.0	0.0	(-37, 26)
	Week 4	153	26.2	23.3	18.0	(8, 175)	153	26.0 (22.8)	0.2	9.4	0.0	(-42, 77)
	Week 6	152	25.3	21.1	19.0	(9, 153)	152	26.0 (22.9)	-0.7	6.8	0.0	(-37, 29)
	Week 8	151	25.7	23.2	20.0	(8, 202)	151	26.0 (22.9)	-0.3	6.6	0.0	(-32, 28)
	Week 10	150	26.3	23.2	20.0	(8, 201)	150	26.1 (23.0)	0.2	9.3	0.0	(-36, 63)
	Week 12	148	26.3	21.8	20.0	(8, 176)	148	26.2 (23.1)	0.1	8.8	0.0	(-38, 32)
	Week 16	148	27.8	28.2	20.0	(8, 240)	148	25.8 (22.8)	2.0	18.9	0.0	(-37, 209)
	Week 20	144	27.2	23.6	19.5	(8, 144)	144	25.9 (23.1)	1.3	11.1	1.0	(-38, 59)
	Week 24	140	29.4	35.2	20.0	(7, 330)	140	26.3 (23.3)	3.1	27.9	0.0	(-32, 299)
	Week 28	137	29.3	32.9	20.0	(8, 235)	137	26.4 (23.4)	2.9	19.4	1.0	(-41, 175)
	Week 32	133	30.8	37.5	20.0	(10, 270)	133	26.4 (23.7)	4.5	24.7	1.0	(-38, 239)
	Week 36	130	31.6	42.1	20.0	(9, 334)	130	26.0 (23.5)	5.6	24.0	1.0	(-28, 171)
	Week 40	128	32.6	54.4	20.0	(8, 477)	128	25.9 (23.6)	6.7	38.5	1.0	(-30, 359)
	Week 44	125	27.8	28.4	21.0	(7, 254)	125	25.3 (22.4)	2.6	12.9	1.0	(-36, 80)
	Week 48	125	29.5	29.1	21.0	(9, 230)	125	25.3 (22.4)	4.3	14.0	1.0	(-40, 69)
	Week 52	123	27.3	26.8	20.0	(8, 225)	123	25.4 (22.5)	1.9	10.8	1.0	(-39, 59)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Sodium (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	140.3	3.3	141.0	(129, 150)						
	Week 2	151	140.1	3.0	140.0	(130, 147)	151	140.3 (3.3)	-0.2	2.7	0.0	(-9, 6)
	Week 4	149	140.1	3.0	140.0	(127, 149)	149	140.2 (3.2)	-0.1	2.3	0.0	(-6, 5)
	Week 6	148	140.0	2.7	140.0	(129, 146)	148	140.3 (3.2)	-0.3	2.5	-0.5	(-7, 8)
	Week 8	145	140.3	2.7	141.0	(131, 146)	145	140.3 (3.2)	0.0	2.6	0.0	(-7, 7)
	Week 10	145	140.2	2.9	140.0	(130, 146)	145	140.4 (3.2)	-0.2	2.6	-1.0	(-8, 7)
	Week 12	145	140.3	2.7	141.0	(130, 145)	145	140.3 (3.2)	0.0	2.6	0.0	(-9, 10)
	Week 16	143	140.1	3.1	140.0	(127, 149)	143	140.3 (3.2)	-0.2	2.7	0.0	(-8, 6)
	Week 20	140	140.4	3.4	141.0	(124, 147)	140	140.3 (3.1)	0.0	3.0	0.0	(-11, 11)
	Week 24	132	140.6	3.0	141.0	(126, 148)	132	140.3 (3.1)	0.2	2.9	0.0	(-9, 10)
	Week 28	126	140.6	3.1	141.0	(132, 152)	126	140.4 (3.1)	0.2	3.2	0.0	(-9, 11)
	Week 32	121	140.9	3.6	141.0	(125, 150)	121	140.4 (3.1)	0.5	2.9	0.0	(-10, 9)
	Week 36	119	141.0	3.0	141.0	(131, 150)	119	140.4 (3.1)	0.6	3.0	1.0	(-10, 11)
	Week 40	115	141.1	2.6	141.0	(135, 147)	115	140.4 (3.1)	0.7	3.0	1.0	(-9, 10)
	Week 44	114	140.8	2.7	141.0	(131, 151)	114	140.5 (3.1)	0.3	3.1	0.0	(-8, 10)
	Week 48	112	140.7	2.9	141.0	(132, 149)	112	140.4 (3.1)	0.3	2.9	0.0	(-7, 9)
	Week 52	111	140.8	2.8	141.0	(132, 149)	111	140.5 (3.1)	0.3	2.7	0.0	(-7, 8)
darbepoetin	Baseline	153	140.5	2.7	140.0	(131, 146)						
	Week 2	153	140.4	2.3	140.0	(131, 146)	153	140.5 (2.7)	-0.1	2.5	0.0	(-11, 6)
	Week 4	153	140.3	2.5	141.0	(131, 146)	153	140.5 (2.7)	-0.1	2.5	0.0	(-6, 7)
	Week 6	152	140.4	2.5	141.0	(132, 147)	152	140.4 (2.6)	0.0	2.7	0.0	(-10, 7)
	Week 8	151	140.3	2.6	140.0	(131, 148)	151	140.5 (2.6)	-0.2	2.4	0.0	(-8, 7)
	Week 10	150	140.1	2.5	140.0	(131, 147)	150	140.4 (2.7)	-0.3	2.6	-0.5	(-9, 11)
	Week 12	148	140.2	2.4	140.0	(131, 146)	148	140.4 (2.7)	-0.2	2.6	0.0	(-7, 9)
	Week 16	148	140.3	2.7	140.0	(131, 148)	148	140.4 (2.7)	-0.1	2.8	0.0	(-10, 9)
	Week 20	144	140.4	2.6	140.0	(134, 147)	144	140.4 (2.7)	0.0	2.6	0.0	(-7, 8)
	Week 24	140	140.7	2.7	141.0	(133, 146)	140	140.4 (2.6)	0.3	3.0	0.0	(-7, 11)
	Week 28	137	140.7	3.1	141.0	(128, 147)	137	140.4 (2.6)	0.3	3.0	0.0	(-7, 11)
	Week 32	133	141.0	2.8	141.0	(132, 149)	133	140.4 (2.6)	0.7	2.8	1.0	(-7, 8)
	Week 36	130	141.0	3.1	141.0	(131, 148)	130	140.3 (2.6)	0.6	3.0	0.5	(-7, 8)
	Week 40	128	140.9	3.2	141.0	(127, 148)	128	140.4 (2.5)	0.5	3.0	1.0	(-9, 7)
	Week 44	125	140.6	2.7	141.0	(130, 147)	125	140.4 (2.5)	0.2	2.9	0.0	(-8, 9)
	Week 48	125	140.2	3.1	141.0	(125, 146)	125	140.4 (2.5)	-0.2	2.9	0.0	(-10, 8)
	Week 52	123	140.3	2.9	141.0	(130, 147)	123	140.4 (2.5)	-0.1	2.6	0.0	(-8, 6)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Potassium (mEq/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	4.72	0.53	4.70	(3.8, 6.3)						
	Week 2	151	4.64	0.55	4.60	(3.6, 6.3)	151	4.72 (0.53)	-0.08	0.48	-0.10	(-1.6, 1.4)
	Week 4	149	4.62	0.52	4.60	(3.5, 6.4)	149	4.72 (0.53)	-0.10	0.42	-0.10	(-2.0, 0.9)
	Week 6	148	4.60	0.51	4.55	(3.6, 6.3)	148	4.72 (0.54)	-0.11	0.42	-0.10	(-1.4, 1.0)
	Week 8	145	4.64	0.48	4.60	(3.2, 6.1)	145	4.72 (0.54)	-0.08	0.47	-0.10	(-1.3, 1.6)
	Week 10	145	4.61	0.50	4.50	(3.6, 6.1)	145	4.72 (0.54)	-0.11	0.49	-0.10	(-1.7, 1.7)
	Week 12	145	4.57	0.48	4.60	(3.4, 6.0)	145	4.72 (0.54)	-0.15	0.45	-0.10	(-1.6, 1.3)
	Week 16	143	4.58	0.49	4.50	(3.6, 6.4)	143	4.72 (0.53)	-0.14	0.50	-0.10	(-1.8, 1.2)
	Week 20	140	4.59	0.54	4.60	(3.4, 6.8)	140	4.70 (0.52)	-0.11	0.53	-0.10	(-1.6, 2.0)
	Week 24	132	4.57	0.55	4.50	(3.3, 6.1)	132	4.71 (0.52)	-0.13	0.54	0.00	(-2.3, 1.2)
	Week 28	126	4.68	0.56	4.70	(3.1, 6.0)	126	4.71 (0.52)	-0.03	0.60	0.00	(-2.1, 1.5)
	Week 32	121	4.68	0.56	4.60	(3.5, 6.3)	121	4.71 (0.52)	-0.04	0.54	0.00	(-2.0, 1.2)
	Week 36	119	4.62	0.49	4.60	(3.4, 6.3)	119	4.71 (0.52)	-0.09	0.53	-0.10	(-1.8, 1.1)
	Week 40	115	4.64	0.56	4.60	(3.6, 6.3)	115	4.72 (0.53)	-0.08	0.54	-0.10	(-2.0, 1.0)
	Week 44	114	4.61	0.51	4.50	(3.7, 6.3)	114	4.72 (0.53)	-0.11	0.55	-0.10	(-1.5, 1.8)
	Week 48	112	4.61	0.50	4.60	(3.3, 5.6)	112	4.73 (0.53)	-0.12	0.55	-0.20	(-2.2, 1.3)
	Week 52	111	4.56	0.52	4.50	(3.4, 6.3)	111	4.72 (0.52)	-0.15	0.57	-0.20	(-2.0, 1.7)
darbepoetin	Baseline	153	4.69	0.59	4.60	(3.3, 6.3)						
	Week 2	153	4.70	0.53	4.70	(3.5, 6.2)	153	4.69 (0.59)	0.01	0.47	0.10	(-1.8, 1.2)
	Week 4	153	4.67	0.64	4.60	(2.8, 6.6)	153	4.69 (0.59)	-0.02	0.56	0.00	(-2.5, 1.6)
	Week 6	152	4.65	0.56	4.60	(3.0, 6.5)	152	4.68 (0.58)	-0.03	0.49	0.00	(-2.0, 1.3)
	Week 8	151	4.60	0.59	4.50	(3.1, 6.3)	151	4.69 (0.58)	-0.08	0.51	0.00	(-1.7, 1.1)
	Week 10	150	4.63	0.53	4.60	(3.1, 6.2)	150	4.68 (0.59)	-0.05	0.49	0.00	(-1.8, 1.1)
	Week 12	148	4.64	0.62	4.50	(3.0, 6.5)	148	4.67 (0.58)	-0.03	0.57	0.00	(-2.1, 2.0)
	Week 16	148	4.60	0.55	4.55	(3.0, 6.0)	148	4.68 (0.59)	-0.08	0.54	-0.05	(-1.7, 1.6)
	Week 20	144	4.66	0.60	4.60	(3.2, 7.2)	144	4.69 (0.59)	-0.03	0.61	0.00	(-1.7, 2.7)
	Week 24	140	4.58	0.52	4.50	(3.6, 6.9)	140	4.69 (0.59)	-0.11	0.56	-0.10	(-2.1, 1.7)
	Week 28	137	4.62	0.54	4.50	(3.6, 7.1)	137	4.70 (0.60)	-0.08	0.56	0.00	(-1.6, 1.6)
	Week 32	133	4.59	0.53	4.50	(3.5, 6.3)	133	4.69 (0.60)	-0.10	0.54	-0.10	(-1.6, 1.2)
	Week 36	130	4.64	0.61	4.60	(3.4, 6.9)	130	4.68 (0.59)	-0.04	0.60	0.00	(-1.7, 1.6)
	Week 40	128	4.59	0.51	4.60	(3.6, 6.3)	128	4.68 (0.59)	-0.09	0.54	-0.10	(-2.0, 1.4)
	Week 44	125	4.61	0.54	4.60	(3.1, 6.2)	125	4.68 (0.58)	-0.07	0.54	0.00	(-1.3, 1.1)
	Week 48	125	4.60	0.55	4.60	(3.3, 6.1)	125	4.68 (0.58)	-0.08	0.58	0.00	(-1.9, 1.3)
	Week 52	123	4.60	0.54	4.60	(2.8, 5.9)	123	4.69 (0.59)	-0.10	0.56	0.00	(-1.8, 1.1)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Chloride (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	106.1	4.2	106.0	(91, 116)						
	Week 2	151	106.5	4.1	106.0	(92, 118)	151	106.1 (4.2)	0.4	2.9	0.0	(-7, 9)
	Week 4	149	106.6	4.0	107.0	(90, 116)	149	106.1 (4.2)	0.5	2.9	0.0	(-7, 11)
	Week 6	148	106.4	4.2	106.0	(91, 115)	148	106.1 (4.2)	0.3	3.2	0.0	(-6, 11)
	Week 8	145	106.7	3.8	107.0	(92, 117)	145	106.2 (4.0)	0.5	3.0	1.0	(-7, 10)
	Week 10	145	106.1	3.9	106.0	(91, 118)	145	106.2 (4.0)	-0.2	3.3	0.0	(-12, 9)
	Week 12	145	106.0	3.4	106.0	(93, 117)	145	106.3 (4.0)	-0.2	3.2	-1.0	(-8, 9)
	Week 16	143	105.9	4.2	106.0	(87, 118)	143	106.2 (4.1)	-0.4	3.2	-1.0	(-11, 9)
	Week 20	140	105.8	4.4	106.0	(87, 121)	140	106.2 (4.1)	-0.4	3.3	0.0	(-11, 8)
	Week 24	132	106.0	3.9	106.0	(88, 114)	132	106.1 (4.0)	-0.2	3.5	0.0	(-10, 9)
	Week 28	126	105.5	3.8	106.0	(93, 116)	126	106.1 (4.1)	-0.6	3.4	0.0	(-10, 7)
	Week 32	121	105.9	4.3	106.0	(86, 114)	121	106.2 (4.1)	-0.2	3.4	0.0	(-9, 12)
	Week 36	119	105.8	3.5	106.0	(93, 115)	119	106.2 (4.0)	-0.4	3.3	0.0	(-9, 10)
	Week 40	115	105.9	3.7	106.0	(95, 115)	115	106.2 (4.0)	-0.3	3.2	0.0	(-9, 8)
	Week 44	114	106.1	3.3	106.0	(97, 114)	114	106.2 (4.0)	-0.1	2.9	0.0	(-7, 8)
	Week 48	112	106.0	3.4	106.0	(93, 114)	112	106.2 (4.0)	-0.2	3.3	-0.5	(-9, 9)
	Week 52	111	106.1	3.4	106.0	(96, 116)	111	106.2 (4.0)	0.0	3.6	0.0	(-10, 9)
darbepoetin	Baseline	153	106.5	3.8	107.0	(94, 116)						
	Week 2	153	106.6	3.5	107.0	(97, 119)	153	106.5 (3.8)	0.1	2.9	0.0	(-14, 10)
	Week 4	153	106.3	3.9	107.0	(94, 117)	153	106.5 (3.8)	-0.2	2.9	0.0	(-8, 7)
	Week 6	152	106.4	3.8	106.5	(96, 118)	152	106.5 (3.8)	-0.1	3.1	0.0	(-8, 10)
	Week 8	151	105.8	3.9	106.0	(95, 118)	151	106.5 (3.8)	-0.7	3.0	-1.0	(-10, 8)
	Week 10	150	105.8	4.1	106.0	(91, 118)	150	106.4 (3.8)	-0.7	3.1	-1.0	(-13, 8)
	Week 12	148	105.8	3.5	106.0	(96, 115)	148	106.5 (3.8)	-0.6	3.2	-1.0	(-11, 8)
	Week 16	148	105.9	3.7	107.0	(96, 114)	148	106.5 (3.8)	-0.6	3.1	0.0	(-12, 5)
	Week 20	144	105.8	3.9	106.0	(91, 120)	144	106.5 (3.8)	-0.7	3.3	-1.0	(-8, 6)
	Week 24	140	105.8	3.8	106.0	(89, 120)	140	106.5 (3.8)	-0.7	3.1	-1.0	(-11, 7)
	Week 28	137	105.6	3.9	106.0	(90, 116)	137	106.6 (3.7)	-1.0	3.8	-1.0	(-12, 13)
	Week 32	133	105.9	3.9	106.0	(94, 118)	133	106.5 (3.7)	-0.6	3.6	0.0	(-16, 7)
