1. 死亡に至った有害事象の詳細

Patient ID: [redacted] - [redacted]				
Treatment Arm: Ravulizumab	Race: Japanese	Country: Japan	Sex: M	Age: 7[redacted]
Medical History [1]: IRON DEFICIENCY ANAEMIA, ATRIAL FIBRILLATION, ABDOMINAL DISCOMFORT, CONSTIPATION, SINUSITIS, DIABETES MELLITUS, HYPERLIPIDAEMIA, SHOULDER OPERATION, SHOULDER OPERATION, HYPERTENSION, LIPOMA, BENIGN PROSTATIC HYPERPLASIA, NERVE ROOT INJURY CERVICAL				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 127			
Concomitant Medication [3]: SITAGLIPTIN PHOSPHATE, FEXOFENADINE HYDROCHLORIDE, PARACETAMOL;TRAMADOL HYDROCHLORIDE, LUBIPROSTONE, EDOXABAN TOSILATE, ATORVASTATIN, FERROUS SODIUM CITRATE, LOSARTAN POTASSIUM, LANSOPRAZOLE, MINODRONIC ACID, CICLOSPORIN, PYRIDOSTIGMINE BROMIDE, PREDNISOLONE				
Non-Serious Adverse Event [4]: No Non-Serious Adverse Event recorded.				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
脳出血	CEREBRAL HEMORRHAGE	RCP Day 138/ Day 145	NR	NC	NONP; OTH: ＊Day 139 SURGICAL OPERATION	REC	Grade 4
脳出血	CEREBRAL HEMORRHAGE	RCP Day 145/ Day 145	NR	NC	N	FATL	Grade 5

治験責任医師の見解：「脳出血」（1 回目）は、入院のため重篤、治験薬に関連なしと判断した。「脳出血」（2 回目）は、死亡・入院・その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。

＊新薬承認情報提供時に置き換え

Patient ID:[redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: M	Age: 7[redacted]
Medical History [1]: ATRIAL SEPTAL DEFECT, EX-TOBACCO USER, OBESITY, HYPERLIPIDAEMIA, HYPERTENSION, POST HERPETIC NEURALGIA, DERMAL CYST, HERPES ZOSTER, LIPOMA, POLLAKIURIA, DISSEMINATED VARICELLA ZOSTER VIRUS INFECTION, SEBORRHOEIC KERATOSIS, PNEUMONIA, PICKWICKIAN SYNDROME, SLEEP APNOEA SYNDROME, MASS EXCISION, TINNITUS, VISUAL IMPAIRMENT, TINEA CRURIS, GLUCOSE TOLERANCE IMPAIRED, HELICOBACTER INFECTION, HAEMATURIA, CYSTOSCOPY, BREAST PAIN, RASH				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 184		
Concomitant Medication [3]: LISINOPRIL, SIMVASTATIN, TAMSULOSIN, ERYTHROMYCIN, DEXTROMETHORPHAN HYDROBROMIDE, PARACETAMOL, PREDNISONE, PYRIDOSTIGMINE, MYCOPHENOLATE MOFETIL				
Non-Serious Adverse Event [4]: ABDOMINAL PAIN, DIARRHOEA, ROAD TRAFFIC ACCIDENT, BALANCE DISORDER, BACK PAIN, COVID-19				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
COVID-19	COVID-19 INFECTION	OLE/ Day 204/ Day 216	NR	NA	MED; NONP	REC	Grade 3
COVID-19	COVID-19 INFECTION	OLE/ Day 216/ Day 216	NR	NA	N	FATL	Grade 5

治験責任医師の見解：「COVID-19」（1 回目）は、入院のため重篤、治験薬に関連なしと判断した。「COVID-19」（2 回目）は、死亡のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted] - [redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Czech Republic	Sex: M	Age: 5[redacted]
Medical History [1]: FOREARM FRACTURE, DIVERTICULUM, CHOLELITHIASIS, HEPATIC STEATOSIS, STEROID DIABETES, ARRHYTHMIA, PLEURISY, DIVERTICULITIS, TRAUMATIC FRACTURE, DRUG-INDUCED LIVER INJURY				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 127		
Concomitant Medication [3]: CALCIUM;COLECALCIFEROL, POTASSIUM CHLORIDE, OMEPRAZOLE, COLECALCIFEROL, CETIRIZINE HYDROCHLORIDE, AMIODARONE, CEFOTAXIME SODIUM, DEXAMETHASONE, NADROPARIN CALCIUM, REMDESIVIR, INSULIN, METOPROLOL, AMIKACIN, MEROPENEM, PYRIDOSTIGMINE, PREDNISONE, METHYLPREDNISOLONE				
Non-Serious Adverse Event [4]: PALPITATIONS, COVID-19, ATRIAL FIBRILLATION, DIABETES MELLITUS, URINARY TRACT INFECTION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
COVID-19 肺炎	COVID-19 PNEUMONIA	RCP/ Day 163/ Day 179	NR	WTHD	MED; NONP; OTH: HOSPITALI-ZATION IN OTHER HOSPITAL, INTUBATED	REC	Grade 4
ブドウ球菌性敗血症	SEPSIS (STAPHYLOCOC-CUS POSITIVE HEMOCUL-TURES)	RCP/ Day 178/ -	NR	NA	N	NORC	Grade 3
COVID-19 肺炎	COVID-19 PNEUMONIA	RCP/ Day 179/ Day 179	NR	NA	MED; NONP; OTH: HOSPITALI-ZATION IN OTHER HOSPITAL, INTUBATED	FATL	Grade 5

治験責任医師の見解：「COVID-19 肺炎」（1 回目）は、生命を脅かすもので、入院・その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。「ブドウ球菌性敗血症」は、生命を脅かすものであるため重篤、治験薬に関連なしと判断した。「COVID-19 肺炎」（2 回目）は、死亡のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: M	Age: 5[redacted]
Medical History [1]: SEASONAL ALLERGY, BLOOD CHOLESTEROL INCREASED, SLEEP APNOEA SYNDROME, HYPERTENSION, THYMECTOMY, ANXIETY, CATHETERISATION CARDIAC, ATRIAL FIBRILLATION, HYPERLIPIDAEMIA, AORTIC ARTERIOSCLEROSIS, OEDEMA PERIPHERAL, BRONCHITIS				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 310		
Concomitant Medication [3]: FLUTICASONE PROPIONATE, OLMESARTAN, ALPRAZOLAM, ACETYLSALICYLIC ACID, CALCIUM, COLECALCIFEROL, ATORVASTATIN, APIXABAN, DILTIAZEM HYDROCHLORIDE, LORATADINE, VITAMIN B12 NOS, POTASSIUM, FUROSEMIDE, AZITHROMYCIN, BENZONATATE, CODEINE PHOSPHATE;GUAIFENESIN, SALBUTAMOL SULFATE, OSELTAMIVIR, MYCOPHENOLATE MOFETIL, PREDNISONE, PYRIDOSTIGMINE BROMIDE				
Non-Serious Adverse Event [4]: INFLUENZA, BLOOD CREATININE INCREASED				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
COVID-19	COVID-19	OLE/ Day 357/ Day 378	NR	NC	NONP	REC	Grade 3
COVID-19	COVID-19 INFECTION	OLE/ Day 379/ Day 379	NR	NA	N	FATL	Grade 5

治験責任医師の見解：「COVID-19」（1 回目）は、入院のため重篤、治験薬に関連なしと判断した。「COVID-19」（2 回目）は、死亡・入院のため重篤、治験薬に関連なしと判断した。

F = female; M = male; MedDRA = Medical Dictionary for Regulatory Activities; OLE = Open-label extension period; PRE = prior to first study drug infusion; PT = preferred term; RCP = randomized-controlled period; USA = United States of America; WHO = World Health Organization.

Note: OLE begins at the start of Day 183 (Week 26) dosing. Starting with Week 26, placebo patients will begin receiving ravulizumab.

[1] Medical history preferred terms are coded using MedDRA version 24.0.

[2] Relative to the first study drug infusion.

[3] Medications are coded using WHO drug dictionary enhanced extended with the Herbal Dictionary version 'March 2021'.

[4] Adverse Event preferred terms are coded using MedDRA version 24.0.

[5] NR = Not Related; REL = Related.

[6] NC = Dose Not Changed; INT = Drug Interrupted; WTHD = Drug Withdrawn; NA = Not Applicable; UNK = Unknown.

[7] N = None; MED = Medication; NONP = Non-Pharmacologic Therapy/Procedure; OTH = Other.

[8] NORC = Not Recovered/Not Resolved; RCSQ = Recovered/Resolved with Sequelae; RCNG = Recovering/Resolving; REC = Recovered/Resolved; FATL = Fatal; UNK = Unknown.

2. その他の重篤な有害事象の詳細

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: F	Age: 7[redacted]
Medical History [1]: ECZEMA, RESTLESS LEGS SYNDROME, GALLBLADDER DISORDER, CHOLECYSTECTOMY, DEPRESSION, GASTROOESOPHAGEAL REFLUX DISEASE, HYSTERECTOMY, SUPRAVENTRICULAR TACHYCARDIA, DRUG HYPERSENSITIVITY, DRUG HYPERSENSITIVITY, DRUG HYPERSENSITIVITY, DIABETES MELLITUS, DIABETIC NEUROPATHY, HYPERLIPIDAEMIA, CATARACT OPERATION, HYPERTENSION, ANGINA PECTORIS, CORONARY ARTERY DISEASE, KNEE ARTHROPLASTY, DIARRHOEA, CORONARY ARTERY BYPASS				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 358		
Concomitant Medication [3]: PANTOPRAZOLE, DILTIAZEM, ROPINIROLE, HYDROCODONE BITARTRATE;PARACETAMOL, CALCIUM;COLECALCIFEROL, COLECALCIFEROL, ATORVASTATIN, ACETYLSALICYLIC ACID, MAGNESIUM, INSULIN ASPART, FAMOTIDINE, HYOSCYAMINE, METOPROLOL, POTASSIUM, ONDANSETRON, PYRIDOSTIGMINE, PREDNISONE, MYCOPHENOLATE MOFETIL				
Non-Serious Adverse Event [4]: DEAFNESS, BACK PAIN, NAUSEA, GASTROENTERITIS, HEADACHE, CHOKING, DYSPNOEA, ANGINA PECTORIS, BLEPHAROSPASM, MUSCULAR WEAKNESS, CHEST DISCOMFORT, DYSPNOEA EXERTIONAL				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
一過性脳虚血発作	TRANSIENT ISCHEMIC ATTACK	RCP/ Day 159/ Day 160	NR	NC	MED; NONP; OTH: PATIENT KEPT OVERNIGHT AT HOSPITAL FOR OBSERVA-TION	REC	Grade 3
悪心	NAUSEA	RCP/ Day 165/ Day 166	NR	NC	MED; OTH: ADMITTED OVERNIGHT FOR OBSERVA-TION	REC	Grade 3
非心臓性胸痛	NON CARDIAC CHEST PAIN	RCP/ Day 165/ Day 166	NR	NC	OTH: OVERNIGHT HOSPITAL STAY	REC	Grade 3

治験責任医師の見解：「一過性脳虚血発作」は、入院のため重篤、治験薬に関連なしと判断した。「悪心」は、入院のため重篤、治験薬に関連なしと判断した。「非心臓性胸痛」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Italy	Sex: F	Age: 7[redacted]
Medical History [1]: MENOPAUSE, HYPERCHOLESTEROLAEMIA, OSTEOPOROSIS, OSTEOPOROSIS, TENDON RUPTURE, CATARACT, DRY EYE, RETINAL ARTERY THROMBOSIS, CATARACT OPERATION, FLATULENCE, COGNITIVE DISORDER, OBSTRUCTIVE AIRWAYS DISORDER, CENTRAL VENOUS CATHETERISATION				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 368		
Concomitant Medication [3]: CETALKONIUM CHLORIDE;GLYCEROL;POLOXALCOL;TROMETAMOL HYDROCHLORIDE;TYLOXAPOL, HYALURONATE SODIUM, LANSOPRAZOLE, COLECALCIFEROL, CALCIUM CARBONATE, DENOSUMAB, EZETIMIBE, POTASSIUM CHLORIDE, BUDESONIDE, FLURBIPROFEN, SODIUM CHLORIDE, LOPERAMIDE, PROBIOTICS NOS, PARACETAMOL, SALICYLIC ACID;UREA, FUROSEMIDE, CLOTRIMAZOLE, PYRIDOSTIGMINE BROMIDE, PREDNISONE				
Non-Serious Adverse Event [4]: PROTEINURIA, PHARYNGITIS, ARTHRALGIA, HYPERKERATOSIS, PAIN IN EXTREMITY, NAUSEA, OEDEMA PERIPHERAL, HYPERTENSION, FUNGAL SKIN INFECTION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
ウイルス性胃腸炎	VIRAL GASTRO-ENTERITIS	RCP/ Day 79/ Day 84	NR	NC	MED	REC	Grade 3
皮膚有棘細胞癌	SPINOCELLULAR CARCINOMA IN SITU (LEFT SUBCLAVEAR SKIN)	RCP/ -/ Day 235	NR	NC	NONP	REC	Grade 2

治験責任医師の見解：「ウイルス性胃腸炎」は、入院のため重篤、治験薬に関連なしと判断した。「皮膚有棘細胞癌」は、その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: F	Age: 6[redacted]
Medical History [1]: URINARY TRACT INFECTION, CYSTOCELE, ANXIETY, POSTMENOPAUSE, SINUS OPERATION, APPENDICITIS, APPENDICECTOMY, THYMOMA, THYMECTOMY, HYPOTHYROIDISM, DEPRESSION, DRY EYE, FATIGUE, HYPERCHOLESTEROLAEMIA, SMALL FIBRE NEUROPATHY, CENTRAL VENOUS CATHETERISATION, ARTHRALGIA, BACK PAIN, NECK PAIN, LACTOSE INTOLERANCE, URINARY RETENTION, BRONCHIAL HYPERREACTIVITY, BLADDER CATHETERISATION, ARTHRALGIA, PANCREATIC CYST, CATARACT, VULVOVAGINAL DRYNESS, MEIBOMIAN GLAND DYSFUNCTION, CHALAZION, ROSACEA, CENTRAL VENOUS CATHETER REMOVAL, DERMATITIS, SLEEP APNOEA SYNDROME, SPINAL OSTEOARTHRITIS				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 358			
Concomitant Medication [3]: LEVOTHYROXINE, MACROGOL 400;PROPYLENE GLYCOL, ALPRAZOLAM, PROBIOTICS NOS, TILACTASE, MODAFINIL, KRILL OIL, ESTRADIOL, METRONIDAZOLE, DOXYCYCLINE, CARMELLOSE SODIUM, HYDROCORTISONE, VITAMIN B NOS, NAPROXEN SODIUM, NITROFURANTOIN, BENZONATATE, FLUTICASONE PROPIONATE, CEFTRIAXONE, SALBUTAMOL, CIPROFLOXACIN HYDROCHLORIDE, GUAIFENESIN, PYRIDOSTIGMINE BROMIDE, MYCOPHENOLATE MOFETIL				
Non-Serious Adverse Event [4]: HEADACHE, VACCINATION SITE PAIN, HEADACHE, HEADACHE, NAUSEA, DIARRHOEA, INCREASED APPETITE, HEADACHE, PAIN IN EXTREMITY, PAIN IN EXTREMITY, VERTIGO, NAUSEA, DEPRESSION, TINNITUS, ABDOMINAL PAIN, GLAUCOMA, ABDOMINAL PAIN, MUSCLE SPASMS, MUSCLE SPASMS, CHILLS, FREQUENT BOWEL MOVEMENTS, NON-CARDIAC CHEST PAIN, ECCHYMOSIS, SYNCOPE, MUSCULOSKELETAL STIFFNESS, URINARY TRACT INFECTION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
ウイルス性肺炎	VIRAL PNEUMONIA	OLE/ Day 317/ -	NR	NC	MED	REC	Grade 3
治験責任医師の見解：「ウイルス性肺炎」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: M	Age: 6[redacted]
Medical History [1]: ANKYLOSING SPONDYLITIS, HODGKIN'S DISEASE, SPLENECTOMY, TUMOUR EXCISION, THYMOMA, THYMECTOMY, HYPERTENSION, BELL'S PALSY, ARTHROSCOPY, ATRIAL FIBRILLATION, BRAIN NEOPLASM BENIGN, ANXIETY, CATARACT, CORNEAL SCAR, HERPES ZOSTER, CELLULITIS, MICTURITION URGENCY				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 365		
Concomitant Medication [3]: CLONIDINE, POTASSIUM CHLORIDE, ALPRAZOLAM, TAMSULOSIN, AMLODIPINE, VALSARTAN, DOXYCYCLINE, PARACETAMOL, CEFTRIAXONE, VANCOMYCIN, CEFDINIR, CIPROFLOXACIN, PYRIDOSTIGMINE BROMIDE, PREDNISONE, IMMUNOGLOBULINS NOS				
Non-Serious Adverse Event [4]: UPPER RESPIRATORY TRACT INFECTION, KIDNEY INFECTION, COUGH				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
RS ウイルス肺炎	PNEUMONIA DUE TO RESPIRATORY SYNCYTIAL VIRUS	RCP/ Day 88/ Day 92	NR	NC	MED	REC	Grade 3

治験責任医師の見解：「RS ウイルス肺炎」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: M	Age: 7[redacted]
Medical History [1]: ATRIAL FIBRILLATION, ATRIAL FIBRILLATION, GASTRIC ULCER, PEPTIC ULCER, GASTROENTERITIS, URINARY TRACT INFECTION, BLOOD CHOLESTEROL, DIABETES MELLITUS, GLUCOSE TOLERANCE IMPAIRED, HYPERLIPIDAEMIA, OBESITY, VITAMIN D DEFICIENCY, MALIGNANT MELANOMA, SKIN CANCER, ESSENTIAL TREMOR, ESSENTIAL TREMOR, NEPHROLITHIASIS, ASTHMA, SLEEP APNOEA SYNDROME, ECCHYMOSIS, OESOPHAGOGASTRIC FUNDOPLASTY, LEFT VENTRICULAR ENLARGEMENT, SINUS BRADYCARDIA, DIZZINESS, ATRIAL FIBRILLATION, BRADYCARDIA, CARDIAC PACEMAKER INSERTION, BRONCHITIS, BACK PAIN, OESOPHAGOGASTRIC FUNDOPLASTY, CORONARY ARTERY OCCLUSION, GASTROOESOPHAGEAL REFLUX DISEASE, OVARIAN CYST, DERMATITIS, DRUG ERUPTION, ARRHYTHMIA SUPRAVENTRICULAR, ANAEMIA VITAMIN B12 DEFICIENCY, VITAMIN B6 DECREASED, ATRIAL FIBRILLATION, ACTINIC KERATOSIS, ACTINIC KERATOSIS, ACTINIC KERATOSIS, ACTINIC KERATOSIS, PHOTODERMATOSIS, HYPERGLYCAEMIA				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 369		
Concomitant Medication [3]: ACETYLSALICYLIC ACID, CALCIUM CARBONATE;VITAMIN D NOS, FLUTICASONE PROPIONATE;SALMETEROL, METOPROLOL TARTRATE, PANTOPRAZOLE, ROSUVASTATIN, HEPARIN SODIUM, SODIUM CHLORIDE, PARACETAMOL, GLUCAGON, GLUCOSE, COLESTYRAMINE, METRONIDAZOLE, CEFUROXIME, NYSTATIN, AMOXICILLIN;CLAVULANATE POTASSIUM, PROBIOTICS NOS, CEFDINIR, OSELTAMIVIR PHOSPHATE, PHENOXYMETHYLPENICILLIN POTASSIUM, TRAMADOL, FUROSEMIDE, PYRIDOSTIGMINE, PREDNISONE				
Non-Serious Adverse Event [4]: DIARRHOEA HAEMORRHAGIC, COLONIC ABSCESS, WHITE BLOOD CELL COUNT INCREASED, SCROTAL DISORDER, FUNGAL SKIN INFECTION, PHARYNGITIS, INFLUENZA, ABDOMINAL PAIN, NEPHROLITHIASIS, OEDEMA PERIPHERAL				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
憩室炎	DIVERTICULITIS	RCP/ Day 19/ Day 477	NR	NC	MED	REC	Grade 3
治験責任医師の見解：「憩室炎」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: M	Age: 7[redacted]
Medical History [1]: CATARACT, DRY EYE, GLAUCOMA, CONSTIPATION, GASTROOESOPHAGEAL REFLUX DISEASE, INFLAMMATION, SEASONAL ALLERGY, HYPERCHOLESTEROLAEMIA, TYPE 2 DIABETES MELLITUS, BACK PAIN, NECK PAIN, OSTEOPOROSIS, SCIATICA, NEPHROLITHIASIS, BENIGN PROSTATIC HYPERPLASIA, RHINITIS ALLERGIC, HYPERTENSION, INTERVERTEBRAL DISC OPERATION, TINEA INFECTION				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 372		
Concomitant Medication [3]: BISACODYL, DENOSUMAB, DIPHENHYDRAMINE HYDROCHLORIDE, DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE, DOXAZOSIN MESILATE, EMPAGLIFLOZIN, FAMOTIDINE, GABAPENTIN, METFORMIN HYDROCHLORIDE, MONTELUKAST SODIUM, PIOGLITAZONE HYDROCHLORIDE, TAMSULOSIN HYDROCHLORIDE, ACETYLSALICYLIC ACID, CARMELLOSE SODIUM, BOSWELLIA SERRATA, ATENOLOL, ATORVASTATIN, PHENOXYMETHYLPENICILLIN POTASSIUM, CICLOPIROX, PREDNISONE, PYRIDOSTIGMINE BROMIDE, MYCOPHENOLATE MOFETIL, IMMUNOGLOBULINS NOS				
Non-Serious Adverse Event [4]: CONTUSION, TINEA PEDIS				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
嚥下障害	CLINICAL DETERIORATION - SWALLOWING ISSUES	RCP/ Day 115/ Day 118	REL	NC	MED	REC	Grade 3