	Week 36	130	105.8	4.1	106.0	(93, 119)	130	106.4 (3.6)	-0.6	3.6	0.0	(-12, 8)
	Week 40	128	105.6	4.0	105.5	(92, 117)	128	106.4 (3.6)	-0.8	3.5	-1.0	(-13, 6)
	Week 44	125	105.6	3.7	106.0	(91, 113)	125	106.4 (3.6)	-0.8	3.4	-1.0	(-11, 7)
	Week 48	125	105.6	4.3	106.0	(90, 118)	125	106.4 (3.6)	-0.8	4.1	0.0	(-15, 8)
	Week 52	123	105.7	3.8	106.0	(94, 118)	123	106.4 (3.7)	-0.7	3.6	0.0	(-13, 8)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Calcium (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	8.81	0.61	8.80	(6.0, 10.8)						
	Week 2	151	8.63	0.54	8.60	(6.7, 10.9)	151	8.81 (0.61)	-0.19	0.35	-0.20	(-1.0, 1.7)
	Week 4	149	8.59	0.55	8.60	(6.7, 10.3)	149	8.81 (0.61)	-0.22	0.35	-0.20	(-1.2, 1.4)
	Week 6	148	8.58	0.54	8.60	(6.7, 10.8)	148	8.81 (0.61)	-0.22	0.38	-0.20	(-1.7, 1.5)
	Week 8	145	8.62	0.51	8.60	(6.7, 10.5)	145	8.81 (0.62)	-0.18	0.40	-0.20	(-2.0, 1.5)
	Week 10	145	8.60	0.53	8.60	(6.6, 11.0)	145	8.81 (0.62)	-0.21	0.45	-0.20	(-2.0, 2.0)
	Week 12	145	8.63	0.54	8.60	(6.5, 11.4)	145	8.80 (0.62)	-0.17	0.41	-0.20	(-2.2, 1.8)
	Week 16	143	8.61	0.53	8.60	(7.2, 10.1)	143	8.81 (0.61)	-0.20	0.50	-0.20	(-2.5, 2.0)
	Week 20	140	8.67	0.60	8.70	(6.4, 10.5)	140	8.81 (0.62)	-0.15	0.48	-0.10	(-2.2, 1.8)
	Week 24	132	8.81	0.57	8.90	(6.7, 10.4)	132	8.84 (0.55)	-0.03	0.46	0.00	(-1.9, 1.3)
	Week 28	126	8.74	0.53	8.80	(7.1, 10.3)	126	8.86 (0.54)	-0.13	0.46	-0.10	(-2.1, 1.4)
	Week 32	121	8.79	0.57	8.90	(7.1, 11.3)	121	8.86 (0.55)	-0.06	0.51	0.00	(-2.5, 2.4)
	Week 36	119	8.79	0.50	8.80	(7.2, 10.8)	119	8.86 (0.55)	-0.08	0.44	-0.10	(-2.5, 1.9)
	Week 40	115	8.77	0.56	8.80	(7.0, 10.8)	115	8.87 (0.56)	-0.10	0.46	0.00	(-2.6, 1.1)
	Week 44	114	8.81	0.57	8.80	(6.1, 10.3)	114	8.86 (0.53)	-0.06	0.41	0.00	(-1.6, 1.2)
	Week 48	112	8.78	0.53	8.80	(7.6, 10.1)	112	8.88 (0.50)	-0.10	0.41	-0.10	(-1.3, 1.2)
	Week 52	111	8.78	0.54	8.70	(7.1, 10.4)	111	8.89 (0.50)	-0.11	0.41	-0.10	(-1.3, 1.2)
darbepoetin	Baseline	153	8.76	0.49	8.80	(6.9, 9.6)						
	Week 2	153	8.65	0.55	8.70	(6.2, 9.8)	153	8.76 (0.49)	-0.11	0.33	-0.10	(-1.4, 0.7)
	Week 4	153	8.65	0.59	8.70	(6.1, 10.3)	153	8.76 (0.49)	-0.11	0.41	-0.10	(-2.1, 1.0)
	Week 6	152	8.65	0.56	8.70	(6.6, 10.4)	152	8.76 (0.50)	-0.11	0.34	-0.10	(-1.0, 0.8)
	Week 8	151	8.68	0.57	8.70	(6.6, 10.0)	151	8.76 (0.50)	-0.08	0.33	-0.10	(-1.0, 0.8)
	Week 10	150	8.66	0.54	8.70	(6.7, 10.2)	150	8.77 (0.48)	-0.11	0.39	-0.10	(-1.3, 0.7)
	Week 12	148	8.69	0.58	8.70	(6.7, 10.3)	148	8.75 (0.49)	-0.06	0.40	-0.10	(-1.5, 0.8)
	Week 16	148	8.66	0.58	8.70	(6.8, 10.1)	148	8.75 (0.50)	-0.09	0.42	-0.10	(-1.4, 1.2)
	Week 20	144	8.71	0.58	8.80	(6.8, 10.1)	144	8.76 (0.48)	-0.05	0.44	-0.10	(-1.1, 1.2)
	Week 24	140	8.86	0.63	8.90	(6.5, 10.1)	140	8.78 (0.48)	0.08	0.47	0.10	(-1.2, 1.5)
	Week 28	137	8.84	0.61	8.90	(6.7, 11.2)	137	8.80 (0.46)	0.04	0.47	0.10	(-1.3, 2.2)
	Week 32	133	8.84	0.59	8.90	(6.7, 9.9)	133	8.81 (0.46)	0.03	0.43	0.00	(-1.5, 0.9)
	Week 36	130	8.90	0.52	8.90	(6.7, 9.9)	130	8.83 (0.43)	0.07	0.39	0.00	(-1.4, 1.0)
	Week 40	128	8.86	0.52	8.80	(6.6, 9.9)	128	8.83 (0.43)	0.03	0.41	0.00	(-1.5, 1.4)
	Week 44	125	8.84	0.53	8.90	(6.4, 9.9)	125	8.84 (0.43)	0.00	0.46	0.00	(-1.7, 1.4)
	Week 48	125	8.88	0.57	9.00	(6.0, 10.2)	125	8.84 (0.43)	0.04	0.45	0.10	(-2.1, 1.3)
	Week 52	123	8.82	0.56	8.80	(6.1, 9.9)	123	8.85 (0.43)	-0.03	0.45	0.00	(-2.0, 1.4)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Phosphate (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	3.99	0.88	3.90	(2.3, 10.8)						
	Week 2	151	4.02	0.74	4.00	(2.1, 6.7)	151	3.99 (0.88)	0.03	0.62	0.00	(-4.1, 2.6)
	Week 4	149	3.97	0.75	3.90	(2.0, 6.8)	149	3.99 (0.88)	-0.02	0.66	0.00	(-4.5, 1.4)
	Week 6	148	3.90	0.67	3.80	(2.1, 6.0)	148	3.99 (0.88)	-0.09	0.61	0.00	(-4.8, 1.5)
	Week 8	145	3.94	0.70	3.80	(2.2, 6.5)	145	3.98 (0.87)	-0.04	0.64	0.00	(-4.3, 1.3)
	Week 10	145	3.90	0.85	3.80	(2.2, 6.9)	145	4.00 (0.88)	-0.09	0.75	-0.10	(-4.0, 2.0)
	Week 12	145	3.87	0.71	3.80	(2.3, 6.7)	145	4.00 (0.88)	-0.13	0.65	-0.10	(-4.1, 1.6)
	Week 16	143	3.89	0.77	3.70	(2.7, 7.6)	143	4.00 (0.88)	-0.10	0.66	-0.10	(-3.2, 1.4)
	Week 20	140	3.97	0.94	3.85	(2.3, 10.7)	140	3.99 (0.87)	-0.02	0.84	-0.05	(-3.7, 5.6)
	Week 24	132	3.88	0.77	3.80	(1.4, 7.0)	132	3.93 (0.65)	-0.05	0.59	0.00	(-2.5, 1.6)
	Week 28	126	3.95	0.80	3.90	(2.0, 6.9)	126	3.90 (0.63)	0.05	0.72	0.00	(-2.2, 2.4)
	Week 32	121	4.00	0.87	3.80	(2.2, 7.2)	121	3.89 (0.64)	0.11	0.71	0.10	(-1.4, 2.8)
	Week 36	119	4.00	0.76	3.90	(2.2, 6.8)	119	3.89 (0.64)	0.11	0.59	0.00	(-1.2, 2.2)
	Week 40	115	4.07	0.91	3.90	(2.2, 8.9)	115	3.89 (0.64)	0.18	0.75	0.20	(-1.8, 4.3)
	Week 44	114	4.06	0.90	4.00	(2.5, 9.1)	114	3.88 (0.64)	0.18	0.62	0.20	(-1.1, 2.7)
	Week 48	112	4.05	0.82	4.00	(2.2, 7.0)	112	3.86 (0.60)	0.20	0.65	0.20	(-1.4, 1.9)
	Week 52	111	4.09	0.95	3.90	(2.2, 7.9)	111	3.86 (0.60)	0.23	0.72	0.20	(-1.2, 2.5)
darbepoetin	Baseline	153	3.91	0.86	3.90	(2.3, 7.4)						
	Week 2	153	3.99	0.85	3.90	(2.2, 7.5)	153	3.91 (0.86)	0.08	0.57	0.00	(-2.2, 1.9)
	Week 4	153	3.89	0.83	3.80	(1.7, 7.1)	153	3.91 (0.86)	-0.02	0.55	0.00	(-2.0, 1.9)
	Week 6	152	3.94	0.89	3.80	(2.1, 8.0)	152	3.90 (0.86)	0.04	0.55	0.10	(-1.9, 2.1)
	Week 8	151	3.96	0.92	3.80	(2.3, 7.5)	151	3.90 (0.86)	0.06	0.57	0.10	(-1.9, 1.7)
	Week 10	150	3.98	0.87	3.85	(2.5, 7.6)	150	3.89 (0.86)	0.09	0.58	0.10	(-1.4, 2.0)
	Week 12	148	3.94	0.94	3.85	(1.6, 7.8)	148	3.88 (0.86)	0.05	0.60	0.10	(-1.3, 2.2)
	Week 16	148	3.95	1.01	3.80	(2.1, 9.5)	148	3.90 (0.85)	0.05	0.66	0.00	(-1.6, 2.5)
	Week 20	144	4.09	1.15	3.90	(2.2, 8.4)	144	3.89 (0.86)	0.20	0.72	0.20	(-1.5, 2.7)
	Week 24	140	4.01	1.11	3.80	(2.5, 9.2)	140	3.87 (0.83)	0.14	0.72	0.10	(-1.0, 3.8)
	Week 28	137	3.98	1.13	3.80	(2.4, 10.6)	137	3.84 (0.80)	0.14	0.77	0.10	(-1.5, 3.6)
	Week 32	133	3.92	0.88	3.80	(2.5, 8.4)	133	3.80 (0.74)	0.12	0.64	0.10	(-1.4, 1.8)
	Week 36	130	3.93	0.75	3.85	(2.4, 6.2)	130	3.77 (0.70)	0.16	0.65	0.15	(-2.4, 1.8)
	Week 40	128	3.88	0.77	3.80	(2.1, 7.5)	128	3.76 (0.70)	0.12	0.67	0.20	(-1.4, 2.3)
	Week 44	125	3.92	0.79	3.80	(2.5, 7.1)	125	3.76 (0.70)	0.15	0.67	0.10	(-1.2, 2.1)
	Week 48	125	3.94	0.89	3.80	(2.5, 8.6)	125	3.76 (0.70)	0.18	0.75	0.10	(-2.0, 3.4)
	Week 52	123	3.91	0.88	3.80	(2.4, 8.5)	123	3.75 (0.69)	0.16	0.76	0.10	(-1.6, 4.6)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Magnesium (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	2.00	0.30	2.00	(1.3, 2.9)						
	Week 2	151	2.02	0.29	2.00	(1.4, 3.3)	151	2.00 (0.30)	0.02	0.16	0.00	(-0.4, 0.5)
	Week 4	149	2.00	0.32	2.00	(1.2, 3.2)	149	2.00 (0.30)	0.00	0.16	0.00	(-0.4, 0.5)
	Week 6	148	2.00	0.30	2.00	(1.3, 3.4)	148	2.00 (0.30)	0.01	0.17	0.00	(-0.3, 0.5)
	Week 8	145	2.03	0.31	2.00	(1.4, 3.5)	145	2.00 (0.30)	0.03	0.18	0.00	(-0.4, 0.8)
	Week 10	145	2.00	0.30	2.00	(1.3, 3.2)	145	2.00 (0.30)	0.00	0.18	0.00	(-0.4, 0.5)
	Week 12	145	2.01	0.29	2.00	(1.3, 3.0)	145	2.00 (0.30)	0.01	0.18	0.00	(-0.4, 0.6)
	Week 16	143	1.99	0.29	2.00	(1.3, 3.0)	143	2.00 (0.30)	-0.01	0.19	0.00	(-0.5, 0.6)
	Week 20	140	2.04	0.32	2.00	(1.2, 3.2)	140	2.00 (0.30)	0.04	0.18	0.00	(-0.3, 0.5)
	Week 24	132	2.03	0.30	2.10	(1.2, 2.9)	132	2.01 (0.30)	0.02	0.19	0.00	(-0.8, 0.5)
	Week 28	126	2.07	0.29	2.00	(1.3, 2.9)	126	2.01 (0.30)	0.06	0.22	0.10	(-0.9, 0.6)
	Week 32	121	2.11	0.29	2.10	(1.3, 2.9)	121	2.01 (0.30)	0.10	0.23	0.10	(-0.9, 0.6)
	Week 36	119	2.12	0.29	2.10	(1.2, 2.7)	119	2.01 (0.30)	0.11	0.21	0.10	(-0.8, 0.7)
	Week 40	115	2.12	0.32	2.10	(1.3, 3.3)	115	2.01 (0.30)	0.11	0.23	0.10	(-0.7, 1.0)
	Week 44	114	2.09	0.29	2.10	(1.2, 2.8)	114	2.01 (0.30)	0.07	0.21	0.10	(-0.7, 0.7)
	Week 48	112	2.09	0.31	2.10	(1.3, 3.3)	112	2.02 (0.31)	0.08	0.23	0.10	(-0.8, 1.2)
	Week 52	111	2.11	0.30	2.10	(1.4, 3.0)	111	2.02 (0.31)	0.09	0.21	0.10	(-0.7, 0.8)
darbepoetin	Baseline	153	2.03	0.50	2.00	(0.8, 6.9)						
	Week 2	153	2.04	0.42	2.00	(0.6, 5.6)	153	2.03 (0.50)	0.01	0.21	0.00	(-1.3, 0.5)
	Week 4	153	2.03	0.43	2.00	(0.6, 5.8)	153	2.03 (0.50)	0.00	0.19	0.00	(-1.1, 0.5)
	Week 6	152	2.03	0.46	2.00	(0.8, 6.4)	152	2.03 (0.50)	0.00	0.17	0.00	(-0.5, 0.5)
	Week 8	151	2.03	0.49	2.00	(0.8, 6.6)	151	2.03 (0.50)	0.00	0.17	0.00	(-0.4, 0.7)
	Week 10	150	2.03	0.56	2.00	(0.8, 7.6)	150	2.03 (0.50)	0.00	0.21	0.00	(-0.5, 1.1)
	Week 12	148	2.04	0.49	2.00	(0.8, 6.5)	148	2.03 (0.50)	0.01	0.21	0.00	(-0.6, 1.0)
	Week 16	148	2.00	0.45	1.95	(0.7, 5.7)	148	2.04 (0.50)	-0.04	0.24	-0.10	(-1.2, 1.4)
	Week 20	144	2.02	0.53	2.00	(0.7, 6.9)	144	2.03 (0.51)	-0.01	0.26	0.00	(-0.9, 1.2)
	Week 24	140	2.07	0.66	2.00	(0.7, 8.8)	140	2.03 (0.51)	0.03	0.29	0.00	(-0.7, 1.9)
	Week 28	137	2.03	0.36	2.00	(0.9, 4.1)	137	2.00 (0.30)	0.03	0.26	0.00	(-0.6, 1.9)
	Week 32	133	2.04	0.34	2.00	(1.3, 3.5)	133	2.01 (0.28)	0.03	0.25	0.00	(-0.6, 1.3)
	Week 36	130	2.07	0.35	2.00	(1.3, 3.9)	130	2.01 (0.28)	0.06	0.26	0.00	(-0.6, 1.7)
	Week 40	128	2.11	0.38	2.10	(1.4, 4.1)	128	2.01 (0.28)	0.10	0.30	0.10	(-0.7, 1.6)
	Week 44	125	2.08	0.31	2.10	(1.4, 3.4)	125	2.00 (0.28)	0.07	0.21	0.10	(-0.4, 0.8)
	Week 48	125	2.06	0.27	2.10	(1.4, 3.0)	125	2.00 (0.28)	0.06	0.20	0.10	(-0.6, 0.6)
	Week 52	123	2.06	0.28	2.00	(1.5, 3.0)	123	2.00 (0.28)	0.05	0.20	0.10	(-0.6, 0.5)

表 2.7.4.9－77 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Bicarbonate (mmol/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	19.57	3.31	19.50	(7.2, 26.4)						
	Week 2	151	18.48	3.67	18.50	(7.2, 25.6)	151	19.57 (3.31)	-1.09	1.82	-1.00	(-8.3, 3.5)
	Week 4	149	18.69	3.44	18.60	(5.5, 26.4)	149	19.58 (3.32)	-0.89	1.73	-0.90	(-6.2, 3.6)
	Week 6	148	18.50	3.39	18.40	(6.3, 25.2)	148	19.56 (3.32)	-1.07	1.68	-1.15	(-5.2, 3.8)
	Week 8	145	18.48	3.60	18.70	(7.5, 25.8)	145	19.59 (3.33)	-1.11	2.14	-1.20	(-7.2, 5.1)
	Week 10	145	18.62	3.63	19.10	(7.2, 25.7)	145	19.57 (3.33)	-0.96	2.51	-0.90	(-8.2, 6.7)
	Week 12	145	18.72	3.55	19.10	(7.0, 26.8)	145	19.55 (3.32)	-0.83	2.36	-0.70	(-7.4, 5.8)
	Week 16	143	18.97	3.23	19.00	(8.0, 27.1)	143	19.54 (3.34)	-0.57	2.38	-0.70	(-7.7, 8.2)
	Week 20	140	19.09	3.41	19.10	(8.2, 25.9)	140	19.65 (3.30)	-0.57	2.45	-0.50	(-7.0, 6.9)
	Week 24	132	19.02	3.17	18.80	(11.2, 26.8)	132	19.71 (3.15)	-0.69	2.63	-0.55	(-8.0, 7.4)
	Week 28	126	19.78	2.95	19.85	(11.9, 26.0)	126	19.80 (3.22)	-0.02	2.34	0.00	(-7.3, 6.7)
	Week 32	121	19.59	2.95	19.70	(11.0, 25.4)	121	19.69 (3.19)	-0.10	2.45	-0.30	(-6.9, 6.4)
	Week 36	119	19.85	3.21	19.80	(12.2, 26.4)	119	19.78 (3.26)	0.07	2.31	0.40	(-5.6, 5.7)
	Week 40	115	20.04	3.31	20.40	(11.4, 29.9)	115	19.73 (3.17)	0.30	2.40	0.30	(-6.4, 8.3)
	Week 44	114	19.91	3.05	19.95	(12.2, 25.8)	114	19.82 (3.21)	0.09	2.53	0.10	(-9.4, 6.5)
	Week 48	112	20.04	3.37	20.30	(11.0, 26.5)	112	19.80 (3.21)	0.24	2.38	0.20	(-6.4, 6.9)
	Week 52	111	19.77	3.11	19.90	(11.8, 25.6)	111	19.86 (3.15)	-0.09	2.26	-0.20	(-6.1, 6.0)
darbepoetin	Baseline	153	19.69	3.22	20.00	(8.4, 26.1)						
	Week 2	153	19.66	3.21	19.80	(7.6, 25.7)	153	19.69 (3.22)	-0.03	1.97	0.10	(-7.1, 5.3)
	Week 4	153	19.61	3.05	20.00	(9.7, 27.6)	153	19.69 (3.22)	-0.08	2.09	-0.20	(-5.2, 7.3)
	Week 6	152	19.64	3.21	20.10	(8.4, 27.6)	152	19.71 (3.22)	-0.07	2.33	-0.20	(-6.6, 6.4)
	Week 8	151	19.70	3.28	20.10	(9.5, 28.7)	151	19.74 (3.21)	-0.04	2.31	-0.10	(-5.9, 7.4)
	Week 10	150	19.74	3.15	19.90	(8.9, 26.6)	150	19.72 (3.24)	0.02	2.36	0.10	(-5.6, 7.5)
	Week 12	148	19.56	3.13	19.70	(9.0, 26.1)	148	19.71 (3.25)	-0.15	2.46	-0.20	(-6.0, 6.7)
	Week 16	148	19.68	3.09	20.10	(9.4, 26.7)	148	19.68 (3.24)	0.00	2.48	-0.10	(-6.1, 6.7)
	Week 20	144	19.84	3.23	20.20	(5.2, 28.7)	144	19.67 (3.27)	0.17	2.61	0.00	(-7.3, 6.3)
	Week 24	140	20.09	3.17	20.30	(5.6, 27.8)	140	19.70 (3.21)	0.39	2.41	0.30	(-5.1, 6.7)
	Week 28	137	20.25	3.28	20.40	(9.2, 29.1)	137	19.67 (3.16)	0.58	2.66	0.80	(-6.2, 6.9)
	Week 32	133	20.62	3.13	20.90	(9.2, 30.2)	133	19.77 (3.11)	0.86	2.59	1.00	(-7.3, 6.8)
	Week 36	130	20.34	3.05	20.60	(9.6, 28.6)	130	19.87 (3.05)	0.48	2.59	0.55	(-6.3, 11.0)
	Week 40	128	20.84	3.37	21.35	(7.4, 31.2)	128	19.96 (2.94)	0.88	2.89	0.90	(-10.6, 7.4)
	Week 44	125	21.09	3.07	21.10	(11.9, 29.0)	125	20.00 (2.95)	1.08	2.50	0.80	(-5.3, 7.9)
	Week 48	125	20.75	3.31	21.00	(10.0, 27.9)	125	20.00 (2.95)	0.75	2.75	0.80	(-6.6, 9.1)
	Week 52	123	20.65	2.99	21.20	(10.9, 27.5)	123	20.09 (2.89)	0.57	2.74	0.30	(-6.2, 8.0)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Total Cholesterol (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	179.9	37.1	176.0	(108, 282)						
	Week 2	151	179.7	41.0	176.0	(101, 313)	151	179.9 (37.1)	-0.2	17.3	3.0	(-58, 47)
	Week 4	149	176.1	41.3	169.0	(103, 321)	149	179.6 (37.0)	-3.5	20.3	-4.0	(-65, 98)
	Week 6	148	175.4	40.8	171.5	(97, 345)	148	179.6 (37.1)	-4.2	23.1	-3.5	(-92, 88)
	Week 8	145	177.7	42.3	176.0	(99, 359)	145	179.2 (37.3)	-1.5	24.7	-4.0	(-132, 85)
	Week 10	145	177.0	41.5	174.0	(101, 330)	145	179.0 (37.2)	-2.0	25.9	-2.0	(-131, 59)
	Week 12	145	179.3	42.9	172.0	(103, 350)	145	179.0 (37.2)	0.2	28.1	1.0	(-134, 97)
	Week 16	143	181.8	44.0	174.0	(104, 368)	143	179.3 (37.4)	2.5	30.5	2.0	(-154, 94)
	Week 20	140	182.1	42.4	178.5	(96, 308)	140	179.8 (37.1)	2.3	30.7	0.5	(-128, 106)
	Week 24	132	184.7	40.6	181.0	(98, 289)	132	180.0 (36.2)	4.8	28.3	4.0	(-134, 80)
	Week 28	126	186.8	41.2	182.0	(102, 312)	126	179.7 (35.4)	7.1	28.1	8.0	(-84, 109)
	Week 32	121	186.8	41.4	185.0	(100, 297)	121	179.9 (34.8)	6.9	28.9	5.0	(-82, 94)
	Week 36	119	190.6	41.5	193.0	(110, 301)	119	180.8 (35.4)	9.8	29.1	11.0	(-78, 117)
	Week 40	115	190.3	40.1	188.0	(113, 309)	115	180.6 (34.6)	9.7	29.4	9.0	(-73, 89)
	Week 44	114	189.8	40.7	187.0	(92, 321)	114	181.4 (34.0)	8.4	27.9	7.0	(-77, 75)
	Week 48	112	189.2	40.8	191.5	(91, 299)	112	181.2 (33.9)	8.0	26.5	8.5	(-78, 78)
	Week 52	111	186.4	40.2	186.0	(106, 324)	111	181.1 (34.0)	5.3	27.7	5.0	(-67, 89)
darbepoetin	Baseline	153	175.9	36.9	171.0	(101, 277)						
	Week 2	153	176.1	37.4	176.0	(93, 305)	153	175.9 (36.9)	0.2	15.4	0.0	(-36, 46)
	Week 4	153	173.4	38.8	166.0	(98, 281)	153	175.9 (36.9)	-2.5	16.5	-2.0	(-47, 48)
	Week 6	152	174.9	38.5	171.0	(104, 293)	152	176.0 (37.0)	-1.2	17.4	-2.5	(-43, 72)
	Week 8	151	175.1	36.9	169.0	(103, 296)	151	176.3 (37.0)	-1.2	16.9	-2.0	(-51, 63)
	Week 10	150	173.9	36.8	168.0	(106, 297)	150	175.3 (36.5)	-1.4	18.6	-3.0	(-55, 62)
	Week 12	148	175.8	37.7	171.0	(117, 295)	148	175.9 (37.3)	-0.1	17.1	1.0	(-66, 62)
	Week 16	148	176.0	38.8	173.0	(109, 293)	148	176.0 (37.2)	0.0	22.1	0.0	(-44, 103)
	Week 20	144	180.3	39.4	176.0	(98, 308)	144	174.1 (35.8)	6.2	24.3	3.5	(-41, 112)
	Week 24	140	181.9	40.5	176.5	(106, 311)	140	175.4 (35.8)	6.5	23.6	4.0	(-48, 80)
	Week 28	137	181.6	39.4	179.0	(96, 321)	137	175.4 (35.9)	6.2	25.0	4.0	(-74, 96)
	Week 32	133	184.8	38.8	185.0	(90, 304)	133	175.2 (36.1)	9.6	22.6	7.0	(-63, 92)
	Week 36	130	187.6	39.0	186.0	(95, 294)	130	175.9 (36.1)	11.7	23.6	11.0	(-58, 81)
	Week 40	128	186.5	38.5	179.5	(98, 298)	128	175.5 (36.0)	11.0	29.4	9.0	(-106, 136)
	Week 44	125	185.6	40.6	178.0	(89, 313)	125	174.9 (36.1)	10.7	25.6	9.0	(-67, 105)
	Week 48	125	182.2	40.7	179.0	(87, 384)	125	174.9 (36.1)	7.3	28.9	7.0	(-66, 107)
	Week 52	123	181.0	42.1	177.0	(87, 410)	123	174.9 (35.9)	6.1	30.7	4.0	(-87, 133)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:LDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	100.4	29.7	95.0	(45, 205)						
	Week 2	151	99.5	32.2	94.0	(43, 222)	151	100.4 (29.7)	-0.9	14.2	-1.0	(-57, 40)
	Week 4	149	97.4	31.6	90.0	(38, 213)	149	100.3 (29.6)	-2.9	15.8	-3.0	(-51, 51)
	Week 6	148	96.5	31.6	90.5	(34, 254)	148	100.3 (29.7)	-3.9	17.7	-4.0	(-89, 70)
	Week 8	145	98.7	32.8	94.0	(35, 269)	145	100.1 (29.8)	-1.4	20.7	-1.0	(-130, 85)
	Week 10	145	98.5	32.5	92.0	(33, 201)	145	100.4 (30.0)	-1.9	21.4	-4.0	(-129, 64)
	Week 12	145	99.8	33.5	94.0	(33, 220)	145	100.2 (29.9)	-0.4	21.6	-2.0	(-130, 63)
	Week 16	143	101.2	36.7	94.0	(39, 264)	143	100.3 (30.1)	0.9	24.5	1.0	(-148, 80)
	Week 20	140	100.4	33.7	93.5	(34, 199)	140	100.9 (30.1)	-0.6	24.1	-1.0	(-129, 69)
	Week 24	132	101.1	32.8	96.5	(36, 196)	132	100.8 (29.5)	0.3	23.0	0.0	(-125, 60)
	Week 28	126	101.7	32.9	96.0	(34, 209)	126	100.1 (28.3)	1.6	20.5	2.5	(-59, 73)
	Week 32	121	100.4	33.2	94.0	(29, 214)	121	100.0 (27.9)	0.4	22.1	0.0	(-60, 78)
	Week 36	119	104.0	35.2	96.0	(39, 205)	119	100.9 (28.8)	3.1	23.3	2.0	(-60, 100)
	Week 40	115	102.8	32.6	99.0	(37, 203)	115	100.2 (27.9)	2.6	23.6	2.0	(-62, 65)
	Week 44	114	105.2	34.4	102.0	(26, 219)	114	100.6 (27.7)	4.6	22.1	4.0	(-58, 56)
	Week 48	112	104.6	33.3	101.5	(24, 204)	112	100.4 (27.8)	4.3	21.4	3.0	(-60, 66)
	Week 52	111	103.4	32.5	100.0	(32, 229)	111	100.2 (27.9)	3.2	22.9	2.0	(-52, 71)
darbepoetin	Baseline	153	95.0	29.2	90.0	(36, 186)						
	Week 2	153	95.0	29.4	94.0	(33, 214)	153	95.0 (29.2)	0.1	12.0	0.0	(-32, 43)
	Week 4	153	93.9	29.5	90.0	(24, 181)	153	95.0 (29.2)	-1.1	12.8	-1.0	(-31, 40)
	Week 6	152	95.1	30.3	91.0	(25, 205)	152	95.0 (29.3)	0.1	14.4	-0.5	(-36, 72)
	Week 8	151	94.0	29.1	90.0	(13, 201)	151	95.2 (29.3)	-1.1	14.4	-1.0	(-48, 54)
	Week 10	150	94.3	30.0	88.5	(30, 198)	150	94.5 (29.0)	-0.1	14.1	-1.0	(-33, 51)
	Week 12	148	94.8	30.2	85.5	(24, 194)	148	94.8 (29.4)	0.0	14.6	0.0	(-60, 55)
	Week 16	148	94.3	30.4	90.0	(21, 192)	148	94.9 (29.3)	-0.5	17.1	-3.0	(-32, 73)
	Week 20	144	96.4	31.9	92.5	(33, 204)	144	94.0 (28.7)	2.4	17.7	0.0	(-33, 83)
	Week 24	140	96.4	32.0	91.0	(35, 204)	140	94.6 (28.7)	1.8	18.1	1.5	(-68, 74)
	Week 28	137	96.1	31.6	91.0	(27, 215)	137	94.9 (28.7)	1.2	19.7	-2.0	(-48, 71)
	Week 32	133	97.9	30.7	92.0	(30, 196)	133	94.6 (29.0)	3.3	16.7	2.0	(-34, 69)
	Week 36	130	100.2	31.9	94.0	(30, 200)	130	95.2 (29.0)	4.9	18.3	5.0	(-58, 66)
	Week 40	128	99.7	31.6	94.0	(32, 187)	128	95.3 (29.1)	4.3	22.8	4.0	(-69, 116)
	Week 44	125	99.7	32.4	94.0	(31, 198)	125	94.2 (29.0)	5.5	20.0	5.0	(-46, 100)
	Week 48	125	96.8	30.8	91.0	(27, 239)	125	94.2 (29.0)	2.5	22.9	2.0	(-57, 88)
	Week 52	123	96.7	32.7	93.0	(25, 280)	123	94.0 (28.7)	2.8	25.4	2.0	(-87, 129)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:HDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	54.5	16.8	51.0	(24, 111)						
	Week 2	151	50.2	16.4	48.0	(22, 102)	151	54.5 (16.8)	-4.3	5.9	-4.0	(-21, 11)
	Week 4	149	50.0	15.9	48.0	(22, 114)	149	54.2 (16.7)	-4.2	6.1	-5.0	(-20, 23)
	Week 6	148	49.1	16.1	47.0	(22, 129)	148	54.3 (16.7)	-5.2	7.1	-5.5	(-36, 38)
	Week 8	145	49.2	15.1	47.0	(22, 105)	145	54.3 (16.8)	-5.1	8.3	-5.0	(-48, 22)
	Week 10	145	48.8	14.2	48.0	(23, 86)	145	53.9 (16.6)	-5.2	9.3	-6.0	(-68, 26)
	Week 12	145	49.3	15.2	47.0	(21, 115)	145	53.9 (16.5)	-4.6	9.7	-5.0	(-75, 24)
	Week 16	143	49.8	15.3	48.0	(25, 119)	143	54.1 (16.5)	-4.3	11.3	-5.0	(-77, 30)
	Week 20	140	51.5	16.2	49.0	(24, 122)	140	53.9 (15.8)	-2.4	9.2	-2.5	(-22, 31)
	Week 24	132	53.2	16.5	50.5	(25, 115)	132	54.4 (15.5)	-1.2	10.0	-2.0	(-25, 45)
	Week 28	126	54.4	16.8	51.0	(26, 113)	126	54.8 (15.7)	-0.4	10.0	0.0	(-25, 50)
	Week 32	121	56.4	19.2	53.0	(26, 145)	121	54.8 (15.8)	1.6	12.2	-1.0	(-32, 54)
	Week 36	119	57.7	16.8	56.0	(25, 119)	119	55.6 (15.7)	2.1	9.7	2.0	(-20, 41)
	Week 40	115	57.4	17.4	55.0	(24, 119)	115	55.8 (15.5)	1.6	10.0	1.0	(-23, 39)
	Week 44	114	56.6	17.2	54.0	(32, 137)	114	56.1 (15.2)	0.5	9.9	1.0	(-21, 46)
	Week 48	112	55.6	16.3	53.0	(30, 131)	112	56.1 (15.2)	-0.4	9.8	-0.5	(-28, 40)
	Week 52	111	53.7	14.6	52.0	(29, 99)	111	56.1 (15.2)	-2.4	9.2	-3.0	(-29, 28)
darbepoetin	Baseline	153	56.4	18.7	52.0	(20, 160)						
	Week 2	153	55.6	18.3	51.0	(20, 151)	153	56.4 (18.7)	-0.8	5.6	-1.0	(-19, 22)
	Week 4	153	55.3	18.7	50.0	(18, 157)	153	56.4 (18.7)	-1.0	6.5	-1.0	(-25, 22)
	Week 6	152	55.6	18.1	52.5	(19, 160)	152	56.5 (18.7)	-0.9	6.4	-1.0	(-25, 17)
	Week 8	151	55.8	17.4	52.0	(20, 138)	151	56.6 (18.8)	-0.8	7.1	0.0	(-22, 22)
	Week 10	150	56.2	17.3	54.0	(21, 137)	150	56.7 (18.8)	-0.4	8.4	0.0	(-25, 28)
	Week 12	148	56.7	16.8	55.0	(21, 127)	148	56.6 (18.8)	0.1	8.6	-1.0	(-33, 25)
	Week 16	148	56.6	17.1	54.0	(21, 138)	148	56.6 (18.7)	0.1	9.7	0.0	(-33, 39)
	Week 20	144	57.7	16.7	56.0	(19, 114)	144	55.8 (16.7)	1.9	9.8	2.0	(-34, 42)
	Week 24	140	59.5	19.8	57.0	(19, 181)	140	56.4 (18.9)	3.2	10.9	3.0	(-30, 44)
	Week 28	137	59.7	19.8	58.0	(20, 158)	137	56.4 (18.7)	3.4	11.1	3.0	(-30, 43)
	Week 32	133	61.0	20.0	60.0	(21, 160)	133	56.4 (18.8)	4.6	9.9	4.0	(-17, 44)
	Week 36	130	61.7	20.3	59.0	(23, 158)	130	56.4 (18.9)	5.3	10.2	4.5	(-33, 42)
	Week 40	128	59.1	18.6	57.0	(22, 142)	128	55.6 (16.7)	3.5	11.0	4.0	(-39, 34)
	Week 44	125	59.1	20.6	55.0	(23, 156)	125	56.4 (19.2)	2.7	9.6	2.0	(-33, 34)
	Week 48	125	58.5	19.7	54.0	(21, 145)	125	56.4 (19.2)	2.1	9.0	2.0	(-29, 28)
	Week 52	123	59.1	19.4	57.0	(21, 145)	123	56.6 (19.3)	2.5	9.8	2.0	(-36, 33)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Triglycerides (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	142.4	78.3	126.0	(56, 509)						
	Week 2	151	165.4	78.5	158.0	(50, 502)	151	142.4 (78.3)	23.0	58.3	21.0	(-180, 161)
	Week 4	149	160.0	90.7	143.0	(23, 568)	149	142.9 (78.7)	17.1	62.1	10.0	(-153, 265)
	Week 6	148	169.9	94.9	149.0	(44, 616)	148	142.8 (78.9)	27.1	67.8	27.0	(-186, 279)
	Week 8	145	171.1	108.0	149.0	(39, 825)	145	142.2 (79.6)	28.9	83.7	19.0	(-148, 662)
	Week 10	145	169.1	82.0	151.0	(40, 446)	145	141.7 (79.2)	27.4	65.2	27.0	(-218, 281)
	Week 12	145	165.4	94.7	154.0	(34, 771)	145	142.6 (79.6)	22.8	74.9	13.0	(-163, 392)
	Week 16	143	173.1	97.3	148.0	(33, 688)	143	142.5 (79.9)	30.6	71.4	26.0	(-253, 278)
	Week 20	140	163.5	92.6	137.5	(30, 616)	140	143.6 (80.4)	19.8	77.5	17.5	(-248, 453)
	Week 24	132	169.6	134.4	142.5	(29, 1339)	132	143.4 (82.1)	26.2	113.9	16.0	(-301, 966)
	Week 28	126	167.2	87.7	140.0	(31, 495)	126	144.2 (83.7)	23.0	80.3	17.5	(-257, 332)
	Week 32	121	163.0	83.2	134.0	(49, 495)	121	145.6 (85.0)	17.4	80.6	15.0	(-330, 332)
	Week 36	119	152.9	82.5	130.0	(37, 474)	119	142.0 (81.0)	11.0	78.9	16.0	(-354, 302)
	Week 40	115	159.6	88.6	127.0	(34, 456)	115	142.5 (83.6)	17.1	77.2	21.0	(-254, 257)
	Week 44	114	152.2	74.4	134.0	(38, 484)	114	141.4 (82.8)	10.8	64.7	16.5	(-314, 148)
	Week 48	112	157.9	81.7	141.5	(53, 463)	112	142.1 (83.2)	15.8	56.7	17.5	(-232, 177)
	Week 52	111	156.6	73.7	139.0	(33, 461)	111	141.6 (83.9)	15.0	59.5	14.0	(-255, 142)
darbepoetin	Baseline	153	143.2	81.5	122.0	(30, 583)						
	Week 2	153	142.4	80.5	127.0	(33, 759)	153	143.2 (81.5)	-0.8	50.7	-2.0	(-187, 176)
	Week 4	153	138.3	76.8	123.0	(35, 528)	153	143.2 (81.5)	-4.9	52.7	-6.0	(-173, 180)
	Week 6	152	141.7	86.4	126.0	(36, 696)	152	143.0 (81.7)	-1.3	45.8	-4.5	(-195, 138)
	Week 8	151	148.2	87.1	131.0	(27, 573)	151	143.4 (81.8)	4.7	52.0	1.0	(-176, 197)
	Week 10	150	139.8	88.7	114.0	(27, 671)	150	140.0 (73.8)	-0.3	59.8	-5.5	(-129, 352)
	Week 12	148	137.7	76.9	121.5	(34, 626)	148	143.7 (82.6)	-6.1	56.4	-2.5	(-159, 307)
	Week 16	148	145.4	91.1	125.5	(30, 573)	148	143.7 (82.6)	1.7	64.6	-2.0	(-185, 254)
	Week 20	144	141.8	88.1	128.0	(36, 768)	144	141.2 (73.9)	0.5	66.7	0.5	(-196, 380)
	Week 24	140	141.3	96.3	130.0	(35, 976)	140	142.2 (74.3)	-0.9	81.6	-4.0	(-212, 588)
	Week 28	137	143.6	73.8	129.0	(29, 476)	137	140.3 (72.6)	3.2	67.5	-2.0	(-237, 289)
	Week 32	133	142.5	73.2	125.0	(33, 494)	133	140.8 (73.4)	1.7	57.5	-2.0	(-264, 206)
	Week 36	130	136.2	66.7	127.0	(35, 453)	130	142.1 (73.1)	-5.9	50.9	-3.0	(-191, 150)
	Week 40	128	152.9	113.1	128.5	(41, 1055)	128	143.5 (72.8)	9.4	79.9	0.0	(-137, 667)
	Week 44	125	147.5	91.0	126.0	(31, 738)	125	141.6 (71.8)	5.9	67.0	2.0	(-157, 350)
	Week 48	125	145.3	94.2	133.0	(46, 927)	125	141.6 (71.8)	3.7	71.9	0.0	(-139, 539)
	Week 52	123	138.4	72.8	127.0	(40, 581)	123	142.0 (72.1)	-3.6	58.7	-6.0	(-188, 193)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:C Reactive Protein (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	0.2501	0.6092	0.0500	(0.009, 5.390)						
	Week 24	132	0.2183	0.6149	0.0400	(0.010, 5.610)	132	0.2433 (0.6230)	-0.0249	0.7376	0.0000	(-3.550, 5.360)
	Week 52	111	0.1651	0.3284	0.0600	(0.009, 2.950)	111	0.2460 (0.6511)	-0.0809	0.6623	0.0000	(-5.230, 2.830)
darbepoetin	Baseline	153	0.1872	0.4744	0.0400	(0.009, 4.020)						
	Week 24	140	0.1872	0.4216	0.0600	(0.009, 3.100)	140	0.1932 (0.4943)	-0.0060	0.5497	0.0100	(-3.980, 2.110)
	Week 52	123	0.2399	0.5892	0.0600	(0.009, 4.260)	123	0.1801 (0.4604)	0.0598	0.6420	0.0100	(-3.780, 3.290)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Vascular Endothelial Growth Factor (pg/mL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	149	36.863	51.010	24.900	(15.59, 549.00)						
	Week 12	145	41.207	58.818	29.200	(15.59, 557.00)	143	35.806 (48.704)	4.741	26.046	0.000	(-53.10, 230.00)
	Week 24	132	43.164	49.223	31.250	(15.59, 413.00)	130	36.951 (50.834)	6.197	31.065	3.300	(-136.00, 187.80)
	Week 36	119	43.600	49.521	31.000	(15.59, 372.00)	117	37.756 (53.359)	5.278	30.957	1.910	(-177.00, 161.00)
	Week 52	111	35.640	39.048	23.700	(15.59, 331.00)	109	38.109 (54.735)	-2.636	26.330	0.000	(-218.00, 46.00)
darbepoetin	Baseline	153	35.720	25.083	28.900	(15.59, 227.00)						
	Week 12	148	31.338	19.823	25.500	(15.59, 146.00)	148	36.179 (25.356)	-4.841	19.727	-0.855	(-118.00, 80.60)
	Week 24	140	32.415	19.534	27.650	(15.59, 163.00)	140	34.486 (19.944)	-2.071	16.771	0.000	(-56.01, 80.80)
	Week 36	130	32.322	21.530	26.650	(15.59, 166.00)	130	34.654 (19.571)	-2.332	19.427	0.000	(-63.00, 70.20)
	Week 52	123	30.270	20.814	23.300	(15.59, 146.00)	123	35.127 (19.934)	-4.858	22.441	-2.000	(-73.30, 110.80)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Dehydroepiandrosterone Sulfate (ug/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	149	90.38	66.82	74.00	(4.0, 361.0)						
	Week 12	145	84.81	64.42	67.00	(5.0, 333.0)	143	89.16 (64.21)	-5.87	19.20	-4.00	(-69.0, 50.0)
	Week 24	132	89.36	69.80	74.50	(5.0, 348.0)	130	89.75 (63.47)	-1.85	24.58	-2.00	(-87.0, 91.0)
	Week 36	119	87.54	63.71	71.00	(7.0, 341.0)	117	87.05 (57.34)	-1.38	23.88	-3.00	(-58.0, 116.0)
	Week 52	111	83.55	65.76	64.00	(4.0, 412.0)	109	89.50 (59.66)	-9.03	23.25	-6.00	(-84.0, 67.0)
darbepoetin	Baseline	153	89.13	77.43	66.00	(2.0, 481.0)						
	Week 12	148	85.16	73.85	65.00	(1.9, 538.0)	148	87.32 (75.20)	-2.16	26.61	-0.55	(-166.0, 116.0)
	Week 24	140	91.83	81.13	69.50	(11.0, 618.0)	140	87.60 (74.94)	4.23	27.47	2.50	(-161.0, 137.0)
	Week 36	130	91.72	81.70	67.00	(8.0, 614.0)	130	87.20 (75.46)	4.52	29.33	3.00	(-160.0, 133.0)
	Week 52	123	86.80	72.78	64.00	(9.0, 463.0)	123	88.81 (77.09)	-2.01	27.17	-1.00	(-172.0, 90.0)