治験責任医師の見解：「嚥下障害」は、入院のため重篤、治験薬に関連ありと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Germany	Sex: M	Age: 6[redacted]
Medical History [1]: HYPERCHOLESTEROLAEMIA, OBESITY, SLEEP APNOEA SYNDROME, DIABETIC FOOT, HYPERTENSION, DIABETES MELLITUS, CEREBRAL ISCHAEMIA, HEPATITIS TOXIC				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 15		
Concomitant Medication [3]: AMLODIPINE, COLECALCIFEROL, INSULIN GLARGINE, INSULIN LISPRO, IPRATROPIUM BROMIDE, CITRIC ACID;POTASSIUM BICARBONATE;POTASSIUM CITRATE, PANTOPRAZOLE, CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE, SALBUTAMOL, TORASEMIDE, INSULIN HUMAN, INSULIN DEGLUDEC, ACETYLSALICYLIC ACID, AMOXICILLIN;CLAVULANIC ACID, AMPICILLIN;SULBACTAM, ENOXAPARIN, PARACETAMOL, DEXAMETHASONE, REMDESIVIR, AMPICILLIN SODIUM;SULBACTAM SODIUM, SULFAMETHOXAZOLE;TRIMETHOPRIM, MYCOPHENOLATE MOFETIL, PYRIDOSTIGMINE BROMIDE, PREDNISONE, PREDNISOLONE				
Non-Serious Adverse Event [4]: COVID-19, ASYMPTOMATIC COVID-19, INFECTED SKIN ULCER				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
壊疽	WET GANGRENE AT THE RIGHT FOREFOOT	RCP/ Day 48/ Day 62	NR	NC	MED; NONP	REC	Grade 3
COVID-19 肺炎	COVID-19 PNEUMONIA	RCP/ Day 70/ Day 98	NR	NC	MED; NONP	REC	Grade 4
感染性皮膚潰瘍	INFECTED ULCER OF THE RIGHT FOREFOOT	RCP/ Day 105/ Day 120	NR	WTHD	MED; NONP	REC	Grade 3

治験責任医師の見解：「壊疽」は、入院のため重篤、治験薬に関連なしと判断した。「COVID-19 肺炎」は、入院のため重篤、治験薬に関連なしと判断した。「感染性皮膚潰瘍」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: Korean	Country: South Korea	Sex: F	Age: 3[redacted]
Medical History [1]: PNEUMONIA ASPIRATION, CATARACT, STEROID DIABETES, HYPERTENSION				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 71			
Concomitant Medication [3]: PIOGLITAZONE HYDROCHLORIDE, PERINDOPRIL ERBUMINE, PROPRANOLOL HYDROCHLORIDE, AMLODIPINE, ARTEMISIA ARGYI LEAF, ASTEMIZOLE, PARACETAMOL, CEFUROXIME AXETIL, PSEUDOEPHEDRINE HYDROCHLORIDE, REBAMIPIDE, STREPTODORNASE;STREPTOKINASE, ARGININE HYDROCHLORIDE;IBUPROFEN, CIMETIDINE, FLOMOXEF SODIUM, FAMOTIDINE, CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, KETOROLAC TROMETHAMINE, LEVODROPROPIZINE, TRAMADOL HYDROCHLORIDE, LIDOCAINE HYDROCHLORIDE, PANTOPRAZOLE SODIUM SESQUIHYDRATE, CALCIUM CARBONATE;COLECALCIFEROL, POTASSIUM CHLORIDE, PARACETAMOL;TRAMADOL HYDROCHLORIDE, CELECOXIB, KETOPROFEN, PYRIDOSTIGMINE BROMIDE, TACROLIMUS, PREDNISOLONE				
Non-Serious Adverse Event [4]: HEADACHE, INFLUENZA LIKE ILLNESS, RIB FRACTURE, DIARRHOEA, PLEURAL EFFUSION, MUSCULOSKELETAL CHEST PAIN, ACUTE KIDNEY INJURY, HYPOKALAEMIA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
労作性呼吸困難	DYSPNEA ON EXERTION	RCP/ Day 93/ Day 117	NR	NC	MED; NONP	REC	Grade 3
多発骨折	MULTIPLE BONE FRACTURE	RCP/ Day 117/ -	NR	NC	MED; NONP	NORC	Grade 2

治験責任医師の見解：「労作性呼吸困難」は、入院のため重篤、治験薬に関連なしと判断した。「多発骨折」は、永続的又は顕著な障害・機能不全に陥るものであるため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: Japanese	Country: Japan	Sex: M	Age: 4[redacted]
Medical History [1]: JAUNDICE, INTRAOCULAR PRESSURE INCREASED, DYSLIPIDAEMIA, INTERVERTEBRAL DISC PROTRUSION, THYMECTOMY, OSTEONECROSIS, EPILEPSY				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 183		
Concomitant Medication [3]: LOXOPROFEN SODIUM, ALENDRONATE SODIUM, PITAVASTATIN CALCIUM, MECOBALAMIN, REBAMIPIDE, VONOPRAZAN FUMARATE, CYANOCOBALAMIN, TIMOLOL MALEATE, HYALURONATE SODIUM, PARACETAMOL, ROPIVACAINE HYDROCHLORIDE, DICLOFENAC SODIUM, PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, LIDOCAINE, IMMUNOGLOBULIN HUMAN NORMAL, CEFAZOLIN SODIUM, CEFALEXIN, LOXOPROFEN, TACROLIMUS, PREDNISOLONE				
Non-Serious Adverse Event [4]: DIARRHOEA, ALANINE AMINOTRANSFERASE INCREASED, ASPARTATE AMINOTRANSFERASE INCREASED, GAMMA-GLUTAMYLTRANSFERASE INCREASED, DIARRHOEA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
腱炎	SUPPURATIVE TENDONITIS	RCP/ Day 62/ Day 127	REL	NC	MED; NONP	REC	Grade 3
治験責任医師の見解：「腱炎」は、入院のため重篤、治験薬に関連ありと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: Japanese	Country: Japan	Sex: F	Age: 5[redacted]
Medical History [1]: IRON DEFICIENCY ANAEMIA, CONSTIPATION, DYSPEPSIA, DRUG HYPERSENSITIVITY, IODINE ALLERGY, RUBBER SENSITIVITY, HEPATITIS B, DYSLIPIDAEMIA, OSTEOPOROSIS, RHEUMATOID ARTHRITIS, DEPRESSION, HYPERTENSION, THYMECTOMY, HYPERPLASTIC CHOLECYSTOPATHY, ORAL NEOPLASM, UTERINE CANCER, HYSTERECTOMY, CATARACT OPERATION				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 184		
Concomitant Medication [3]: AMLODIPINE BESILATE, CELECOXIB, DIASTASE;GENTIANA LUTEA;SODIUM BICARBONATE, VENLAFAXINE HYDROCHLORIDE, FOLIC ACID, TERIPARATIDE, MECOBALAMIN, METHOTREXATE, TANDOSPIRONE CITRATE, CLOSTRIDIUM BUTYRICUM, VONOPRAZAN FUMARATE, ASPARTATE CALCIUM, NUTRIENTS NOS, MAGNESIUM OXIDE, POTASSIUM ASPARTATE, GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, ROMOSOZUMAB, LEVOFLOXACIN, TRIAMCINOLONE ACETONIDE, SACCHARATED IRON OXIDE, ROSUVASTATIN CALCIUM, PYRIDOSTIGMINE BROMIDE, PREDNISOLONE, TACROLIMUS				
Non-Serious Adverse Event [4]: DEHYDRATION, RETINAL VEIN OCCLUSION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
結節性変形性関節症	HEBERDEN'S NODE	RCP/ -/ -	NR	NC	MED; NONP	RCNG	Grade 2

治験責任医師の見解：「結節性変形性関節症」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]				
Treatment Arm: Ravulizumab	Race: Korean	Country: South Korea	Sex: F	Age: 6[redacted]
Medical History [1]: MENOPAUSE, THYMECTOMY, AUTOIMMUNE HEPATITIS, AUTOIMMUNE THYROIDITIS, HYPERLIPIDAEMIA, THYROID ADENOMA, NORMAL TENSION GLAUCOMA, VIRAL HEPATITIS CARRIER, THYMECTOMY, SEBORRHOEIC KERATOSIS, OSTEOPOROSIS, ORAL HERPES, MALACOPLAKIA				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 279			
Concomitant Medication [3]: TRAVOPROST, CARMELLOSE SODIUM, LANSOPRAZOLE, ALENDRONATE SODIUM;COLECALCIFEROL, ACICLOVIR, MIRABEGRON, SULFAMETHOXAZOLE;TRIMETHOPRIM, CEFPODOXIME PROXETIL, PROPACETAMOL HYDROCHLORIDE, PARACETAMOL, LACTOBACILLUS ACIDOPHILUS, LEVOFLOXACIN, ITOPRIDE HYDROCHLORIDE, BUPIVACAINE HYDROCHLORIDE;GLUCOSE, DEXMEDETOMIDINE HYDROCHLORIDE, CEFTRIAXONE, GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE, ALANINE;ARGININE;CALCIUM CHLORIDE;FISH OIL;GLUCOSE MONOHYDRATE;GLYCINE;GLYCINE MAX SEED OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;MAGNESIUM SULFATE;MEDIUM-CHAIN TRIGLYCERID, ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORIDE;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FATS NOS;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORU, ALANINE;ARGININE HYDROCHLORIDE;ASPARAGINE;CYSTEINE;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TYROSINE;V, ASCORBIC ACID;BIOTIN;CALCIUM CITRATE;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FERROUS SULFATE;FIBRE,DIETARY;FOLIC ACID;GLYCINE MAX SEED OIL;MAGNESIUM CARBONATE;MALTODEXTRIN;NICOTINA, RABEPRAZOLE SODIUM, ZOLEDRONIC ACID, AMBROXOL HYDROCHLORIDE, ERTAPENEM SODIUM, ACETYLCYSTEINE, CALCIUM GLUCONATE, FISH OIL;GLYCINE MAX SEED OIL;OLEA EUROPAEA OIL;TRIGLYCERIDES, ALBUMIN HUMAN, PHENIRAMINE, ETOMIDATE, REMIFENTANIL HYDROCHLORIDE, AMBROXOL, FLUMAZENIL, CIMETROPIUM BROMIDE, FAMOTIDINE, LIDOCAINE HYDROCHLORIDE, MIDAZOLAM, PETHIDINE HYDROCHLORIDE, IPRATROPIUM BROMIDE, LAFUTIDINE, VANCOMYCIN HYDROCHLORIDE, ESOMEPRAZOLE MAGNESIUM DIHYDRATE, COPTIS SPP. RHIZOME;HEDERA HELIX LEAF, TACROLIMUS, PREDNISOLONE, IMMUNOGLOBULINS NOS				
Non-Serious Adverse Event [4]: URINARY TRACT INFECTION, WHITE BLOOD CELL COUNT DECREASED, ALANINE AMINOTRANSFERASE INCREASED, C-REACTIVE PROTEIN INCREASED, GAMMA-GLUTAMYLTRANSFERASE INCREASED, URETERAL NEOPLASM, PNEUMONIA ASPIRATION, URINARY TRACT INFECTION, URETERAL NEOPLASM, DYSPNOEA, NON-CARDIAC CHEST PAIN, PYELONEPHRITIS CHRONIC, PRODUCTIVE COUGH, URTICARIA, CLOSTRIDIUM DIFFICILE INFECTION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
尿管新生物	R/O LEFT UPPER URETER CANCER	RCP/ Day 57/ Day 59	NR	NC	MED; NONP	REC	Grade 3
呼吸困難	DYSPNEA	RCP/ Day 96/ Day 101	NR	NC	MED; NONP	REC	Grade 3
胸痛	CHEST PAIN	OLE/ Day 187/ Day 189	NR	NC	NONP	REC	Grade 1