Data Source: Listing 16.2.6.1, Listing 16.2.6.2, Listing 16.2.6.3, Listing 16.2.6.4
Source: t_14_3_2_1_1.sas

5.3.5.1—8 表 14.3.2.1.1 より引用

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Albumin/Creatinine (mg/g Cr)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	986.98	1221.59	593.60	(2.7, 7025.5)						
	Week 12	145	1100.50	1728.06	579.50	(4.0, 11123.4)	145	1018.25 (1236.06)	82.25	836.08	-2.20	(-1758.0, 4950.1)
	Week 24	132	1112.49	1352.50	659.15	(2.9, 8818.3)	132	901.30 (1057.88)	211.19	751.80	11.75	(-1580.7, 3817.1)
	Week 36	118	1094.53	1193.67	726.15	(3.3, 5939.8)	118	793.52 (952.49)	301.01	634.93	48.80	(-1427.6, 2076.5)
	Week 52	111	827.48	976.44	556.20	(2.6, 6146.9)	111	729.92 (872.79)	97.56	526.73	11.20	(-1641.5, 1559.3)
darbepoetin	Baseline	153	936.09	1319.29	364.20	(0.6, 9159.5)						
	Week 12	148	1057.05	1440.11	413.85	(1.8, 7790.7)	148	932.58 (1323.58)	124.46	644.88	4.40	(-2087.4, 2615.6)
	Week 24	140	1172.20	1481.63	653.10	(0.5, 6543.6)	140	877.61 (1298.36)	294.59	891.81	37.80	(-2615.9, 3467.5)
	Week 36	130	1136.27	1344.76	608.45	(0.8, 5370.0)	130	754.46 (1063.98)	381.81	935.82	120.20	(-3036.8, 5011.0)
	Week 52	123	1020.17	1320.21	339.10	(0.5, 6942.1)	123	717.09 (1038.92)	303.07	1079.70	41.80	(-3639.7, 4174.3)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter:Protein/Creatinine (mg/g Cr)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	1757.6	2180.2	1049.0	(21, 15529)						
	Week 12	145	1938.7	3013.8	1013.0	(19, 22331)	145	1811.4 (2207.3)	127.3	1350.0	-18.0	(-2727, 8016)
	Week 24	132	1943.5	2245.6	1138.5	(24, 14349)	132	1589.7 (1767.4)	353.8	1273.6	59.5	(-2328, 6143)
	Week 36	118	1936.6	1994.2	1273.0	(18, 9741)	118	1407.6 (1581.6)	529.0	1115.2	97.0	(-2655, 3712)
	Week 52	111	1504.6	1595.9	1117.0	(38, 10043)	111	1290.0 (1392.2)	214.6	917.7	60.0	(-2612, 2863)
darbepoetin	Baseline	153	1640.7	2268.0	620.0	(19, 16119)						
	Week 12	148	1853.2	2489.3	779.0	(13, 13711)	148	1636.6 (2279.1)	216.6	1085.8	16.0	(-3007, 5293)
	Week 24	140	2025.7	2564.2	1081.5	(24, 12324)	140	1540.6 (2230.7)	485.1	1525.0	68.5	(-4315, 6035)
	Week 36	130	1986.8	2352.8	1024.0	(16, 11845)	130	1324.3 (1807.7)	662.4	1597.4	221.5	(-5483, 7748)
	Week 52	123	1791.0	2279.8	768.0	(19, 11550)	123	1253.3 (1758.1)	537.6	1834.1	94.0	(-6989, 7133)

Data Source: Listing 16.2.6.4
Source: t_14_3_2_3_1.sas

5.3.5.1—8 表 14.3.2.3.1 より引用

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter	Visit	MT-6548(N=151) Total N*	- n (%)	+- n (%)	+ n (%)	2+ n (%)	3+ n (%)	darbepoetin(N=153) Total N*	- n (%)	+- n (%)	+ n (%)	2+ n (%)	3+ n (%)
Urine Glucose	Baseline	151	121(80.1)	13(8.6)	10(6.6)	3(2.0)	4(2.6)	153	123(80.4)	5(3.3)	16(10.5)	8(5.2)	1(0.7)
	Week 2	151	123(81.5)	17(11.3)	3(2.0)	4(2.6)	4(2.6)	152	118(77.6)	15(9.9)	8(5.3)	9(5.9)	2(1.3)
	Week 4	149	123(82.6)	10(6.7)	9(6.0)	4(2.7)	3(2.0)	153	118(77.1)	11(7.2)	14(9.2)	5(3.3)	5(3.3)
	Week 6	148	124(83.8)	14(9.5)	4(2.7)	3(2.0)	3(2.0)	152	122(80.3)	7(4.6)	16(10.5)	4(2.6)	3(2.0)
	Week 8	145	122(84.1)	9(6.2)	8(5.5)	3(2.1)	3(2.1)	151	120(79.5)	9(6.0)	13(8.6)	5(3.3)	4(2.6)
	Week 10	145	118(81.4)	17(11.7)	3(2.1)	3(2.1)	4(2.8)	150	112(74.7)	15(10.0)	10(6.7)	8(5.3)	5(3.3)
	Week 12	145	110(75.9)	20(13.8)	8(5.5)	3(2.1)	4(2.8)	148	114(77.0)	11(7.4)	9(6.1)	7(4.7)	7(4.7)
	Week 16	143	114(79.7)	12(8.4)	7(4.9)	4(2.8)	6(4.2)	147	109(74.1)	16(10.9)	11(7.5)	5(3.4)	6(4.1)
	Week 20	140	113(80.7)	8(5.7)	9(6.4)	5(3.6)	5(3.6)	143	111(77.6)	9(6.3)	12(8.4)	8(5.6)	3(2.1)
	Week 24	132	111(84.1)	9(6.8)	4(3.0)	4(3.0)	4(3.0)	140	109(77.9)	12(8.6)	11(7.9)	6(4.3)	2(1.4)
	Week 28	126	102(81.0)	14(11.1)	3(2.4)	2(1.6)	5(4.0)	137	100(73.0)	13(9.5)	10(7.3)	9(6.6)	5(3.6)
	Week 32	120	97(80.8)	15(12.5)	1(0.8)	2(1.7)	5(4.2)	133	102(76.7)	13(9.8)	6(4.5)	6(4.5)	6(4.5)
	Week 36	118	96(81.4)	8(6.8)	8(6.8)	2(1.7)	4(3.4)	130	94(72.3)	15(11.5)	10(7.7)	7(5.4)	4(3.1)
	Week 40	115	91(79.1)	11(9.6)	4(3.5)	4(3.5)	5(4.3)	127	93(73.2)	11(8.7)	8(6.3)	9(7.1)	6(4.7)
	Week 44	113	96(85.0)	11(9.7)	1(0.9)	1(0.9)	4(3.5)	124	95(76.6)	14(11.3)	5(4.0)	4(3.2)	6(4.8)
	Week 48	112	92(82.1)	10(8.9)	5(4.5)	2(1.8)	3(2.7)	125	99(79.2)	11(8.8)	8(6.4)	2(1.6)	5(4.0)
	Week 52	111	88(79.3)	13(11.7)	3(2.7)	3(2.7)	4(3.6)	123	94(76.4)	12(9.8)	9(7.3)	3(2.4)	5(4.1)
Urine Protein	Baseline	151	35(23.2)	15(9.9)	27(17.9)	46(30.5)	28(18.5)	153	34(22.2)	19(12.4)	39(25.5)	38(24.8)	23(15.0)
	Week 2	151	37(24.5)	13(8.6)	25(16.6)	59(39.1)	17(11.3)	152	38(25.0)	18(11.8)	36(23.7)	38(25.0)	22(14.5)
	Week 4	149	40(26.8)	12(8.1)	27(18.1)	52(34.9)	18(12.1)	153	45(29.4)	13(8.5)	31(20.3)	45(29.4)	19(12.4)
	Week 6	148	39(26.4)	10(6.8)	26(17.6)	54(36.5)	19(12.8)	152	40(26.3)	16(10.5)	38(25.0)	34(22.4)	24(15.8)
	Week 8	145	35(24.1)	13(9.0)	29(20.0)	48(33.1)	20(13.8)	151	42(27.8)	15(9.9)	32(21.2)	39(25.8)	23(15.2)
	Week 10	145	37(25.5)	11(7.6)	31(21.4)	43(29.7)	23(15.9)	150	40(26.7)	15(10.0)	32(21.3)	37(24.7)	26(17.3)
	Week 12	145	33(22.8)	19(13.1)	21(14.5)	46(31.7)	26(17.9)	148	31(20.9)	22(14.9)	33(22.3)	36(24.3)	26(17.6)
	Week 16	143	35(24.5)	11(7.7)	29(20.3)	44(30.8)	24(16.8)	147	40(27.2)	13(8.8)	31(21.1)	37(25.2)	26(17.7)
	Week 20	140	36(25.7)	12(8.6)	19(13.6)	49(35.0)	24(17.1)	143	35(24.5)	16(11.2)	28(19.6)	42(29.4)	22(15.4)
	Week 24	132	27(20.5)	17(12.9)	24(18.2)	40(30.3)	24(18.2)	140	32(22.9)	18(12.9)	35(25.0)	25(17.9)	30(21.4)
	Week 28	126	27(21.4)	12(9.5)	27(21.4)	44(34.9)	16(12.7)	137	31(22.6)	17(12.4)	24(17.5)	42(30.7)	23(16.8)
	Week 32	120	31(25.8)	6(5.0)	19(15.8)	47(39.2)	17(14.2)	133	29(21.8)	13(9.8)	27(20.3)	35(26.3)	29(21.8)
	Week 36	118	20(16.9)	17(14.4)	18(15.3)	36(30.5)	27(22.9)	130	20(15.4)	22(16.9)	25(19.2)	39(30.0)	24(18.5)
	Week 40	115	24(20.9)	10(8.7)	17(14.8)	44(38.3)	20(17.4)	127	25(19.7)	16(12.6)	24(18.9)	39(30.7)	23(18.1)
	Week 44	113	24(21.2)	9(8.0)	20(17.7)	44(38.9)	16(14.2)	124	25(20.2)	15(12.1)	29(23.4)	36(29.0)	19(15.3)
	Week 48	112	21(18.8)	14(12.5)	18(16.1)	41(36.6)	18(16.1)	125	26(20.8)	18(14.4)	30(24.0)	35(28.0)	16(12.8)
	Week 52	111	26(23.4)	8(7.2)	23(20.7)	38(34.2)	16(14.4)	123	21(17.1)	26(21.1)	24(19.5)	35(28.5)	17(13.8)

表 2.7.4.9－77　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験／52 週）（続き）

Parameter	Visit	MT-6548(N=151) Total N*	- n (%)	+- n (%)	+ n (%)	2+ n (%)	3+ n (%)	darbepoetin(N=153) Total N*	- n (%)	+- n (%)	+ n (%)	2+ n (%)	3+ n (%)
Urine Urobilinogen	Baseline	151	-	151(100.0)	0(0.0)	0(0.0)	0(0.0)	153	-	153(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 2	151	-	151(100.0)	0(0.0)	0(0.0)	0(0.0)	152	-	152(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 4	149	-	149(100.0)	0(0.0)	0(0.0)	0(0.0)	153	-	153(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 6	148	-	148(100.0)	0(0.0)	0(0.0)	0(0.0)	152	-	151(99.3)	1(0.7)	0(0.0)	0(0.0)
	Week 8	145	-	145(100.0)	0(0.0)	0(0.0)	0(0.0)	151	-	150(99.3)	0(0.0)	1(0.7)	0(0.0)
	Week 10	145	-	145(100.0)	0(0.0)	0(0.0)	0(0.0)	150	-	150(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 12	145	-	145(100.0)	0(0.0)	0(0.0)	0(0.0)	148	-	147(99.3)	1(0.7)	0(0.0)	0(0.0)
	Week 16	143	-	143(100.0)	0(0.0)	0(0.0)	0(0.0)	147	-	146(99.3)	1(0.7)	0(0.0)	0(0.0)
	Week 20	140	-	140(100.0)	0(0.0)	0(0.0)	0(0.0)	143	-	142(99.3)	0(0.0)	1(0.7)	0(0.0)
	Week 24	132	-	132(100.0)	0(0.0)	0(0.0)	0(0.0)	140	-	138(98.6)	2(1.4)	0(0.0)	0(0.0)
	Week 28	126	-	126(100.0)	0(0.0)	0(0.0)	0(0.0)	137	-	137(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 32	120	-	120(100.0)	0(0.0)	0(0.0)	0(0.0)	133	-	133(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 36	118	-	118(100.0)	0(0.0)	0(0.0)	0(0.0)	130	-	130(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 40	115	-	115(100.0)	0(0.0)	0(0.0)	0(0.0)	127	-	126(99.2)	1(0.8)	0(0.0)	0(0.0)
	Week 44	113	-	113(100.0)	0(0.0)	0(0.0)	0(0.0)	124	-	124(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 48	112	-	112(100.0)	0(0.0)	0(0.0)	0(0.0)	125	-	125(100.0)	0(0.0)	0(0.0)	0(0.0)
	Week 52	111	-	110(99.1)	1(0.9)	0(0.0)	0(0.0)	123	-	123(100.0)	0(0.0)	0(0.0)	0(0.0)
Urine Occult Blood	Baseline	151	108(71.5)	22(14.6)	10(6.6)	5(3.3)	6(4.0)	153	107(69.9)	27(17.6)	10(6.5)	5(3.3)	4(2.6)
	Week 2	151	98(64.9)	34(22.5)	7(4.6)	8(5.3)	4(2.6)	152	97(63.8)	33(21.7)	10(6.6)	7(4.6)	5(3.3)
	Week 4	149	100(67.1)	29(19.5)	13(8.7)	3(2.0)	4(2.7)	153	96(62.7)	38(24.8)	7(4.6)	7(4.6)	5(3.3)
	Week 6	148	97(65.5)	28(18.9)	12(8.1)	7(4.7)	4(2.7)	152	96(63.2)	36(23.7)	6(3.9)	8(5.3)	6(3.9)
	Week 8	145	98(67.6)	27(18.6)	13(9.0)	3(2.1)	4(2.8)	151	94(62.3)	31(20.5)	15(9.9)	7(4.6)	4(2.6)
	Week 10	145	95(65.5)	32(22.1)	9(6.2)	6(4.1)	3(2.1)	150	95(63.3)	29(19.3)	14(9.3)	6(4.0)	6(4.0)
	Week 12	145	94(64.8)	35(24.1)	7(4.8)	4(2.8)	5(3.4)	148	96(64.9)	32(21.6)	10(6.8)	8(5.4)	2(1.4)
	Week 16	143	90(62.9)	32(22.4)	13(9.1)	4(2.8)	4(2.8)	147	88(59.9)	36(24.5)	11(7.5)	8(5.4)	4(2.7)
	Week 20	140	85(60.7)	33(23.6)	10(7.1)	8(5.7)	4(2.9)	143	86(60.1)	32(22.4)	14(9.8)	5(3.5)	6(4.2)
	Week 24	132	81(61.4)	33(25.0)	7(5.3)	8(6.1)	3(2.3)	140	82(58.6)	35(25.0)	10(7.1)	7(5.0)	6(4.3)
	Week 28	126	73(57.9)	34(27.0)	10(7.9)	6(4.8)	3(2.4)	137	81(59.1)	23(16.8)	22(16.1)	5(3.6)	6(4.4)
	Week 32	120	74(61.7)	26(21.7)	7(5.8)	8(6.7)	5(4.2)	133	77(57.9)	31(23.3)	12(9.0)	8(6.0)	5(3.8)
	Week 36	118	66(55.9)	27(22.9)	14(11.9)	6(5.1)	5(4.2)	130	74(56.9)	35(26.9)	11(8.5)	5(3.8)	5(3.8)
	Week 40	115	64(55.7)	30(26.1)	9(7.8)	8(7.0)	4(3.5)	127	72(56.7)	33(26.0)	9(7.1)	6(4.7)	7(5.5)
	Week 44	113	70(61.9)	26(23.0)	9(8.0)	4(3.5)	4(3.5)	124	75(60.5)	29(23.4)	8(6.5)	7(5.6)	5(4.0)
	Week 48	112	66(58.9)	26(23.2)	8(7.1)	8(7.1)	4(3.6)	125	77(61.6)	28(22.4)	9(7.2)	4(3.2)	7(5.6)
	Week 52	111	65(58.6)	27(24.3)	12(10.8)	2(1.8)	5(4.5)	123	73(59.3)	26(21.1)	13(10.6)	5(4.1)	6(4.9)

Data Source: Listing 16.2.6.5
Source: t_14_3_2_4_1.sas

5.3.5.1—8 表 14.3.2.4.1 より引用

表 2.7.4.9－78　規定した基準（臨床検査値）に該当した被験者数及び割合（MT-6548-J01 試験／52 週）

Criteria	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Uric Acid		
Any post-baseline value		
25% increase and >7.0 mg/dL	0 (0.0)	0 (0.0)
Potassium		
Any post-baseline value		
>6.0 - 7.0 mmol/L	13 (8.6)	19 (12.4)
>7.0 mmol/L	0 (0.0)	2 (1.3)
VEGF		
Any post-baseline value		
>= 2 x baseline and 200 pg/mL	3 (2.0)	0 (0.0)
Hb		
Any post-baseline value		
NDD: >= 13 g/dL	47 (31.1)	75 (49.0)
NDD: >= 14 g/dL	4 (2.6)	13 (8.5)
eGFR		
Any post-baseline value		
NDD：30% decrease from BL	42 (27.8)	45 (29.4)
AST, ALT		
Any post-baseline value		
AST >3.0 x ULN	2 (1.3)	5 (3.3)
AST >5.0 x ULN	1 (0.7)	3 (2.0)
ALT >3.0 x ULN	1 (0.7)	3 (2.0)
ALT >5.0 x ULN	0 (0.0)	1 (0.7)
AST >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	1 (0.7)
ALT >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	1 (0.7)
AST or ALT >3.0 x ULN + ALP < 2.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)

Note(s): Percentages are calculated using the number of subjects with post-baseline values as the denominator.
Source: t_14_3_5_1_1_1.sas