治験責任医師の見解：「尿管新生物」は、入院のため重篤、治験薬に関連なしと判断した。「呼吸困難」は、入院のため重篤、治験薬に関連なしと判断した。「胸痛」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: Korean	Country: South Korea	Sex: F	Age: 6[redacted]
Medical History [1]: HYPERLIPIDAEMIA, TYPE 2 DIABETES MELLITUS, HYPOTHYROIDISM, PANCREATIC CYST, HEPATIC STEATOSIS, RASH, HYPERTENSION, GASTRIC POLYPS, CYSTOCELE, HYSTEROCELE, OVARIAN CYST, RECTOCELE, UROGENITAL PROLAPSE, UTERINE PROLAPSE, THYROID MASS, PAPILLOMA VIRAL INFECTION, HYSTERECTOMY, MUSCLE SPASMS				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 364		
Concomitant Medication [3]: LINAGLIPTIN, OMEGA-3-ACID ETHYL ESTER, LEVOTHYROXINE SODIUM, ATORVASTATIN CALCIUM, AMLODIPINE CAMSILATE;LOSARTAN POTASSIUM, GLIMEPIRIDE, CLONAZEPAM, METFORMIN HYDROCHLORIDE, ESOMEPRAZOLE MAGNESIUM, CALCIUM CARBONATE, ACICLOVIR, MUPIROCIN, REBAMIPIDE, PANTOPRAZOLE SODIUM SESQUIHYDRATE, VALACICLOVIR HYDROCHLORIDE, TRAMADOL, PARACETAMOL;TRAMADOL HYDROCHLORIDE, ANAGLIPTIN, BROMFENAC SODIUM, LEVOFLOXACIN, PREDNISOLONE ACETATE, BLOOD,CALF,DEPROT.,LMW PORTION, PARACETAMOL, KETOROLAC TROMETHAMINE, MOSAPRIDE CITRATE, MAGNESIUM HYDROXIDE, ACHILLEA MILLEFOLIUM;ACONITUM NAPELLUS;ARNICA MONTANA;ATROPA BELLADONNA;BELLIS PERENNIS;CALCIUM SULFIDE;CALENDULA OFFICINALIS;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;H, DICLOFENAC DEANOL, BUPRENORPHINE, DIOSMECTITE, DEXPANTHENOL, MYCOPHENOLATE MOFETIL, PYRIDOSTIGMINE BROMIDE, PREDNISOLONE				
Non-Serious Adverse Event [4]: ABDOMINAL DISCOMFORT, CATARACT, GASTRITIS, BREAST MASS, CATARACT				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
帯状疱疹	HERPES ZOSTER	RCP/ Day 99/ Day 106	NR	NC	MED	REC	Grade 3
白内障	OTHER SENILE CATARACT, RIGHT	OLE/ Day 302/ Day 303	NR	NC	MED; NONP	REC	Grade 2
腰椎骨折	FRACTURE OF L1 LEVEL, CLOSED	OLE/ Day 318/ Day 348	NR	NC	MED; NONP	REC	Grade 2

治験責任医師の見解：「帯状疱疹」は、入院のため重篤、治験薬に関連なしと判断した。「白内障」は、入院のため重篤、治験薬に関連なしと判断した。「腰椎骨折」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: Japanese	Country: Japan	Sex: M	Age: 5[redacted]
Medical History [1]: HEPATIC STEATOSIS, DYSLIPIDAEMIA, STEROID DIABETES, THYMUS ENLARGEMENT, MUSCLE SPASMS				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 184			
Concomitant Medication [3]: LIRAGLUTIDE, GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT, SULFAMETHOXAZOLE;TRIMETHOPRIM, ALENDRONATE SODIUM, METFORMIN HYDROCHLORIDE, ROSUVASTATIN, INSULIN LISPRO, INSULIN GLARGINE, ESOMEPRAZOLE MAGNESIUM, EFINACONAZOLE, LULICONAZOLE, BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS, GLUCOSE, INFLUENZA VACCINE, PREDNISOLONE, AMBENONIUM CHLORIDE, TACROLIMUS				
Non-Serious Adverse Event [4]: ANGULAR CHEILITIS, STEROID DIABETES, DERMATOPHYTOSIS OF NAIL, TINEA PEDIS, DIARRHOEA, STEROID DIABETES, HYPOGLYCAEMIA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
ステロイド糖尿病	WORSENING OF STEROID DIABETES	RCP/ Day 10/ Day 24	NR	NC	MED	REC	Grade 3
治験責任医師の見解：「ステロイド糖尿病」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: M	Age: 6[redacted]
Medical History [1]: FEMUR FRACTURE, HYPERLIPIDAEMIA, INTERVERTEBRAL DISC OPERATION, HYPERTENSION, BASILAR ARTERY ANEURYSM, ANEURYSM REPAIR, CEREBROVASCULAR ACCIDENT				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 364			
Concomitant Medication [3]: ALTEPLASE, AMLODIPINE, CALCIUM;VITAMIN D NOS, IRON, LISINOPRIL, THIAMINE, ACETYLSALICYLIC ACID, CLOPIDOGREL BISULFATE, AZITHROMYCIN, COLCHICINE, BACLOFEN, HEPARIN, VANCOMYCIN, ENOXAPARIN, SULFAMETHOXAZOLE;TRIMETHOPRIM, CEFTRIAXONE, PYRIDOSTIGMINE BROMIDE, PREDNISONE				
Non-Serious Adverse Event [4]: FALL, SWELLING OF EYELID, INFUSION SITE EXTRAVASATION, GOUT, NECK PAIN, ROTATOR CUFF SYNDROME, OSTEOARTHRITIS, HEMIPARESIS, FATIGUE, INFUSION SITE EXTRAVASATION, WOUND				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
細菌性関節炎	SEPTIC ARTHRITIS OF RIGHT WRIST	RCP/ Day 112/ Day 133	NR	INT	MED; NONP	REC	Grade 4

治験責任医師の見解：「細菌性関節炎」は、先天異常を来すもので、その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Germany	Sex: M	Age: 6[redacted]
Medical History [1]: HYPOACUSIS, GAMMOPATHY, HYPERTENSION, THYROIDECTOMY, CROHN'S DISEASE, ATRIAL FIBRILLATION, BUNDLE BRANCH BLOCK LEFT				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 365			
Concomitant Medication [3]: LEVOTHYROXINE SODIUM, APIXABAN, ACICLOVIR, CARVEDILOL, SACUBITRIL VALSARTAN SODIUM HYDRATE, AMIODARONE, EPLERENONE, METOPROLOL, PYRIDOSTIGMINE BROMIDE, MYCOPHENOLATE MOFETIL				
Non-Serious Adverse Event [4]: ORAL HERPES, FATIGUE, PRURITUS, SYNCOPE, HAEMATOMA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
うっ血性心筋症	DILATED CARDIO-MYOPATHY	RCP/ Day 162/ -	NR	NC	MED; NONP	RCNG	Grade 3
失神	SYNCOPE	RCP/ Day 162/ Day 171	NR	NC	MED; NONP	REC	Grade 3
治験責任医師の見解：「うっ血性心筋症」は、入院のため重篤、治験薬に関連なしと判断した。「失神」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: USA	Sex: M	Age: 6[redacted]
Medical History [1]: SEASONAL ALLERGY, TONSILLITIS, ASTHMA, TONSILLECTOMY, CHRONIC SINUSITIS, OBESITY, SLEEP APNOEA SYNDROME, BACK PAIN, NECK PAIN, LUMBAR RADICULOPATHY, CORONARY ARTERY DISEASE, OEDEMA PERIPHERAL, CARPAL TUNNEL SYNDROME, HEADACHE, ACUTE KIDNEY INJURY, PRURITUS, RASH, CARDIAC FAILURE CONGESTIVE, MYOCARDIAL INFARCTION, GASTROOESOPHAGEAL REFLUX DISEASE, NAUSEA, HYPERLIPIDAEMIA, STENT PLACEMENT, HYPERTENSION, PAIN IN EXTREMITY, VASCULAR CATHETERISATION, AMNESIA, OESOPHAGOGASTRODUODENOSCOPY, SEIZURE, CONSTIPATION, FUNCTIONAL GASTROINTESTINAL DISORDER, OBSTRUCTIVE AIRWAYS DISORDER				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 182			
Concomitant Medication [3]: LORATADINE, ACETYLSALICYLIC ACID, CARVEDILOL, FUROSEMIDE, LACOSAMIDE, ROSUVASTATIN, CEFALEXIN, PYRIDOSTIGMINE BROMIDE, MYCOPHENOLATE MOFETIL, PREDNISONE				
Non-Serious Adverse Event [4]: GLUCOSE URINE PRESENT, PROTEIN URINE PRESENT, RETICULOCYTE COUNT INCREASED, RED BLOOD CELL COUNT DECREASED, ABDOMINAL PAIN, DIARRHOEA, ASTHENIA, FATIGUE, DYSPNOEA, FATIGUE				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
全身健康状態悪化	GENERAL PHYSICAL HEALTH DETERIORATION	RCP/ Day 150/ Day 163	NR	NC	MED	REC	Grade 3
無力症	GENERALIZED WEAKNESS	RCP/ Day 150/ Day 163	NR	NC	N	REC	Grade 3

治験責任医師の見解：「全身健康状態悪化」は、その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。「無力症」は、永続的又は顕著な障害・機能不全に陥るもの・その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Czech Republic	Sex: F	Age: 4[redacted]
Medical History [1]: ALLERGY TO CHEMICALS, DRUG HYPERSENSITIVITY, THYMECTOMY, DYSLIPIDAEMIA, HYPERTENSION, ANAEMIA, CATARACT, KNEE ARTHROPLASTY, CHOLECYSTECTOMY, OSTEOTOMY				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 185		
Concomitant Medication [3]: DROSPIRENONE;ETHINYLESTRADIOL BETADEX, OMEPRAZOLE, CALCIUM CARBONATE, INDAPAMIDE;PERINDOPRIL ARGININE, ROSUVASTATIN CALCIUM, FERROUS SULFATE, TRIMECAINE HYDROCHLORIDE, ACETYLSALICYLIC ACID;GLYCINE, NIFURATEL;NYSTATIN, PYRIDOSTIGMINE BROMIDE, CICLOSPORIN, METHYLPREDNISOLONE				
Non-Serious Adverse Event [4]: VAGINAL INFECTION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
一過性脳虚血発作	TRANSIENT ISCHEMIC ATTACK ARTERIA CAROTIS INTERNA SIN.	RCP/ Day 17/ Day 17	NR	NC	MED; NONP	REC	Grade 2

治験責任医師の見解：「一過性脳虚血発作」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Germany	Sex: F	Age: 6[redacted]
Medical History [1]: ASTHMA, NEPHROLITHIASIS, ABDOMINAL PAIN UPPER, GLUCOSE TOLERANCE IMPAIRED, HYPERLIPIDAEMIA, CEREBROVASCULAR ACCIDENT, HYPERTENSION, MENOPAUSE, PERICARDIAL EFFUSION				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 183		
Concomitant Medication [3]: BECLOMETASONE DIPROPIONATE, FLUNISOLIDE, CROMOGLICIC ACID;REPROTEROL, SALBUTAMOL, ACETYLSALICYLIC ACID, PANTOPRAZOLE, SIMVASTATIN, VALSARTAN, SPIRONOLACTONE, PIRETANIDE, CHLORMADINONE, CEFTRIAXONE SODIUM, CODEINE PHOSPHATE, PREDNISONE, POTASSIUM CITRATE, MYCOPHENOLATE MOFETIL, PYRIDOSTIGMINE BROMIDE				
Non-Serious Adverse Event [4]: LUNG INFILTRATION, MENOPAUSAL DISORDER, PATHOGEN RESISTANCE, HYPERTHYROIDISM, PNEUMONIA, HYPOKALAEMIA, LUNG INFILTRATION, URINARY RETENTION, LUNG INFILTRATION, EAR PAIN, DEAFNESS UNILATERAL, EAR DISCOMFORT				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
肺浸潤	CHRONIC INFLAMMATORY ENCAPSULATED LUNG INFILTRATION	RCP/ Day 64/ Day 77	NR	NC	MED	REC	Grade 2