5.3.5.3—4 Table 14.3.5.1.1.1 より引用

表 2.7.4.9－79　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）

Parameter:Ery. Mean Corpuscular Volume (fL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	95.6	5.3	95.0	(78, 111)						
	Week 2	160	95.8	5.2	95.0	(77, 110)	160	95.6 (5.3)	0.2	1.1	0.0	(-2, 4)
	Week 4	157	95.7	5.1	96.0	(78, 110)	157	95.6 (5.3)	0.1	1.6	0.0	(-4, 4)
	Week 6	155	95.9	5.2	96.0	(78, 110)	155	95.6 (5.3)	0.3	1.8	0.0	(-4, 6)
	Week 8	152	96.3	5.2	96.0	(78, 110)	152	95.5 (5.3)	0.8	2.1	0.0	(-4, 8)
	Week 10	150	96.7	5.2	97.0	(81, 110)	150	95.6 (5.3)	1.1	2.4	1.0	(-5, 9)
	Week 12	148	97.2	5.3	97.0	(81, 111)	148	95.6 (5.3)	1.6	2.5	2.0	(-5, 10)
	Week 16	144	97.8	5.3	98.0	(85, 114)	144	95.6 (5.0)	2.2	2.8	2.0	(-5, 12)
	Week 20	140	97.5	5.1	98.0	(85, 111)	140	95.5 (4.9)	2.1	3.0	2.0	(-7, 12)
	Week 24	138	97.1	5.1	97.0	(84, 111)	138	95.4 (4.9)	1.7	3.0	1.0	(-8, 13)
	Week 28	132	97.1	4.7	97.0	(87, 110)	132	95.6 (4.7)	1.5	3.1	1.0	(-8, 13)
	Week 32	132	96.8	4.8	97.0	(85, 109)	132	95.6 (4.8)	1.2	3.0	1.0	(-7, 13)
	Week 36	130	96.6	4.8	97.0	(85, 109)	130	95.6 (4.8)	1.0	3.1	1.0	(-6, 13)
	Week 40	126	96.7	4.7	97.0	(86, 110)	126	95.6 (4.8)	1.0	2.8	1.0	(-5, 13)
	Week 44	125	96.6	4.8	97.0	(86, 111)	125	95.7 (4.7)	0.9	3.1	1.0	(-10, 13)
	Week 48	123	96.8	4.7	97.0	(86, 110)	123	95.6 (4.7)	1.1	3.1	1.0	(-13, 13)
	Week 52	120	96.8	4.7	97.0	(86, 114)	120	95.6 (4.7)	1.2	3.2	1.0	(-13, 13)
darbepoetin	Baseline	161	95.5	4.2	95.0	(85, 109)						
	Week 2	160	95.6	4.1	95.0	(86, 110)	160	95.5 (4.2)	0.1	0.9	0.0	(-3, 3)
	Week 4	159	95.6	4.0	95.0	(86, 108)	159	95.5 (4.2)	0.1	1.3	0.0	(-4, 3)
	Week 6	159	95.7	4.1	96.0	(85, 108)	159	95.5 (4.2)	0.2	1.5	0.0	(-6, 5)
	Week 8	158	95.6	4.1	95.0	(86, 109)	158	95.5 (4.2)	0.2	1.8	0.0	(-7, 5)
	Week 10	157	95.7	4.1	96.0	(86, 108)	157	95.5 (4.2)	0.2	2.0	0.0	(-7, 7)
	Week 12	157	95.8	4.2	95.0	(86, 109)	157	95.5 (4.2)	0.3	2.2	0.0	(-9, 6)
	Week 16	156	95.6	4.2	95.0	(84, 108)	156	95.4 (4.2)	0.1	2.5	0.0	(-6, 6)
	Week 20	154	95.6	4.2	95.0	(84, 106)	154	95.4 (4.1)	0.3	2.5	0.0	(-6, 8)
	Week 24	153	95.8	4.4	95.0	(80, 107)	153	95.4 (4.1)	0.4	2.7	0.0	(-8, 8)
	Week 28	150	95.6	4.3	96.0	(79, 108)	150	95.3 (4.1)	0.2	2.8	0.5	(-9, 7)
	Week 32	147	95.4	4.5	96.0	(78, 106)	147	95.3 (4.0)	0.1	2.8	0.0	(-10, 8)
	Week 36	144	95.0	4.8	95.0	(79, 107)	144	95.3 (4.0)	-0.3	3.0	0.0	(-10, 7)
	Week 40	144	94.9	4.9	95.0	(79, 108)	144	95.3 (4.0)	-0.4	3.2	0.0	(-11, 7)
	Week 44	141	94.7	5.0	95.0	(80, 106)	141	95.3 (4.0)	-0.6	3.2	0.0	(-13, 9)
	Week 48	135	94.9	5.2	95.0	(80, 107)	135	95.4 (4.0)	-0.5	3.3	0.0	(-12, 7)
	Week 52	135	95.1	5.1	95.0	(79, 108)	135	95.4 (4.0)	-0.3	3.3	0.0	(-12, 8)

表 2.7.4.9－79 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Ery. Mean Corpuscular Hemoglobin (pg)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	31.63	1.92	31.50	(25.1, 36.8)						
	Week 2	160	31.65	1.89	31.70	(25.4, 36.7)	160	31.64 (1.93)	0.01	0.51	0.00	(-1.3, 1.7)
	Week 4	157	31.73	1.85	31.80	(25.1, 36.7)	157	31.66 (1.94)	0.08	0.63	0.00	(-1.4, 2.0)
	Week 6	155	31.77	1.88	31.80	(25.7, 36.9)	155	31.64 (1.94)	0.13	0.76	0.10	(-1.5, 3.1)
	Week 8	152	31.94	1.89	32.00	(25.6, 37.0)	152	31.61 (1.94)	0.33	0.96	0.30	(-1.9, 3.7)
	Week 10	150	32.12	1.91	32.10	(26.7, 36.9)	150	31.64 (1.94)	0.48	1.00	0.40	(-1.7, 4.0)
	Week 12	148	32.36	1.92	32.40	(27.1, 37.6)	148	31.65 (1.95)	0.72	1.02	0.60	(-1.9, 4.1)
	Week 16	144	32.53	1.95	32.60	(27.1, 38.9)	144	31.64 (1.84)	0.89	1.12	0.75	(-2.1, 5.2)
	Week 20	140	32.50	1.87	32.60	(27.9, 37.7)	140	31.60 (1.83)	0.90	1.17	0.80	(-2.4, 5.0)
	Week 24	138	32.54	1.90	32.60	(26.9, 38.4)	138	31.61 (1.82)	0.94	1.20	0.80	(-2.1, 5.6)
	Week 28	132	32.57	1.73	32.50	(28.0, 38.5)	132	31.65 (1.74)	0.92	1.17	0.95	(-1.6, 5.2)
	Week 32	132	32.49	1.81	32.40	(27.7, 37.7)	132	31.69 (1.78)	0.80	1.23	0.70	(-2.0, 6.0)
	Week 36	130	32.40	1.80	32.55	(27.4, 38.1)	130	31.68 (1.78)	0.71	1.30	0.70	(-3.0, 5.7)
	Week 40	126	32.35	1.79	32.40	(28.1, 38.3)	126	31.69 (1.78)	0.66	1.21	0.60	(-2.0, 6.2)
	Week 44	125	32.38	1.81	32.30	(28.2, 38.8)	125	31.71 (1.75)	0.67	1.33	0.70	(-4.5, 6.1)
	Week 48	123	32.52	1.90	32.60	(27.8, 38.7)	123	31.68 (1.75)	0.84	1.36	0.70	(-4.1, 5.9)
	Week 52	120	32.54	1.75	32.50	(28.0, 39.4)	120	31.69 (1.72)	0.85	1.29	0.80	(-5.4, 5.8)
darbepoetin	Baseline	161	31.57	1.55	31.60	(28.1, 35.4)						
	Week 2	160	31.56	1.53	31.50	(27.7, 35.7)	160	31.56 (1.55)	0.00	0.51	0.00	(-2.0, 1.1)
	Week 4	159	31.53	1.47	31.40	(28.3, 35.4)	159	31.56 (1.55)	-0.03	0.61	0.00	(-2.3, 1.3)
	Week 6	159	31.58	1.57	31.30	(28.0, 36.6)	159	31.56 (1.55)	0.02	0.71	0.10	(-2.6, 2.2)
	Week 8	158	31.53	1.48	31.50	(27.9, 36.0)	158	31.57 (1.55)	-0.04	0.81	0.00	(-2.6, 2.1)
	Week 10	157	31.60	1.59	31.50	(27.5, 35.8)	157	31.55 (1.55)	0.05	0.90	0.10	(-2.7, 2.8)
	Week 12	157	31.60	1.57	31.70	(27.5, 35.3)	157	31.55 (1.55)	0.05	0.97	0.10	(-3.2, 2.8)
	Week 16	156	31.64	1.57	31.50	(27.0, 35.7)	156	31.54 (1.55)	0.09	1.07	0.15	(-3.8, 2.7)
	Week 20	154	31.67	1.59	31.70	(26.9, 35.1)	154	31.52 (1.53)	0.15	1.11	0.20	(-3.9, 3.2)
	Week 24	153	31.87	1.71	31.80	(25.6, 37.5)	153	31.53 (1.53)	0.33	1.24	0.30	(-3.7, 4.6)
	Week 28	150	31.85	1.64	31.90	(24.4, 36.0)	150	31.50 (1.52)	0.35	1.29	0.40	(-4.9, 3.5)
	Week 32	147	31.76	1.74	31.80	(24.5, 35.7)	147	31.49 (1.50)	0.26	1.20	0.30	(-4.8, 3.2)
	Week 36	144	31.67	1.92	31.90	(25.1, 36.7)	144	31.51 (1.51)	0.16	1.32	0.15	(-4.2, 3.7)
	Week 40	144	31.47	1.91	31.80	(24.8, 36.1)	144	31.51 (1.50)	-0.04	1.35	0.20	(-4.5, 3.8)
	Week 44	141	31.58	2.03	31.60	(24.7, 36.1)	141	31.51 (1.50)	0.07	1.42	0.30	(-5.1, 3.6)
	Week 48	135	31.71	2.11	31.80	(24.7, 37.7)	135	31.55 (1.49)	0.16	1.52	0.30	(-4.8, 4.1)
	Week 52	135	31.68	2.11	31.80	(24.8, 36.6)	135	31.55 (1.49)	0.13	1.51	0.30	(-4.7, 3.7)

表 2.7.4.9－79 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Ery. Mean Corpuscular HGB Concentration (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	33.09	0.50	33.10	(31.8, 34.3)						
	Week 2	160	33.06	0.59	33.00	(31.5, 35.2)	160	33.09 (0.50)	-0.03	0.52	-0.10	(-1.6, 1.5)
	Week 4	157	33.14	0.56	33.10	(31.8, 35.2)	157	33.10 (0.51)	0.04	0.49	0.00	(-1.6, 1.2)
	Week 6	155	33.10	0.63	33.10	(31.1, 35.0)	155	33.09 (0.51)	0.01	0.58	0.00	(-1.7, 1.6)
	Week 8	152	33.18	0.64	33.10	(31.3, 37.1)	152	33.09 (0.50)	0.09	0.59	0.05	(-1.9, 3.1)
	Week 10	150	33.17	0.52	33.20	(31.3, 34.9)	150	33.09 (0.51)	0.09	0.51	0.10	(-1.3, 2.2)
	Week 12	148	33.28	0.55	33.30	(31.3, 35.1)	148	33.09 (0.51)	0.19	0.50	0.20	(-1.1, 1.6)
	Week 16	144	33.25	0.57	33.20	(31.3, 35.2)	144	33.09 (0.51)	0.16	0.53	0.20	(-1.5, 1.6)
	Week 20	140	33.32	0.55	33.30	(31.8, 35.2)	140	33.09 (0.51)	0.22	0.51	0.20	(-1.5, 1.5)
	Week 24	138	33.49	0.59	33.40	(31.5, 35.4)	138	33.10 (0.51)	0.39	0.57	0.40	(-1.4, 2.1)
	Week 28	132	33.56	0.55	33.60	(31.9, 35.4)	132	33.11 (0.51)	0.45	0.55	0.40	(-0.9, 2.1)
	Week 32	132	33.55	0.58	33.60	(31.8, 35.4)	132	33.12 (0.51)	0.43	0.61	0.35	(-0.8, 2.2)
	Week 36	130	33.52	0.56	33.50	(31.3, 35.0)	130	33.12 (0.51)	0.40	0.61	0.40	(-1.1, 2.1)
	Week 40	126	33.45	0.57	33.50	(31.4, 35.6)	126	33.12 (0.51)	0.32	0.58	0.30	(-1.2, 2.1)
	Week 44	125	33.50	0.60	33.40	(31.3, 35.1)	125	33.12 (0.51)	0.38	0.63	0.30	(-1.8, 2.0)
	Week 48	123	33.60	0.73	33.60	(30.6, 35.9)	123	33.12 (0.51)	0.48	0.76	0.40	(-2.5, 2.7)
	Week 52	120	33.62	0.65	33.60	(31.0, 35.5)	120	33.13 (0.50)	0.49	0.67	0.50	(-1.1, 1.9)
darbepoetin	Baseline	161	33.04	0.59	33.10	(31.2, 34.6)						
	Week 2	160	33.02	0.61	33.00	(31.3, 34.3)	160	33.04 (0.59)	-0.02	0.44	0.00	(-1.2, 0.9)
	Week 4	159	32.97	0.55	32.90	(31.3, 34.4)	159	33.05 (0.59)	-0.08	0.50	-0.10	(-1.8, 1.3)
	Week 6	159	32.99	0.59	32.90	(31.4, 36.0)	159	33.05 (0.59)	-0.06	0.51	-0.10	(-1.4, 2.1)
	Week 8	158	32.96	0.60	32.90	(31.4, 35.5)	158	33.05 (0.59)	-0.09	0.58	-0.10	(-1.6, 1.6)
	Week 10	157	33.02	0.58	33.00	(31.6, 35.2)	157	33.04 (0.58)	-0.02	0.55	0.00	(-1.2, 1.7)
	Week 12	157	33.00	0.54	33.00	(31.4, 34.3)	157	33.04 (0.58)	-0.04	0.56	-0.10	(-1.5, 1.5)
	Week 16	156	33.08	0.54	33.10	(31.6, 34.5)	156	33.04 (0.58)	0.04	0.57	0.10	(-1.8, 1.5)
	Week 20	154	33.12	0.53	33.10	(31.7, 34.5)	154	33.04 (0.58)	0.08	0.56	0.10	(-1.8, 1.3)
	Week 24	153	33.24	0.60	33.20	(31.8, 35.9)	153	33.04 (0.59)	0.20	0.62	0.20	(-1.6, 3.0)
	Week 28	150	33.31	0.59	33.30	(31.0, 34.5)	150	33.03 (0.59)	0.28	0.64	0.30	(-2.1, 1.7)
	Week 32	147	33.28	0.65	33.20	(31.4, 35.0)	147	33.04 (0.59)	0.24	0.57	0.30	(-1.7, 1.7)
	Week 36	144	33.30	0.72	33.30	(30.9, 34.9)	144	33.04 (0.59)	0.26	0.60	0.30	(-1.8, 1.8)
	Week 40	144	33.13	0.69	33.20	(30.9, 34.9)	144	33.05 (0.59)	0.08	0.61	0.10	(-1.6, 1.4)
	Week 44	141	33.33	0.71	33.30	(30.9, 35.1)	141	33.05 (0.59)	0.27	0.65	0.20	(-1.2, 1.9)
	Week 48	135	33.38	0.77	33.40	(30.9, 35.2)	135	33.07 (0.59)	0.31	0.72	0.30	(-1.7, 1.8)
	Week 52	135	33.28	0.84	33.40	(30.5, 35.0)	135	33.07 (0.59)	0.22	0.77	0.20	(-1.8, 2.4)