治験責任医師の見解：「肺浸潤」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Ravulizumab	Race: White	Country: Denmark	Sex: M	Age: 7[redacted]
Medical History [1]: CORNEAL PERFORATION, HYDROCELE, DEAFNESS NEUROSENSORY, ABDOMINAL PAIN, TOXICITY TO VARIOUS AGENTS, SUICIDE ATTEMPT, CHOLELITHIASIS, PANCREATITIS ACUTE, MUSCLE SPASMS, OSTEOPOROSIS, INGUINAL HERNIA REPAIR, ARTHRALGIA, ROTATOR CUFF SYNDROME, MESENTERIC ARTERY THROMBOSIS, POLYNEUROPATHY, ANAEMIA VITAMIN B12 DEFICIENCY, DEPRESSION, CATARACT, ASTIGMATISM, HAEMATOMA, UMBILICAL HERNIA REPAIR, INGUINAL HERNIA REPAIR, LIPOMA, LIPOMA				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 181		
Concomitant Medication [3]: ATROPINE SULFATE, ESOMEPRAZOLE, CALCIUM;COLECALCIFEROL, BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE, ACETYLSALICYLIC ACID, ATORVASTATIN CALCIUM, MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE, HYDROXOCOBALAMIN, FUROSEMIDE, COLECALCIFEROL, PARACETAMOL, CALCIUM CARBONATE;CALCIUM LACTATE GLUCONATE, PIVMECILLINAM HYDROCHLORIDE, HYDROCHLOROTHIAZIDE, METFORMIN, DICLOXACILLIN, GABAPENTIN, TRAMADOL, BISACODYL, DIAZEPAM, TOZINAMERAN, AZATHIOPRINE, PREDNISOLONE, PYRIDOSTIGMINE BROMIDE, IMMUNOGLOBULIN HUMAN NORMAL				
Non-Serious Adverse Event [4]: URINARY TRACT INFECTION, DIABETES MELLITUS, PYREXIA, CELLULITIS, CONSTIPATION, OEDEMA PERIPHERAL, PAIN IN EXTREMITY				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
視力障害	IMPAIRED VISION BILATERALLY	RCP/ Day 90/ Day 98	NR	NC	N	REC	Grade 3
椎間板突出	DISC HERNIATION AT L2 / L3 LEVEL ON THE LEFT SIDE	RCP/ Day 98/ -	NR	NC	MED; NONP	NORC	Grade 3
重症筋無力症クリーゼ	MG CRISIS	RCP/ Day 105/ Day 112	NR	NC	MED	REC	Grade 3
自殺企図	ATTEMPTED SUICIDE	RCP/ Day 122/ Day 132	NR	NC	NONP	REC	Grade 3

治験責任医師の見解：「視力障害」は、入院のため重篤、治験薬に関連なしと判断した。「椎間板突出」は、入院のため重篤、治験薬に関連なしと判断した。「重症筋無力症クリーゼ」は、入院のため重篤、治験薬に関連なしと判断した。「自殺企図」は、入院・生命を脅かすものであるため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]							
Treatment Arm: Placebo		Race: White		Country: Germany	Sex: F	Age: 4[redacted]	
Medical History [1]: DIABETIC RETINOPATHY, DIABETIC NEUROPATHY, DIABETIC NEPHROPATHY, ECZEMA, TYPE 1 DIABETES MELLITUS, DEPRESSION, AUTOIMMUNE THYROIDITIS, HYPERTENSION, THYMECTOMY, APLASTIC ANAEMIA, VITREOUS HAEMORRHAGE, VITREOUS HAEMORRHAGE							
Treatment First Dose Day [2]: Day 1			Last Dose Day [2]: Day 1				
Concomitant Medication [3]: INSULIN ASPART, VENLAFAXINE HYDROCHLORIDE, METOPROLOL SUCCINATE, URAPIDIL, LERCANIDIPINE, FUROSEMIDE, PANTOPRAZOLE, LEVOTHYROXINE, MOXONIDINE, CANDESARTAN, ERYTHROPOIETIN, DIMETINDENE MALEATE, FOLIC ACID, SODIUM BICARBONATE, PYRIDOSTIGMINE BROMIDE, IMMUNOGLOBULINS NOS							
Non-Serious Adverse Event [4]: No Non-Serious Adverse Event recorded.							
Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
注入に伴う反応	INFUSION REACTION	RCP/ Day 1/ Day 1	REL	WTHD	MED; OTH: WITH-DRAWAL OF IP,MEDICA-TION WITH DIMETINDEN 4MG IV	REC	Grade 3
腎不全	RENAL FAILURE	RCP/ Day 20/ -	NR	NA	MED	NORC	Grade 3
治験責任医師の見解：「注入に伴う反応」は、その他の医学的に重要であるため重篤、治験薬に関連ありと判断した。「腎不全」は、その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: F	Age: 6[redacted]
Medical History [1]: URINARY INCONTINENCE, MENOPAUSE, ANXIETY, ATTENTION DEFICIT HYPERACTIVITY DISORDER, DEPRESSION, INSOMNIA, OBSESSIVE-COMPULSIVE DISORDER, GASTROOESOPHAGEAL REFLUX DISEASE, MENINGITIS ASEPTIC, THYMECTOMY, OSTEOPENIA, THROMBOCYTOPENIA, CATARACT NUCLEAR, CATARACT, DRY EYE, GLAUCOMA, OPEN ANGLE GLAUCOMA, NEPHROLITHIASIS, UPPER LIMB FRACTURE, JOINT ARTHROPLASTY, CONSTIPATION, URINARY TRACT INFECTION, HIATUS HERNIA				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 361		
Concomitant Medication [3]: HYPROMELLOSE, CICLOSPORIN, CALCIUM;COLECALCIFEROL, ERGOCALCIFEROL, VITAMINS NOS, PANTOPRAZOLE, ZOLPIDEM, GUAIFENESIN, METHYLPHENIDATE, ESTRADIOL, FLUTICASONE, MONTELUKAST, NITROFURANTOIN, MACROGOL, MIRABEGRON, TRIMETHOPRIM, SALBUTAMOL, CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, ERYTHROMYCIN, PREDNISONE, VALACICLOVIR, OTHER OPHTHALMOLOGICALS, MACROGOL 3350, MYCOPHENOLATE MOFETIL				
Non-Serious Adverse Event [4]: URINARY TRACT INFECTION, COUGH, DYSPNOEA, COUGH, RASH, DIPLOPIA, EYE MOVEMENT DISORDER, DIPLOPIA, VISION BLURRED, PHOTOPHOBIA, EYELID PTOSIS, POLLAKIURIA, CONSTIPATION, HYPOAESTHESIA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
帯状疱疹	HERPES ZOSTER	RCP/ Day 126/ Day 135	REL	INT	MED; OTH: EMERGENCY DEPARTMENT VISIT	REC	Grade 3

治験責任医師の見解：「帯状疱疹」は、その他の医学的に重要であるため重篤、治験薬に関連ありと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: Italy	Sex: F	Age: 5[redacted]
Medical History [1]: OSTEOPOROSIS, THYMOMA, THYMECTOMY, ARRHYTHMIA SUPRAVENTRICULAR, SPINAL FRACTURE, LUMBAR HERNIA, CATARACT, RHEUMATOID ARTHRITIS, DYSLIPIDAEMIA, URINARY INCONTINENCE, MENOPAUSE, DIABETES MELLITUS, INFLUENZA LIKE ILLNESS				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 372		
Concomitant Medication [3]: CALCIUM CARBONATE, CALCIUM CARBONATE;COLECALCIFEROL, DENOSUMAB, ESTERS OF UNSATURATED FATTY ACIDS, TORASEMIDE, LANSOPRAZOLE, EZETIMIBE, ASTAXANTHIN;FOLIC ACID;MONASCUS PURPUREUS;POLICOSANOL;UBIDECARENONE, COLECALCIFEROL, VILDAGLIPTIN, BECLOMETASONE DIPROPIONATE, AMBROXOL HYDROCHLORIDE, PARACETAMOL, METHOTREXATE, FOLIC ACID, ENOXAPARIN, PREDNISONE				
Non-Serious Adverse Event [4]: PAIN IN EXTREMITY, ASTHENIA, ASTHENIA, PAIN IN EXTREMITY, PAIN IN EXTREMITY, PSORIATIC ARTHROPATHY				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
膝蓋骨骨折	RIGHT PATELLA FRACTURE DUE TO ACCIDENTAL FALL	OLE/ Day 282/ Day 323	NR	NC	NONP	REC	Grade 3

治験責任医師の見解：「膝蓋骨骨折」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: Denmark	Sex: F	Age: 7[redacted]
Medical History [1]: TONSILLECTOMY, BREAST CANCER, MASTECTOMY, HYSTERECTOMY, BLOOD CALCIUM DECREASED, HYPERTENSION, FLUID RETENTION, VERTIGO, HYPOTHYROIDISM				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 181		
Concomitant Medication [3]: POTASSIUM CHLORIDE, ATROPINE SULFATE, CANDESARTAN, FUROSEMIDE, LEVOTHYROXINE SODIUM, SODIUM CHLORIDE, CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE, GLUCOSE;POTASSIUM;SODIUM, TOZINAMERAN, AZATHIOPRINE, PYRIDOSTIGMINE BROMIDE				
Non-Serious Adverse Event [4]: HEADACHE, ALOPECIA, COVID-19, CONFUSIONAL STATE, WHITE BLOOD CELL COUNT DECREASED, DEHYDRATION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
COVID-19	COVID-19	RCP/ Day 95/ Day 98	NR	NC	N	REC	Grade 3

治験責任医師の見解：「COVID-19」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: Other	Country: Canada	Sex: M	Age: 8[redacted]
Medical History [1]: INGUINAL HERNIA REPAIR, HYPERCHOLESTEROLAEMIA, NEPHROLITHIASIS, HYPOTHYROIDISM, THYROIDECTOMY, BENIGN PROSTATIC HYPERPLASIA, AORTIC STENOSIS, AORTIC VALVE REPAIR, HYPERTENSION, OEDEMA PERIPHERAL, OSTEOPOROSIS, RALES, DIVERTICULITIS, INTERVERTEBRAL DISC DEGENERATION, PERIPHERAL SWELLING				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 183		
Concomitant Medication [3]: DOXAZOSIN, ACETYLSALICYLIC ACID, LEVOTHYROXINE SODIUM, ATORVASTATIN, VITAMIN D NOS, PERINDOPRIL, RISEDRONATE SODIUM, FUROSEMIDE, SPIRONOLACTONE, NITROFURANTOIN, PYRIDOSTIGMINE BROMIDE, PREDNISONE				
Non-Serious Adverse Event [4]: URINARY TRACT INFECTION, CHOLELITHIASIS, RENAL CYST, CONTUSION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
脊柱管狭窄症	SPINAL STENOSIS SECONDARY TO DEGENERATIVE DISC DISEASE	RCP/ Day 12/ -	NR	NC	NONP; OTH: STILL UNDER INVESTI-GATION AT THE HOSPITAL	NORC	Grade 3
治験責任医師の見解：「脊柱管狭窄症」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: M	Age: 5[redacted]
Medical History [1]: CORONARY ARTERY DISEASE, NONALCOHOLIC FATTY LIVER DISEASE, NEUROPATHY PERIPHERAL, TONSILLECTOMY, SPINAL FUSION SURGERY, DIABETES MELLITUS, ANXIETY				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 253			
Concomitant Medication [3]: ACETYLSALICYLIC ACID, METFORMIN, ALPRAZOLAM, UBIQUINOL, INSULIN GLARGINE, INSULIN LISPRO, FUROSEMIDE, INFLUENZA VACCINE, AMOXICILLIN, OSELTAMIVIR PHOSPHATE, IBUPROFEN, BENZONATATE, GUAIFENESIN, OMEPRAZOLE, CEFTRIAXONE SODIUM, VANCOMYCIN, SULFAMETHOXAZOLE;TRIMETHOPRIM, PREDNISONE, IMMUNOGLOBULINS NOS				
Non-Serious Adverse Event [4]: NAUSEA, FAECES SOFT, HEADACHE, FALL, NAUSEA, VOMITING, SEIZURE, DIABETES MELLITUS, INFLUENZA LIKE ILLNESS, HAEMOPTYSIS, COUGH, HEADACHE, SINUS CONGESTION, CONSTIPATION, DIARRHOEA, OEDEMA PERIPHERAL, UPPER RESPIRATORY TRACT INFECTION, FALL				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
重症筋無力症	MYASTHENIA GRAVIS EXACERBATION	RCP/ Day 93/ Day 96	NR	NC	MED	REC	Grade 3
COVID-19 の疑い	SUSPECTED COVID-19	OLE/ Day 267/ -	NR	NC	MED; NONP; OTH: ADMITTED	REC	Grade 4
発熱	FEVER	OLE/ Day 295/ -	NR	NC	MED; NONP; OTH: ADMITTED OVER NIGHT	REC	Grade 3

治験責任医師の見解:「重症筋無力症」は、入院のため重篤、治験薬に関連なしと判断した。「COVID-19 の疑い」は、入院・生命を脅かすものであるため重篤、治験薬に関連なしと判断した。「発熱」は、入院・その他の医学的に重要であるため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: F	Age: 7[redacted]
Medical History [1]: ABORTION SPONTANEOUS, UTERINE DILATION AND CURETTAGE, SPINAL COMPRESSION FRACTURE, HYPOTHYROIDISM, OSTEOPOROSIS, POSTMENOPAUSE, CATARACT, GASTROOESOPHAGEAL REFLUX DISEASE, DRUG HYPERSENSITIVITY, COLITIS ULCERATIVE, CATARACT OPERATION, CORNEAL IMPLANT, HYPERTRIGLYCERIDAEMIA				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 364		
Concomitant Medication [3]: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRICOXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NIC, CALCIUM, ALENDRONATE SODIUM, LEVOTHYROXINE SODIUM, OMEPRAZOLE, BALSALAZIDE DISODIUM DIHYDRATE, BIFIDOBACTERIUM INFANTIS, FENOFIBRATE, PSEUDOEPHEDRINE HYDROCHLORIDE, LEVOTHYROXINE, FAMOTIDINE, SODIUM CHLORIDE, VITAMINS NOS, PARACETAMOL, ONDANSETRON, AZATHIOPRINE, PYRIDOSTIGMINE BROMIDE, IMMUNOGLOBULINS NOS				
Non-Serious Adverse Event [4]: SINUS CONGESTION, AORTIC DILATATION, ENDOMETRIAL THICKENING				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
尿路感染	URINARY TRACT INFECTION	OLE/ Day 362/ Day 363	NR	NC	MED	REC	Grade 3
治験責任医師の見解：「尿路感染」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: Korean	Country: South Korea	Sex: F	Age: 5[redacted]
Medical History [1]: MEDIASTINUM NEOPLASM, THYMECTOMY, PNEUMONIA, HYPERLIPIDAEMIA, NEPHROTIC SYNDROME, CHRONIC GASTRITIS, GASTROOESOPHAGEAL REFLUX DISEASE, ONYCHOMYCOSIS, HYSTERECTOMY				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 364			
Concomitant Medication [3]: SARPOGRELATE HYDROCHLORIDE, ATORVASTATIN CALCIUM, CALCIUM CARBONATE;COLECALCIFEROL, ASCORBIC ACID, RABEPRAZOLE SODIUM, INFLUENZA VACCINE INACT SAG 4V, ACECLOFENAC, ALBUMIN HUMAN, FUROSEMIDE, CALCIUM CITRATE;COLECALCIFEROL, MAGNESIUM SULFATE, PETHIDINE, METHYLPREDNISOLONE SODIUM SUCCINATE, ACETIC ACID;ACETYL CYSTEINE;ALANINE;ARGININE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN,L-;VALINE, FLUCONAZOLE, PROPOFOL, SULFAMETHOXAZOLE;TRIMETHOPRIM, SPIRONOLACTONE, POTASSIUM CHLORIDE, FLUNITRAZEPAM, TRAZODONE, BROMAZEPAM, QUETIAPINE FUMARATE, OLANZAPINE, LORAZEPAM, CLONAZEPAM, ESOMEPRAZOLE, PREDNISOLONE, PYRIDOSTIGMINE BROMIDE, TACROLIMUS				
Non-Serious Adverse Event [4]: RESTLESS LEGS SYNDROME, NEPHROTIC SYNDROME, INSOMNIA, OESOPHAGEAL CANDIDIASIS, HYPOKALAEMIA, NEPHROTIC SYNDROME, GLOMERULONEPHRITIS MINIMAL LESION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
ネフローゼ症候群	RECCURED MCD (MINIMAL CHANGE DISEASE)	RCP/ Day 127/ Day 137	NR	NC	MED; NONP	REC	Grade 3
治験責任医師の見解：「ネフローゼ症候群」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: F	Age: 6[redacted]
Medical History [1]: HYPOTHYROIDISM, CATARACT, GASTROOESOPHAGEAL REFLUX DISEASE, DRUG HYPERSENSITIVITY, DRUG HYPERSENSITIVITY, DRUG HYPERSENSITIVITY, CLOSTRIDIUM DIFFICILE COLITIS, POST LAMINECTOMY SYNDROME, BLOOD CHOLESTEROL INCREASED, INTERVERTEBRAL DISC PROTRUSION, OSTEOARTHRITIS, OSTEOPOROSIS, SPINAL PAIN, THYMOMA, RADICULOPATHY, RHINITIS ALLERGIC, THYMECTOMY, PERIPHERAL VASCULAR DISORDER, EX-TOBACCO USER, THYROIDECTOMY, CAESAREAN SECTION, HYSTERECTOMY, THROMBOCYTOSIS, ANAEMIA, HYPOGAMMAGLOBULINAEMIA, ASTHMA, HERPES ZOSTER, DEPRESSION, HYPERTENSION, CARPAL TUNNEL SYNDROME, LUMBAR SPINAL STENOSIS, DIVERTICULITIS, COLONOSCOPY, RESPIRATORY FAILURE, LIVEDO RETICULARIS, DRY EYE, OESOPHAGEAL CANDIDIASIS, OBESITY, LEUKOCYTOSIS, HYPERTHYROIDISM, HYPERGLYCAEMIA, IRON DEFICIENCY, VITAMIN D DEFICIENCY, HYPERTENSIVE NEPHROPATHY, DIVERTICULAR PERFORATION, SIGMOIDECTOMY, LOCALISED INFECTION, INCISIONAL HERNIA, BRONCHITIS, MUSCLE SPASMS, HYPERKALAEMIA, PNEUMONIA, EXPLORATIVE LAPAROTOMY, OSTEONECROSIS, RENAL CYST, POLYURIA, CATHETER PLACEMENT, ATRIAL FIBRILLATION, LEFT VENTRICULAR HYPERTROPHY, CARDIAC FAILURE CONGESTIVE, ANORECTAL OPERATION, HERNIA REPAIR, SMALL INTESTINAL RESECTION, CATHETER REMOVAL			
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 366			
Concomitant Medication [3]: ACETYLSALICYLIC ACID, SALBUTAMOL SULFATE, DILTIAZEM HYDROCHLORIDE, FLUTICASONE PROPIONATE, CALCIUM;VITAMIN D NOS, ALPRAZOLAM, MIRTAZAPINE, MONTELUKAST SODIUM, OMEPRAZOLE, METOPROLOL TARTRATE, EZETIMIBE, BUPIVACAINE, DEXAMETHASONE, FENTANYL, MIDAZOLAM HYDROCHLORIDE, CLONIDINE, GABAPENTIN, HYDROCODONE;PARACETAMOL, FUROSEMIDE, LISINOPRIL, VERAPAMIL, LORATADINE, AZITHROMYCIN, LOPERAMIDE HYDROCHLORIDE, CIPROFLOXACIN, AMOXICILLIN;CLAVULANIC ACID, AZELASTINE, FLUTICASONE;VILANTEROL, DOXYCYCLINE, METRONIDAZOLE, NITROFURANTOIN, PREDNISONE, GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, AMOXICILLIN;CLAVULANATE POTASSIUM, CALCIUM CARBONATE, DIPHENHYDRAMINE, METHYLPREDNISOLONE, NYSTATIN, FAMOTIDINE, PYRIDOSTIGMINE BROMIDE, IMMUNOGLOBULINS NOS			
Non-Serious Adverse Event [4]: SINUSITIS, PAIN IN EXTREMITY, EYE HAEMORRHAGE, PRURITUS, ABDOMINAL DISTENSION, DIARRHOEA, ABDOMINAL PAIN UPPER, ABDOMINAL DISTENSION, ABDOMINAL PAIN UPPER, RESPIRATORY TRACT CONGESTION, BRONCHITIS, DIARRHOEA, DYSPEPSIA, HYPOTENSION, STOMA SITE INFECTION, BACK PAIN, RESPIRATORY SYMPTOM, SKIN LESION, NASOPHARYNGITIS, ABDOMINAL PAIN, MYASTHENIA GRAVIS, THYROID MASS, UPPER RESPIRATORY TRACT INFECTION, PHARYNGITIS, BRONCHITIS, CANDIDA INFECTION							