表 2.7.4.9－79 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Erythrocytes Distribution Width (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	14.74	1.31	14.50	(12.0, 19.9)						
	Week 2	160	14.64	1.31	14.45	(12.3, 21.1)	160	14.75 (1.32)	-0.11	0.59	-0.10	(-1.6, 1.3)
	Week 4	157	14.56	1.33	14.30	(12.4, 20.7)	157	14.74 (1.32)	-0.17	0.77	-0.20	(-2.1, 2.1)
	Week 6	155	14.68	1.31	14.60	(11.9, 20.2)	155	14.75 (1.33)	-0.07	0.93	0.00	(-2.7, 3.3)
	Week 8	152	14.77	1.36	14.50	(12.2, 19.3)	152	14.77 (1.32)	0.00	1.08	0.05	(-3.1, 3.5)
	Week 10	150	14.82	1.30	14.60	(12.2, 20.0)	150	14.75 (1.31)	0.08	1.17	0.10	(-3.9, 4.1)
	Week 12	148	14.72	1.29	14.50	(12.6, 21.0)	148	14.72 (1.28)	-0.01	1.30	0.00	(-4.9, 4.5)
	Week 16	144	14.36	1.10	14.20	(12.1, 19.5)	144	14.70 (1.27)	-0.34	1.28	-0.30	(-6.0, 2.5)
	Week 20	140	14.12	1.14	13.90	(12.2, 20.1)	140	14.69 (1.29)	-0.57	1.42	-0.40	(-6.2, 3.6)
	Week 24	138	14.06	1.17	13.80	(12.3, 19.2)	138	14.70 (1.30)	-0.63	1.49	-0.40	(-5.9, 3.8)
	Week 28	132	14.04	1.04	13.90	(12.1, 18.3)	132	14.68 (1.30)	-0.64	1.44	-0.50	(-6.0, 4.3)
	Week 32	132	14.00	0.94	13.95	(12.2, 16.8)	132	14.68 (1.30)	-0.68	1.40	-0.50	(-6.3, 2.4)
	Week 36	129	14.19	1.16	13.90	(12.1, 19.1)	129	14.68 (1.31)	-0.49	1.50	-0.40	(-7.0, 3.2)
	Week 40	126	14.25	1.27	14.00	(11.9, 22.1)	126	14.66 (1.32)	-0.41	1.53	-0.30	(-6.7, 4.6)
	Week 44	125	14.27	1.52	14.00	(12.3, 23.4)	125	14.67 (1.33)	-0.40	1.70	-0.50	(-7.2, 7.3)
	Week 48	123	14.23	1.30	13.90	(12.0, 20.0)	123	14.68 (1.33)	-0.44	1.51	-0.20	(-6.6, 5.2)
	Week 52	120	14.21	1.12	14.00	(12.3, 19.6)	120	14.66 (1.34)	-0.45	1.49	-0.30	(-6.3, 5.5)
darbepoetin	Baseline	161	14.80	1.51	14.40	(12.1, 20.5)						
	Week 2	160	14.82	1.42	14.55	(12.7, 21.3)	160	14.78 (1.49)	0.03	0.49	0.00	(-1.7, 1.2)
	Week 4	159	14.78	1.33	14.50	(12.4, 20.8)	159	14.77 (1.49)	0.01	0.67	0.00	(-2.6, 2.2)
	Week 6	159	14.71	1.26	14.50	(12.5, 19.6)	159	14.77 (1.49)	-0.06	0.89	0.00	(-3.2, 3.6)
	Week 8	158	14.67	1.15	14.45	(12.3, 18.1)	158	14.77 (1.50)	-0.10	1.04	0.00	(-3.5, 2.8)
	Week 10	157	14.64	1.13	14.50	(12.6, 18.7)	157	14.78 (1.50)	-0.14	1.05	-0.10	(-3.8, 2.0)
	Week 12	157	14.68	1.08	14.50	(12.6, 18.1)	157	14.78 (1.50)	-0.10	1.11	0.00	(-4.1, 2.5)
	Week 16	156	14.69	1.12	14.40	(12.7, 18.1)	156	14.78 (1.50)	-0.09	1.20	0.10	(-4.7, 3.3)
	Week 20	154	14.62	1.17	14.35	(12.7, 17.8)	154	14.78 (1.51)	-0.16	1.25	-0.05	(-5.0, 3.2)
	Week 24	153	14.69	1.18	14.40	(12.5, 17.9)	153	14.77 (1.51)	-0.08	1.33	-0.10	(-6.0, 3.6)
	Week 28	150	14.68	1.34	14.40	(12.2, 19.6)	150	14.78 (1.53)	-0.10	1.42	0.00	(-6.3, 3.7)
	Week 32	147	14.64	1.51	14.20	(12.1, 22.0)	147	14.79 (1.54)	-0.15	1.51	0.00	(-6.4, 3.0)
	Week 36	144	14.72	1.57	14.35	(12.2, 21.0)	144	14.80 (1.54)	-0.08	1.57	0.00	(-5.9, 4.5)
	Week 40	144	14.87	1.70	14.55	(11.9, 22.4)	144	14.79 (1.55)	0.08	1.56	0.10	(-5.4, 5.1)
	Week 44	141	14.96	1.64	14.50	(12.2, 21.2)	141	14.80 (1.55)	0.16	1.45	0.20	(-5.9, 5.6)
	Week 48	135	15.08	1.75	14.60	(12.4, 22.0)	135	14.82 (1.57)	0.25	1.53	0.20	(-5.8, 6.0)
	Week 52	135	15.12	1.75	14.60	(12.9, 21.8)	135	14.82 (1.57)	0.30	1.59	0.30	(-4.9, 7.2)

表 2.7.4.9－79　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Leukocytes (/uL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	5852.5	1816.3	5500.0	(2500, 13100)						
	Week 2	160	5886.9	1762.1	5500.0	(3100, 14400)	160	5863.1 (1825.1)	23.8	1025.4	-150.0	(-3000, 4600)
	Week 4	157	5886.6	1843.6	5400.0	(2600, 14600)	157	5863.7 (1830.3)	22.9	1063.7	0.0	(-3200, 3800)
	Week 6	155	5835.5	1758.0	5600.0	(2800, 12900)	155	5876.8 (1835.9)	-41.3	1050.5	0.0	(-3600, 3700)
	Week 8	152	5846.1	1745.6	5600.0	(2300, 12600)	152	5902.6 (1844.3)	-56.6	1159.2	-100.0	(-5000, 4700)
	Week 10	150	5872.0	1892.8	5400.0	(2600, 12400)	150	5891.3 (1850.7)	-19.3	1224.3	-150.0	(-4100, 3400)
	Week 12	148	5830.4	1970.9	5400.0	(2800, 14100)	148	5879.1 (1851.9)	-48.6	1190.5	-200.0	(-5100, 4800)
	Week 16	144	5860.4	1931.2	5500.0	(2700, 14100)	144	5894.4 (1864.3)	-34.0	1140.5	0.0	(-5000, 4900)
	Week 20	140	5915.7	1865.5	5550.0	(2800, 11800)	140	5936.4 (1872.6)	-20.7	1009.1	0.0	(-3200, 3000)
	Week 24	138	5845.7	1823.2	5650.0	(2400, 12600)	138	5946.4 (1862.9)	-100.7	1145.4	-100.0	(-4400, 4700)
	Week 28	132	5870.5	1834.0	5600.0	(2500, 11700)	132	6000.8 (1847.7)	-130.3	1138.0	-50.0	(-4700, 3000)
	Week 32	132	5879.5	1714.9	5650.0	(2300, 12700)	132	5981.1 (1865.8)	-101.5	1160.3	-100.0	(-4000, 2400)
	Week 36	129	5779.8	1796.4	5400.0	(2600, 11100)	129	5916.3 (1769.2)	-136.4	1279.5	-100.0	(-4100, 4200)
	Week 40	125	5920.8	1819.0	5400.0	(2600, 14700)	125	5904.8 (1745.2)	16.0	1553.3	-200.0	(-4400, 8600)
	Week 44	125	5893.6	1760.2	5500.0	(2800, 13000)	125	5975.2 (1782.9)	-81.6	1162.5	-100.0	(-4000, 3400)
	Week 48	123	5835.8	1679.0	5600.0	(2100, 11400)	123	5961.8 (1774.0)	-126.0	1314.0	0.0	(-4200, 6500)
	Week 52	120	5761.7	1774.0	5250.0	(2300, 14100)	120	5949.2 (1758.8)	-187.5	1408.5	-200.0	(-4000, 8000)
darbepoetin	Baseline	161	5623.0	1568.1	5500.0	(2000, 15400)						
	Week 2	160	5695.0	1632.4	5500.0	(2400, 17900)	160	5645.6 (1546.4)	49.4	789.4	50.0	(-2500, 2500)
	Week 4	159	5578.6	1406.8	5500.0	(2700, 12800)	159	5644.0 (1551.1)	-65.4	840.0	-100.0	(-4200, 1900)
	Week 6	159	5636.5	1563.9	5400.0	(2800, 14200)	159	5644.0 (1551.1)	-7.5	954.1	100.0	(-3600, 3600)
	Week 8	158	5694.3	1458.5	5550.0	(3400, 11700)	158	5634.8 (1551.7)	59.5	1008.2	100.0	(-3700, 3000)
	Week 10	157	5679.0	1544.2	5500.0	(2900, 12800)	157	5637.6 (1556.3)	41.4	1073.5	0.0	(-3500, 5800)
	Week 12	157	5756.7	1684.3	5500.0	(2900, 15200)	157	5637.6 (1556.3)	119.1	1223.2	100.0	(-4900, 4500)
	Week 16	156	5625.6	1623.0	5400.0	(3000, 17600)	156	5637.8 (1561.3)	-12.2	1063.7	100.0	(-4000, 5300)
	Week 20	154	5851.3	1914.7	5550.0	(2700, 19000)	154	5637.0 (1568.1)	214.3	1466.7	100.0	(-4500, 13400)
	Week 24	153	5774.5	1663.3	5500.0	(2400, 16100)	153	5641.2 (1572.4)	133.3	997.5	0.0	(-3600, 3400)
	Week 28	150	5792.7	1684.4	5650.0	(2800, 16600)	150	5637.3 (1577.0)	155.3	1071.4	50.0	(-3400, 4100)
	Week 32	147	5929.3	1958.5	5800.0	(2500, 18900)	147	5639.5 (1576.9)	289.8	1203.2	200.0	(-3700, 6300)
	Week 36	144	5672.9	1736.1	5400.0	(2600, 18000)	144	5648.6 (1580.1)	24.3	959.0	100.0	(-2700, 2600)
	Week 40	144	5793.1	1651.6	5700.0	(2400, 13700)	144	5660.4 (1589.1)	132.6	1057.6	100.0	(-2300, 3800)
	Week 44	141	5733.3	1759.8	5400.0	(2700, 17100)	141	5639.7 (1585.7)	93.6	1104.5	100.0	(-3700, 3000)
	Week 48	135	5634.1	1677.4	5300.0	(2600, 12300)	135	5637.0 (1609.0)	-3.0	1119.2	0.0	(-4100, 5200)
	Week 52	135	5593.3	1588.7	5400.0	(2300, 12000)	135	5637.0 (1609.0)	-43.7	1058.3	0.0	(-3400, 2100)

表 2.7.4.9－79　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Neutrophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	67.60	8.40	67.85	(42.0, 88.5)						
	Week 2	159	66.94	8.37	67.10	(40.1, 88.5)	159	67.77 (8.27)	-0.83	5.82	-1.00	(-12.9, 17.5)
	Week 4	156	67.27	7.80	67.55	(41.0, 85.5)	156	67.78 (8.34)	-0.51	5.89	-0.70	(-18.0, 16.0)
	Week 6	154	66.74	7.43	66.85	(48.6, 86.5)	154	67.77 (8.39)	-1.03	6.17	-0.80	(-18.5, 17.0)
	Week 8	151	67.30	7.77	67.00	(47.3, 84.6)	151	68.01 (8.28)	-0.71	6.65	-1.20	(-18.1, 28.1)
	Week 10	149	66.90	8.41	67.60	(41.6, 88.0)	149	68.08 (8.10)	-1.18	7.05	-1.50	(-31.1, 23.0)
	Week 12	147	66.63	7.99	66.60	(45.6, 85.5)	147	67.96 (8.09)	-1.33	6.61	-1.50	(-29.5, 21.5)
	Week 16	144	67.48	7.90	67.95	(45.7, 85.7)	144	67.78 (8.27)	-0.30	6.85	-0.60	(-23.2, 17.9)
	Week 20	139	68.36	8.15	68.00	(43.3, 89.0)	139	67.87 (8.40)	0.49	6.88	0.00	(-16.7, 26.3)
	Week 24	137	69.59	8.00	69.50	(46.0, 90.5)	137	67.89 (8.34)	1.69	6.46	1.20	(-15.0, 24.5)
	Week 28	130	69.11	8.18	69.20	(47.0, 90.0)	130	67.98 (8.24)	1.13	6.47	1.55	(-17.6, 17.0)
	Week 32	132	68.39	7.96	69.45	(44.7, 90.0)	132	67.92 (8.34)	0.47	6.60	0.00	(-15.6, 18.0)
	Week 36	127	68.56	7.64	69.00	(53.0, 89.0)	127	68.01 (8.26)	0.54	6.77	0.30	(-20.1, 21.5)
	Week 40	125	68.82	7.80	68.50	(47.4, 82.8)	125	68.07 (8.34)	0.75	7.22	1.00	(-18.8, 22.5)
	Week 44	124	69.04	7.28	69.05	(50.0, 86.5)	124	68.23 (8.35)	0.81	6.55	1.10	(-19.7, 22.2)
	Week 48	123	69.02	8.01	69.00	(43.4, 88.0)	123	68.21 (8.14)	0.82	7.35	1.30	(-19.5, 37.5)
	Week 52	119	69.10	7.40	69.00	(43.0, 87.5)	119	68.56 (7.81)	0.54	7.09	0.60	(-28.3, 18.0)
darbepoetin	Baseline	160	67.17	7.44	67.20	(45.0, 83.0)						
	Week 2	159	68.05	6.83	68.40	(46.0, 84.0)	158	67.33 (7.30)	0.86	5.13	0.60	(-12.8, 19.9)
	Week 4	159	67.29	7.15	67.60	(48.2, 84.0)	158	67.22 (7.47)	0.15	5.58	0.40	(-15.0, 19.2)
	Week 6	159	67.51	7.32	68.00	(46.0, 86.5)	158	67.22 (7.47)	0.33	5.76	0.05	(-14.9, 16.1)
	Week 8	157	67.45	7.32	67.20	(48.5, 83.0)	156	67.30 (7.48)	0.21	6.01	0.80	(-24.0, 15.9)
	Week 10	157	67.26	7.35	68.00	(52.0, 84.0)	156	67.22 (7.47)	0.10	6.56	0.45	(-20.0, 19.4)
	Week 12	157	67.79	7.54	68.00	(45.0, 83.9)	156	67.22 (7.47)	0.63	6.42	1.20	(-16.9, 19.1)
	Week 16	156	68.29	7.46	69.15	(48.5, 83.5)	155	67.22 (7.49)	1.14	6.00	1.50	(-15.9, 15.6)
	Week 20	154	68.65	7.82	68.95	(48.0, 89.0)	153	67.22 (7.53)	1.49	6.35	1.50	(-14.2, 26.5)
	Week 24	153	69.41	7.37	69.80	(37.5, 87.2)	152	67.24 (7.56)	2.23	6.14	2.10	(-20.0, 19.1)
	Week 28	150	69.01	8.33	69.00	(36.0, 87.5)	149	67.28 (7.55)	1.75	6.86	1.70	(-33.5, 26.3)
	Week 32	147	69.18	7.79	69.00	(49.1, 86.5)	146	67.16 (7.58)	2.05	6.05	1.50	(-13.0, 20.1)
	Week 36	143	69.46	7.44	69.00	(51.6, 88.0)	142	67.16 (7.68)	2.36	5.95	2.50	(-15.0, 19.0)
	Week 40	144	69.09	7.45	69.00	(49.3, 83.5)	143	67.16 (7.64)	1.93	6.23	2.10	(-13.0, 16.0)
	Week 44	141	68.78	7.52	69.00	(46.0, 84.5)	140	67.16 (7.67)	1.68	7.01	1.75	(-21.0, 21.5)
	Week 48	134	68.22	7.55	69.15	(43.5, 85.5)	133	67.03 (7.80)	1.21	6.70	1.70	(-16.0, 20.5)
	Week 52	135	68.38	7.56	69.00	(41.5, 82.5)	134	67.00 (7.78)	1.42	5.88	1.15	(-13.0, 17.4)