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
重症筋無力症	WORSENING OF MG SYMPTOMS	OLE/ Day 289/ Day 309	REL	NC	MED	REC	Grade 3
治験責任医師の見解：「重症筋無力症」は、入院のため重篤、治験薬に関連ありと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: M	Age: 8[redacted]
Medical History [1]: BLEPHARITIS, DERMATOCHALASIS, HEPATIC LESION, ONYCHOMYCOSIS, PNEUMONIA, PAIN IN EXTREMITY, CARPAL TUNNEL SYNDROME, ADENOMA BENIGN, ANGINA PECTORIS, DIABETES MELLITUS, HYPERLIPIDAEMIA, HYPERTENSION, HYPERMETROPIA, ASTIGMATISM, PRESBYOPIA, BORDERLINE GLAUCOMA, HYPERMETROPIA, OCULAR HYPERTENSION, INTRAOCULAR PRESSURE TEST, ACTINIC KERATOSIS, ROSACEA, TYPE V HYPERLIPIDAEMIA, SLEEP APNOEA SYNDROME, ARTERIOSCLEROSIS CORONARY ARTERY, ANGINA PECTORIS, GASTROOESOPHAGEAL REFLUX DISEASE, COAGULATION TIME PROLONGED, CENTRAL OBESITY, ACUTE KIDNEY INJURY, BLADDER OBSTRUCTION, DIABETIC NEPHROPATHY, URINARY RETENTION, ESSENTIAL HYPERTENSION, HYPERGLYCAEMIA, OSTEOPOROSIS, ATRIAL FIBRILLATION, HYPONATRAEMIA, TRANSURETHRAL PROSTATECTOMY, NAUSEA, CYSTITIS, HAEMATURIA, URINARY TRACT INFECTION PSEUDOMONAL, RENAL FAILURE, ATRIAL FIBRILLATION, ATRIAL FLUTTER, URINARY TRACT INFECTION, LOWER URINARY TRACT SYMPTOMS, URINARY TRACT OBSTRUCTION, BENIGN PROSTATIC HYPERPLASIA, POLYNEUROPATHY, FLUID RETENTION, MUSCLE SPASMS				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 370		
Concomitant Medication [3]: ONDANSETRON, INSULIN GLARGINE, EZETIMIBE, ALIROCUMAB, AMLODIPINE BESILATE, EXENATIDE, FUROSEMIDE, INSULIN LISPRO, METOPROLOL SUCCINATE, CANNABIDIOL, APIXABAN, POTASSIUM GLUCONATE, ALLOPURINOL, CEFALEXIN, MUPIROCIN, TORASEMIDE, CEFTRIAXONE, PARACETAMOL, ALTEPLASE, CEFEPIME, DOCUSATE SODIUM, HYDROMORPHONE, LIDOCAINE, MELATONIN, OXYCODONE, MACROGOL, SULFADIAZINE SILVER, VANCOMYCIN, COVID-19 VACCINE MRNA (MRNA1273), PREDNISONE				
Non-Serious Adverse Event [4]: DRUG INTOLERANCE, SKIN LESION, SKIN ULCER, CELLULITIS, NASAL PRURITUS, RHINORRHOEA, VACCINATION COMPLICATION, BACK PAIN				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
蜂巣炎	PERSISTENT LEFT LEG CELLULITIS	RCP/ Day 169/ Day 175	REL	NC	MED; NONP	REC	Grade 3
治験責任医師の見解：「蜂巣炎」は、入院のため重篤、治験薬に関連ありと判断した。							

Patient ID: [redacted]				
Treatment Arm: Placebo	Race: Korean	Country: South Korea	Sex: M	Age: 3[redacted]
Medical History [1]: APPENDICITIS, INFLUENZA, DERMAL CYST, BENIGN NEOPLASM OF THYROID GLAND, MASS, THYROIDITIS CHRONIC, MASS EXCISION, OSTEOPENIA				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 363			
Concomitant Medication [3]: CALCIUM CARBONATE;COLECALCIFEROL, ROPIVACAINE, ALPROSTADIL, CEFAZOLIN, FENTANYL, LIDOCAINE, RAMOSETRON HYDROCHLORIDE, GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE, ESOMEPRAZOLE MAGNESIUM;NAPROXEN, BERAPROST SODIUM, CEFADROXIL, LAFUTIDINE, PARACETAMOL;TRAMADOL HYDROCHLORIDE, COLECALCIFEROL, ALENDRONATE SODIUM;COLECALCIFEROL, TACROLIMUS, PYRIDOSTIGMINE BROMIDE, PREDNISOLONE, HYDROCORTISONE SODIUM SUCCINATE, NEOSTIGMINE METILSULFATE				
Non-Serious Adverse Event [4]: INJECTION SITE BRUISING, GRANULOMA SKIN, PAIN IN EXTREMITY				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
皮膚肉芽腫	GRANULOMA OF SKIN	RCP/ Day 104/ Day 106	NR	NC	MED; NONP	REC	Grade 2

治験責任医師の見解：「皮膚肉芽腫」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: Germany	Sex: M	Age: 6[redacted]
Medical History [1]: HYPERLIPIDAEMIA, HYPERTENSION, CEREBROVASCULAR ACCIDENT, BACK PAIN, TRIGEMINAL NEURALGIA, DIARRHOEA, BASAL CELL CARCINOMA, BASAL CELL CARCINOMA, CARPAL TUNNEL SYNDROME, GYNAECOMASTIA				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 181		
Concomitant Medication [3]: SIMVASTATIN, LISINOPRIL, ACETYLSALICYLIC ACID, CARBAMAZEPINE, DICLOFENAC, IBUPROFEN, PANTOPRAZOLE SODIUM SESQUIHYDRATE, LOPERAMIDE HYDROCHLORIDE, LERCANIDIPINE, PYRIDOSTIGMINE BROMIDE, PREDNISOLONE, AZATHIOPRINE				
Non-Serious Adverse Event [4]: ENTERITIS, HYPERTENSION, MYASTHENIA GRAVIS				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
三叉神経痛	INCREASED TRIGEMINUS-NEURALGIA RIGHT SIDE	RCP/ -/ -	NR	NC	MED; NONP; OTH: JANETTA SURGERY	RCNG	Grade 1
顔面不全麻痺	IDIOPATHIC PERIPHERAL FACIAL NERVE PARESIS	RCP/ Day 172/ -	NR	NC	MED; NONP; OTH: SPEECH THERAPY	RCNG	Grade 2
治験責任医師の見解：「三叉神経痛」は、入院のため重篤、治験薬に関連なしと判断した。「顔面不全麻痺」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: Japanese	Country: Japan	Sex: F	Age: 5[redacted]
Medical History [1]: DIABETES MELLITUS, HYPERLIPIDAEMIA, HYPOKALAEMIA, BACK PAIN, HYPERKERATOSIS, PITUITARY GLAND OPERATION, THYMECTOMY, AMENORRHOEA, CATARACT, HYPERTENSION, FIBROADENOMA OF BREAST				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 183			
Concomitant Medication [3]: ALENDRONATE SODIUM, AMLODIPINE, BEZAFIBRATE, INDOMETACIN, FAMOTIDINE, HYALURONATE SODIUM, POTASSIUM CHLORIDE, NITROFURANTOIN, OLMESARTAN MEDOXOMIL, POVIDONE-IODINE, FELBINAC, EZETIMIBE, CLOBETASOL PROPIONATE, AMENAMEVIR, EPINASTINE HYDROCHLORIDE, VIDARABINE, CEFTRIAXONE SODIUM, LOXOPROFEN SODIUM, MEROPENEM, MINOCYCLINE HYDROCHLORIDE, CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, CELECOXIB, VALACICLOVIR HYDROCHLORIDE, CEFACLOR, AMOXICILLIN, LORATADINE, BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM INFANTIS, PREDNISOLONE, TACROLIMUS MONOHYDRATE				
Non-Serious Adverse Event [4]: OCCIPITAL NEURALGIA, ECZEMA, VARICELLA ZOSTER VIRUS INFECTION, RHINITIS ALLERGIC, BRONCHITIS, ABDOMINAL DISTENSION				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
蜂巣炎	CELLULITIS OF LEFT FOOT	RCP/ Day 106/ Day 169	REL	INT	MED	REC	Grade 2

治験責任医師の見解：「蜂巣炎」は、入院のため重篤、治験薬に関連ありと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: Japanese	Country: Japan	Sex: F	Age: 5[redacted]
Medical History [1]: ASTHMA, SEASONAL ALLERGY, SJOGREN'S SYNDROME				
Treatment First Dose Day [2]: Day 1	Last Dose Day [2]: Day 15			
Concomitant Medication [3]: PROCATEROL HYDROCHLORIDE, ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PINELLIA TERNATA TUBER;SCHISANDRA CHINENSIS FRUIT;ZINGI, PARACETAMOL, PENTAZOCINE HYDROCHLORIDE, CARBOHYDRATES NOS;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, ALBUMIN TANNATE, LOPERAMIDE HYDROCHLORIDE, CLOSTRIDIUM BUTYRICUM, AZATHIOPRINE, AMBENONIUM CHLORIDE, PREDNISOLONE				
Non-Serious Adverse Event [4]: No Non-Serious Adverse Event recorded.				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
小腸炎	SMALL INTESTINAL MUCOSITIS	RCP/ Day 62/ Day 71	NR	NC	MED	REC	Grade 3
治験責任医師の見解：「小腸炎」は、入院のため重篤、治験薬に関連なしと判断した。							

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: M	Age: 2[redacted]
Medical History [1]: VON WILLEBRAND'S DISEASE, PAIN, SLEEP APNOEA SYNDROME, TONSILLECTOMY, MIGRAINE, OBESITY, ATTENTION DEFICIT HYPERACTIVITY DISORDER, TACHYCARDIA, COMA, ACARODERMATITIS, SEPSIS, RESPIRATORY FAILURE, TYPE 2 DIABETES MELLITUS, GASTROOESOPHAGEAL REFLUX DISEASE				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 184		
Concomitant Medication [3]: IBUPROFEN, METFORMIN, METHYLPHENIDATE, INSULIN GLARGINE, INSULIN LISPRO, PANTOPRAZOLE, INSULIN, ENOXAPARIN SODIUM, POTASSIUM PHOSPHATE DIBASIC, PYRIDOSTIGMINE BROMIDE, PREDNISONE, MYCOPHENOLATE MOFETIL				
Non-Serious Adverse Event [4]: POLLAKIURIA, DRY MOUTH, FATIGUE, HYPOGEUSIA, ABDOMINAL PAIN UPPER, LEUKOCYTOSIS				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
糖尿病性ケトアシドーシス	DIABETIC KETOACIDOSIS	RCP/ Day 126/ Day 128	NR	NC	MED	REC	Grade 4

治験責任医師の見解：「糖尿病性ケトアシドーシス」は、入院のため重篤、治験薬に関連なしと判断した。

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: White	Country: USA	Sex: F	Age: 5[redacted]
Medical History [1]: CONSTIPATION, DIABETIC NEUROPATHY, CHRONIC KIDNEY DISEASE, DIABETIC NEPHROPATHY, TYPE 2 DIABETES MELLITUS, MENOPAUSE, INTRAOCULAR LENS IMPLANT, CATARACT, DRY EYE, MEIBOMIAN GLAND DYSFUNCTION, NEURALGIA, SYSTEMIC LUPUS ERYTHEMATOSUS, HYPERTENSION, NEUROPATHIC ARTHROPATHY				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 315		
Concomitant Medication [3]: FUROSEMIDE, GABAPENTIN, INSULIN GLARGINE, VITAMIN D NOS, INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, HYDROCODONE BITARTRATE;PARACETAMOL, LACTULOSE, FLUOXETINE, CARVEDILOL, PREDNISONE				
Non-Serious Adverse Event [4]: INSOMNIA, CHOKING, DYSPNOEA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
重症筋無力症	SHORTNESS OF BREATH DUE TO MG WORSENING	RCP/ Day 100/ Day 113	NR	NC	OTH: PLEX ON ＊Day 103	REC	Grade 3

治験責任医師の見解：「重症筋無力症」は、入院のため重篤、治験薬に関連なしと判断した。

＊新薬承認情報提供時に置き換え

Patient ID: [redacted]-[redacted]				
Treatment Arm: Placebo	Race: Not Reported	Country: France	Sex: F	Age: 4[redacted]
Medical History [1]: MIGRAINE, ANXIETY, DEPRESSION, MENOPAUSE, STRABISMUS, PARACENTESIS, TONSILLAR ERYTHEMA, PNEUMOCYSTIS JIROVECII INFECTION, BACTERAEMIA, ESCHERICHIA PYELONEPHRITIS				
Treatment First Dose Day [2]: Day 1		Last Dose Day [2]: Day 184		
Concomitant Medication [3]: RISEDRONATE SODIUM, HYDROXYZINE HYDROCHLORIDE, CALCIUM CARBONATE;COLECALCIFEROL, PARACETAMOL, PAROXETINE HYDROCHLORIDE, ATOVAQUONE, FOLIC ACID, ENOXAPARIN SODIUM, PHENOXYMETHYLPENICILLIN, PNEUMOCOCCAL VACCINE POLYSACCH 23V, PYRIDOSTIGMINE BROMIDE, AMBENONIUM CHLORIDE, CICLOSPORIN, PREDNISONE, IMMUNOGLOBULIN HUMAN NORMAL				
Non-Serious Adverse Event [4]: HAEMATOMA				

Serious Adverse Event (PT) [4]	Verbatim Term	Phase/ Start Day/ End Day [2]	Relationship [5]	Action Taken [6]	Other Action Taken [7]	Outcome [8]	Toxicity
重症筋無力症	WORSENING OF MYASTHENIA GRAVIS	RCP/ Day 182/ Day 185	NR	NC	MED	REC	Grade 3
治験責任医師の見解：「重症筋無力症」は、入院のため重篤、治験薬に関連なしと判断した。							

F = female; M = male; MedDRA = Medical Dictionary for Regulatory Activities; OLE = Open-label extension period; PRE = prior to first study drug infusion; PT = preferred term; RCP = randomized-controlled period; USA = United States of America; WHO = World Health Organization.