表 2.7.4.9－79　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Eosinophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	4.72	3.58	4.00	(0.5, 23.0)						
	Week 2	159	4.85	3.76	4.00	(0.5, 27.0)	159	4.75 (3.60)	0.10	2.05	0.10	(-6.0, 5.1)
	Week 4	156	4.53	3.55	4.00	(0.0, 26.5)	156	4.76 (3.60)	-0.23	2.17	0.00	(-9.0, 5.2)
	Week 6	154	4.56	3.72	3.35	(0.0, 28.0)	154	4.79 (3.61)	-0.23	2.30	0.00	(-6.7, 5.5)
	Week 8	151	4.72	3.66	4.00	(0.0, 30.0)	151	4.78 (3.62)	-0.06	2.32	0.00	(-9.4, 7.4)
	Week 10	149	4.74	3.70	4.00	(0.0, 26.0)	149	4.73 (3.56)	0.01	3.00	0.00	(-10.2, 22.2)
	Week 12	147	4.69	3.85	3.60	(0.0, 19.6)	147	4.74 (3.58)	-0.05	2.68	-0.10	(-9.7, 14.6)
	Week 16	144	4.58	3.83	3.40	(0.0, 22.0)	144	4.73 (3.59)	-0.14	2.83	-0.20	(-8.7, 10.4)
	Week 20	139	4.37	3.25	3.90	(0.4, 19.6)	139	4.75 (3.63)	-0.38	2.33	-0.10	(-10.4, 4.7)
	Week 24	137	4.44	3.16	3.80	(0.0, 15.9)	137	4.75 (3.65)	-0.31	2.23	0.00	(-7.1, 5.7)
	Week 28	130	4.75	3.50	4.00	(0.5, 25.5)	130	4.85 (3.70)	-0.10	2.21	-0.10	(-7.9, 5.0)
	Week 32	132	4.83	3.77	4.00	(0.4, 24.5)	132	4.81 (3.68)	0.02	2.54	0.00	(-8.8, 13.4)
	Week 36	127	4.79	3.48	4.00	(0.0, 18.0)	127	4.75 (3.69)	0.04	2.45	0.00	(-9.4, 6.0)
	Week 40	125	4.96	3.45	4.00	(0.5, 17.0)	125	4.82 (3.70)	0.14	2.73	0.10	(-9.7, 12.6)
	Week 44	124	4.75	3.61	4.00	(0.0, 20.0)	124	4.70 (3.67)	0.05	2.85	0.15	(-11.2, 13.0)
	Week 48	123	4.85	3.72	3.80	(0.2, 19.6)	123	4.67 (3.66)	0.17	2.82	0.00	(-10.4, 12.1)
	Week 52	119	4.58	3.87	4.00	(0.0, 28.0)	119	4.55 (3.47)	0.04	2.94	0.00	(-11.0, 15.8)
darbepoetin	Baseline	160	4.37	3.64	3.40	(0.0, 24.0)						
	Week 2	159	4.31	3.29	3.40	(0.0, 25.0)	158	4.29 (3.48)	0.00	2.03	0.00	(-11.5, 5.3)
	Week 4	159	4.35	3.49	3.40	(0.0, 22.5)	158	4.38 (3.65)	-0.04	2.15	-0.05	(-10.0, 6.7)
	Week 6	159	4.43	3.74	3.50	(0.0, 28.5)	158	4.38 (3.65)	0.05	2.26	0.00	(-11.0, 8.5)
	Week 8	157	4.12	3.20	3.20	(0.0, 20.0)	156	4.27 (3.48)	-0.16	2.28	0.00	(-11.0, 6.9)
	Week 10	157	4.37	3.26	3.70	(0.0, 22.5)	156	4.30 (3.48)	0.04	2.05	0.10	(-12.0, 6.5)
	Week 12	157	4.22	3.33	3.50	(0.0, 22.0)	156	4.30 (3.48)	-0.11	2.24	0.00	(-11.5, 7.4)
	Week 16	156	4.45	3.35	3.50	(0.0, 20.0)	155	4.31 (3.49)	0.11	2.40	0.00	(-10.0, 9.0)
	Week 20	154	4.72	3.62	4.00	(0.0, 24.0)	153	4.35 (3.49)	0.34	2.55	0.10	(-10.0, 9.6)
	Week 24	153	4.41	3.72	3.50	(0.0, 26.5)	152	4.31 (3.47)	0.07	2.88	0.00	(-12.0, 12.6)
	Week 28	150	4.31	3.32	3.65	(0.0, 28.0)	149	4.20 (3.25)	0.09	2.36	0.10	(-11.4, 7.5)
	Week 32	147	4.48	3.12	4.00	(0.5, 20.5)	146	4.22 (3.27)	0.23	2.57	0.30	(-13.2, 12.5)
	Week 36	143	4.30	3.02	3.40	(0.0, 18.0)	142	4.23 (3.32)	0.02	2.62	0.00	(-12.0, 7.5)
	Week 40	144	4.36	2.88	4.00	(0.5, 19.0)	143	4.23 (3.31)	0.11	2.76	0.20	(-15.0, 9.3)
	Week 44	141	4.42	3.12	4.00	(0.0, 18.5)	140	4.24 (3.34)	0.16	3.17	0.10	(-15.0, 12.5)
	Week 48	134	4.52	2.88	4.00	(0.0, 20.0)	133	4.29 (3.38)	0.25	3.02	0.30	(-16.0, 10.0)
	Week 52	135	4.22	2.84	3.80	(0.0, 16.6)	134	4.29 (3.37)	-0.08	2.47	0.00	(-12.3, 7.0)

表 2.7.4.9－79　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Monocytes/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	6.57	2.10	6.25	(2.0, 12.6)						
	Week 2	159	6.72	2.19	6.60	(3.0, 12.2)	159	6.55 (2.02)	0.17	2.10	0.20	(-5.6, 5.9)
	Week 4	156	6.60	1.88	6.50	(2.6, 12.9)	156	6.51 (2.02)	0.09	2.00	0.00	(-5.0, 4.7)
	Week 6	154	7.05	1.95	7.10	(1.2, 12.3)	154	6.52 (2.03)	0.52	2.15	0.60	(-7.8, 6.0)
	Week 8	151	6.84	2.05	6.70	(0.5, 12.0)	151	6.52 (2.04)	0.32	2.19	0.50	(-5.5, 5.9)
	Week 10	149	6.64	1.98	6.80	(2.0, 12.2)	149	6.52 (2.05)	0.13	2.33	0.00	(-7.0, 7.0)
	Week 12	147	6.90	2.02	6.80	(1.4, 11.8)	147	6.56 (2.03)	0.33	2.00	0.30	(-4.4, 5.6)
	Week 16	144	6.94	2.28	6.95	(2.0, 12.6)	144	6.59 (2.08)	0.36	2.28	0.50	(-7.5, 7.3)
	Week 20	139	6.82	2.15	7.00	(1.8, 11.6)	139	6.58 (2.07)	0.24	2.06	0.20	(-6.5, 5.0)
	Week 24	137	6.55	2.32	6.60	(1.0, 12.7)	137	6.56 (2.06)	-0.01	2.47	0.10	(-6.5, 7.3)
	Week 28	130	6.80	1.99	7.00	(1.5, 12.3)	130	6.45 (1.95)	0.35	2.26	0.35	(-5.5, 7.6)
	Week 32	132	6.96	2.01	7.00	(2.0, 13.0)	132	6.54 (2.04)	0.42	2.38	0.70	(-7.4, 7.1)
	Week 36	127	6.97	1.97	7.00	(3.0, 14.0)	127	6.51 (2.00)	0.46	2.23	0.70	(-6.6, 6.6)
	Week 40	125	6.65	1.94	6.80	(2.4, 12.1)	125	6.49 (2.01)	0.17	2.07	0.20	(-5.0, 5.8)
	Week 44	124	6.74	1.85	6.85	(1.8, 12.3)	124	6.48 (1.97)	0.25	2.07	0.50	(-5.5, 4.6)
	Week 48	123	6.89	2.01	7.00	(2.5, 12.0)	123	6.56 (2.01)	0.33	2.22	0.50	(-7.5, 5.5)
	Week 52	119	6.91	1.97	7.00	(1.6, 12.5)	119	6.48 (1.96)	0.42	2.06	0.70	(-6.0, 5.6)
darbepoetin	Baseline	160	6.96	2.20	7.00	(2.0, 13.5)						
	Week 2	159	6.80	2.23	6.90	(2.0, 12.4)	158	6.94 (2.20)	-0.17	2.09	-0.20	(-7.7, 7.0)
	Week 4	159	6.81	2.12	6.50	(2.0, 12.4)	158	6.95 (2.21)	-0.15	1.99	0.00	(-6.6, 5.0)
	Week 6	159	6.66	2.13	6.50	(1.7, 15.0)	158	6.95 (2.21)	-0.27	2.03	-0.40	(-7.1, 5.0)
	Week 8	157	6.76	2.20	6.80	(2.8, 14.5)	156	6.94 (2.22)	-0.15	2.20	0.00	(-5.6, 6.0)
	Week 10	157	7.17	2.30	7.00	(2.0, 15.5)	156	6.97 (2.21)	0.23	2.02	0.00	(-5.7, 6.0)
	Week 12	157	6.88	2.21	6.70	(3.1, 12.3)	156	6.97 (2.21)	-0.07	2.11	0.00	(-5.5, 6.0)
	Week 16	156	6.62	2.07	6.50	(2.0, 13.5)	155	6.97 (2.21)	-0.34	1.96	-0.10	(-6.0, 4.0)
	Week 20	154	6.68	2.07	6.50	(1.5, 12.8)	153	6.96 (2.22)	-0.26	2.05	0.00	(-6.1, 5.5)
	Week 24	153	6.48	2.20	6.00	(1.9, 14.5)	152	6.95 (2.23)	-0.47	2.01	-0.50	(-7.1, 4.3)
	Week 28	150	6.66	2.18	6.70	(1.5, 15.0)	149	6.95 (2.23)	-0.30	2.09	-0.40	(-5.5, 8.0)
	Week 32	147	6.70	2.19	6.50	(2.0, 14.5)	146	6.90 (2.23)	-0.19	2.02	-0.10	(-7.7, 5.3)
	Week 36	143	6.49	2.33	6.10	(0.4, 15.0)	142	6.91 (2.21)	-0.40	2.10	-0.40	(-5.0, 7.2)
	Week 40	144	6.87	2.22	6.70	(2.4, 15.0)	143	6.95 (2.22)	-0.06	2.04	0.00	(-6.7, 5.0)
	Week 44	141	6.70	2.21	6.70	(1.9, 14.0)	140	6.98 (2.23)	-0.26	2.24	-0.50	(-8.6, 5.7)
	Week 48	134	7.01	2.25	6.80	(2.5, 17.5)	133	7.03 (2.24)	0.00	1.90	0.00	(-6.8, 6.9)
	Week 52	135	6.73	2.29	6.40	(2.4, 18.0)	134	7.04 (2.24)	-0.29	1.93	-0.15	(-5.5, 5.0)

表 2.7.4.9－79　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験／52 週）（続き）

Parameter:Lymphocytes/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	20.77	6.81	20.00	(6.5, 42.0)						
	Week 2	159	21.13	6.43	21.00	(5.5, 38.3)	159	20.59 (6.72)	0.53	4.34	0.90	(-14.0, 10.6)
	Week 4	156	21.23	6.47	20.85	(7.5, 39.0)	156	20.61 (6.74)	0.62	4.48	1.00	(-13.0, 16.5)
	Week 6	154	21.34	6.13	21.00	(7.0, 37.3)	154	20.57 (6.77)	0.76	4.67	0.85	(-12.1, 12.0)
	Week 8	151	20.81	6.24	20.90	(7.5, 36.0)	151	20.35 (6.63)	0.47	4.94	1.00	(-19.3, 10.0)
	Week 10	149	21.38	6.83	20.40	(7.5, 40.1)	149	20.33 (6.60)	1.05	5.35	1.70	(-19.4, 14.0)
	Week 12	147	21.43	6.62	21.10	(7.0, 39.3)	147	20.40 (6.61)	1.03	5.42	0.90	(-20.0, 14.9)
	Week 16	144	20.70	6.25	20.50	(7.0, 39.6)	144	20.56 (6.64)	0.14	5.25	0.00	(-13.0, 13.6)
	Week 20	139	20.10	6.36	20.00	(6.5, 42.9)	139	20.45 (6.70)	-0.34	5.60	0.00	(-17.2, 13.5)
	Week 24	137	19.16	6.35	19.10	(5.5, 37.1)	137	20.45 (6.68)	-1.29	4.96	-1.00	(-16.5, 11.5)
	Week 28	130	19.06	6.32	19.00	(6.0, 36.8)	130	20.39 (6.70)	-1.34	5.09	-1.15	(-14.5, 16.2)
	Week 32	132	19.48	6.15	18.90	(6.0, 44.0)	132	20.39 (6.71)	-0.90	5.38	-0.75	(-18.5, 11.6)
	Week 36	127	19.29	5.97	19.00	(6.9, 37.0)	127	20.41 (6.69)	-1.11	5.26	-0.40	(-19.2, 13.4)
	Week 40	125	19.13	6.20	18.10	(7.5, 38.9)	125	20.31 (6.77)	-1.18	5.64	-1.00	(-25.0, 16.3)
	Week 44	124	19.18	5.94	18.60	(5.5, 40.7)	124	20.27 (6.77)	-1.09	5.15	-1.25	(-22.3, 17.3)
	Week 48	123	18.93	6.24	18.00	(3.5, 39.6)	123	20.23 (6.57)	-1.29	5.48	-1.60	(-28.0, 18.5)
	Week 52	119	19.12	6.23	18.90	(5.5, 39.1)	119	20.08 (6.56)	-0.96	5.83	-0.80	(-15.8, 22.6)
darbepoetin	Baseline	160	21.15	6.02	21.00	(8.5, 42.6)						
	Week 2	159	20.46	5.53	20.00	(8.3, 35.5)	158	21.09 (6.03)	-0.73	4.25	-1.00	(-14.6, 10.5)
	Week 4	159	21.20	5.76	21.00	(8.3, 42.5)	158	21.10 (6.03)	0.04	4.08	-0.05	(-12.5, 12.7)
	Week 6	159	21.04	5.82	20.90	(8.0, 41.1)	158	21.10 (6.03)	-0.12	4.68	-0.05	(-12.9, 12.1)
	Week 8	157	21.36	5.86	21.00	(8.5, 38.5)	156	21.13 (6.05)	0.15	4.71	0.00	(-12.6, 18.5)
	Week 10	157	20.86	5.98	20.00	(8.6, 36.7)	156	21.16 (6.05)	-0.35	5.31	-0.30	(-17.3, 15.0)
	Week 12	157	20.75	5.80	20.10	(8.7, 37.8)	156	21.16 (6.05)	-0.46	5.10	-1.00	(-15.9, 14.5)
	Week 16	156	20.26	5.83	20.00	(6.0, 40.0)	155	21.14 (6.06)	-0.92	4.73	-1.00	(-13.0, 11.4)
	Week 20	154	19.66	6.26	19.00	(6.0, 36.9)	153	21.10 (6.08)	-1.48	4.79	-1.20	(-18.0, 11.6)
	Week 24	153	19.41	5.83	19.00	(6.7, 40.0)	152	21.13 (6.09)	-1.75	4.55	-1.65	(-14.0, 9.1)
	Week 28	150	19.70	7.07	18.10	(8.0, 55.4)	149	21.21 (6.05)	-1.49	5.42	-1.60	(-17.3, 24.5)
	Week 32	147	19.32	6.25	18.70	(8.5, 37.0)	146	21.34 (6.04)	-2.05	4.73	-2.25	(-17.5, 9.9)
	Week 36	143	19.42	6.11	19.00	(5.5, 39.0)	142	21.32 (6.08)	-1.93	4.96	-1.85	(-17.5, 10.1)
	Week 40	144	19.30	6.01	18.75	(7.0, 40.1)	143	21.30 (6.09)	-2.00	4.75	-1.50	(-13.3, 11.1)
	Week 44	141	19.75	6.61	19.00	(4.5, 44.0)	140	21.25 (6.02)	-1.56	4.98	-1.65	(-13.5, 15.1)
	Week 48	134	19.89	6.21	19.10	(6.5, 40.5)	133	21.27 (6.14)	-1.45	5.05	-2.00	(-12.5, 12.6)
	Week 52	135	20.38	6.37	19.00	(7.0, 39.9)	134	21.30 (6.13)	-0.99	4.84	-1.05	(-12.0, 11.5)