Note: OLE begins at the start of Day 183 (Week 26) dosing. Starting with Week 26, placebo patients will begin receiving ravulizumab.

[1] Medical history preferred terms are coded using MedDRA version 24.0.

[2] Relative to the first study drug infusion.

[3] Medications are coded using WHO drug dictionary enhanced extended with the Herbal Dictionary version ‘March 2021’.

[4] Adverse Event preferred terms are coded using MedDRA version 24.0.

[5] NR = Not Related; REL = Related.

[6] NC = Dose Not Changed; INT = Drug Interrupted; WTHD = Drug Withdrawn; NA = Not Applicable; UNK = Unknown.

[7] N = None; MED = Medication; NONP = Non-Pharmacologic Therapy/Procedure; OTH = Other.

[8] NORC = Not Recovered/Not Resolved; RCSQ = Recovered/Resolved with Sequelae; RCNG = Recovering/Resolving; REC = Recovered/Resolved; FATL = Fatal; UNK = Unknown.

Table 14.3.3.1.2.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	79 (91.9)	357 (850.5)	60 (75.0)	212 (549.3)	23 (30.7)	38 (388.0)	82 (95.3)	607 (671.7)
感染症および寄生虫症	39 (45.3)	65 (154.9)	26 (32.5)	38 (98.5)	7 (9.3)	7 (71.5)	56 (65.1)	110 (121.7)
尿路感染	5 (5.8)	7 (16.7)	5 (6.3)	5 (13.0)	1 (1.3)	1 (10.2)	11 (12.8)	13 (14.4)
ＣＯＶＩＤ－１９	5 (5.8)	5 (11.9)	2 (2.5)	5 (13.0)	1 (1.3)	1 (10.2)	8 (9.3)	11 (12.2)
帯状疱疹	2 (2.3)	2 (4.8)	3 (3.8)	3 (7.8)	0	0	5 (5.8)	5 (5.5)
上咽頭炎	3 (3.5)	3 (7.1)	2 (2.5)	2 (5.2)	1 (1.3)	1 (10.2)	5 (5.8)	6 (6.6)
上気道感染	3 (3.5)	3 (7.1)	2 (2.5)	3 (7.8)	0	0	5 (5.8)	6 (6.6)
皮膚真菌感染	2 (2.3)	2 (4.8)	2 (2.5)	2 (5.2)	0	0	4 (4.7)	4 (4.4)
咽頭炎	4 (4.7)	4 (9.5)	0	0	0	0	4 (4.7)	4 (4.4)
副鼻腔炎	3 (3.5)	3 (7.1)	1 (1.3)	1 (2.6)	0	0	4 (4.7)	4 (4.4)
肺炎	2 (2.3)	2 (4.8)	1 (1.3)	2 (5.2)	0	0	3 (3.5)	4 (4.4)
無症候性ＣＯＶＩＤ－１９	1 (1.2)	1 (2.4)	0	0	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
気管支炎	1 (1.2)	1 (2.4)	0	0	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
ＣＯＶＩＤ－１９肺炎	2 (2.3)	3 (7.1)	0	0	0	0	2 (2.3)	3 (3.3)
蜂巣炎	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
結膜炎	0	0	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
胃腸炎	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
ウイルス性胃腸炎	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
ウイルス性消化管感染	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
インフルエンザ	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
中耳炎	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
足部白癬	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
膣感染	1 (1.2)	1 (2.4)	0	0	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
細菌性関節炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
クロストリジウム・ディフィシレ感染	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
結腸膿瘍	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
爪の皮膚糸状菌症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
憩室炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
耳感染	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
丹毒	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
壊疽	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
消化管感染	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
膿痂疹	1 (1.2)	2 (4.8)	1 (1.3)	1 (2.6)	0	0	1 (1.2)	3 (3.3)
感染性皮膚潰瘍	1 (1.2)	2 (4.8)	0	0	0	0	1 (1.2)	2 (2.2)
腎感染	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
限局性感染	0	0	1 (1.3)	3 (7.8)	0	0	1 (1.2)	3 (3.3)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
下気道感染	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
病原体耐性	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
誤嚥性肺炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ＲＳウイルス肺炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ウイルス性肺炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
術後創感染	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
慢性腎盂腎炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
ブドウ球菌性敗血症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
歯膿瘍	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
外陰膣真菌感染	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
胃腸障害	29 (33.7)	51 (121.5)	17 (21.3)	24 (62.2)	1 (1.3)	1 (10.2)	41 (47.7)	76 (84.1)
下痢	12 (14.0)	13 (31.0)	4 (5.0)	4 (10.4)	0	0	16 (18.6)	17 (18.8)
悪心	9 (10.5)	13 (31.0)	4 (5.0)	4 (10.4)	0	0	11 (12.8)	17 (18.8)
腹痛	5 (5.8)	6 (14.3)	1 (1.3)	1 (2.6)	0	0	6 (7.0)	7 (7.7)
腹部不快感	2 (2.3)	3 (7.1)	2 (2.5)	3 (7.8)	0	0	3 (3.5)	6 (6.6)
齲歯	3 (3.5)	3 (7.1)	0	0	0	0	3 (3.5)	3 (3.3)
嘔吐	1 (1.2)	3 (7.1)	2 (2.5)	2 (5.2)	0	0	3 (3.5)	5 (5.5)
腹部膨満	0	0	2 (2.5)	2 (5.2)	0	0	2 (2.3)	2 (2.2)
嚥下障害	1 (1.2)	1 (2.4)	1 (1.3)	2 (5.2)	0	0	2 (2.3)	3 (3.3)
胃炎	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
嚥下痛	1 (1.2)	1 (2.4)	0	0	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
口角口唇炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
胃腸障害（続き）								
便秘	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
血性下痢	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
腸憩室	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
口内乾燥	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
消化不良	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
軟便	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
排便回数増加	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
胃食道逆流性疾患	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
痔核	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
口腔知覚不全	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
歯痛	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害	29 (33.7)	44 (104.8)	19 (23.8)	28 (72.5)	4 (5.3)	4 (40.8)	39 (45.3)	76 (84.1)
頭痛	17 (19.8)	20 (47.6)	9 (11.3)	14 (36.3)	2 (2.7)	2 (20.4)	21 (24.4)	36 (39.8)
浮動性めまい	8 (9.3)	9 (21.4)	4 (5.0)	4 (10.4)	0	0	11 (12.8)	13 (14.4)
重症筋無力症	1 (1.2)	3 (7.1)	5 (6.3)	5 (13.0)	0	0	6 (7.0)	8 (8.9)
失神	2 (2.3)	3 (7.1)	1 (1.3)	1 (2.6)	0	0	3 (3.5)	4 (4.4)
平衡障害	0	0	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
一過性脳虚血発作	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
脳出血	1 (1.2)	2 (4.8)	0	0	0	0	1 (1.2)	2 (2.2)
認知障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
構語障害	0	0	1 (1.3)	2 (5.2)	0	0	1 (1.2)	2 (2.2)
不全片麻痺	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
肋間神経痛	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
腰仙部神経根障害	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
重症筋無力症クリーゼ	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害（続き）								
ヘルペス後神経痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
振戦	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
筋骨格系および結合組織障害	24 (27.9)	40 (95.3)	17 (21.3)	24 (62.2)	3 (4.0)	5 (51.1)	33 (38.4)	69 (76.4)
関節痛	6 (7.0)	8 (19.1)	6 (7.5)	7 (18.1)	2 (2.7)	2 (20.4)	10 (11.6)	17 (18.8)
背部痛	7 (8.1)	7 (16.7)	3 (3.8)	3 (7.8)	0	0	10 (11.6)	10 (11.1)
四肢痛	3 (3.5)	4 (9.5)	2 (2.5)	2 (5.2)	1 (1.3)	1 (10.2)	6 (7.0)	7 (7.7)
椎間板突出	1 (1.2)	1 (2.4)	2 (2.5)	2 (5.2)	1 (1.3)	1 (10.2)	4 (4.7)	4 (4.4)
筋痙縮	2 (2.3)	4 (9.5)	2 (2.5)	2 (5.2)	0	0	4 (4.7)	6 (6.6)
頚部痛	2 (2.3)	2 (4.8)	1 (1.3)	1 (2.6)	0	0	3 (3.5)	3 (3.3)
筋力低下	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
筋骨格硬直	0	0	2 (2.5)	2 (5.2)	0	0	2 (2.3)	2 (2.2)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
筋骨格系および結合組織障害（続き）								
筋肉痛	2 (2.3)	2 (4.8)	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	2 (2.3)	4 (4.4)
腱炎	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
尾骨痛	1 (1.2)	2 (4.8)	0	0	0	0	1 (1.2)	2 (2.2)
肛径部痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
出血性関節症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
筋攣縮	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
筋骨格系胸痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
結節性変形性関節症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
変形性関節症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
骨減少症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
骨粗鬆症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
肩回旋筋腱板症候群	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
滑膜炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態	23 (26.7)	32 (76.2)	14 (17.5)	14 (36.3)	3 (4.0)	3 (30.6)	30 (34.9)	49 (54.2)
疲労	7 (8.1)	8 (19.1)	4 (5.0)	4 (10.4)	1 (1.3)	1 (10.2)	11 (12.8)	13 (14.4)
末梢性浮腫	3 (3.5)	4 (9.5)	2 (2.5)	2 (5.2)	0	0	5 (5.8)	6 (6.6)
インフルエンザ様疾患	2 (2.3)	2 (4.8)	1 (1.3)	1 (2.6)	0	0	3 (3.5)	3 (3.3)
非心臓性胸痛	3 (3.5)	3 (7.1)	0	0	0	0	3 (3.5)	3 (3.3)
発熱	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	3 (3.5)	3 (3.3)
胸痛	1 (1.2)	2 (4.8)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	3 (3.3)
ワクチン接種部位反応	2 (2.3)	2 (4.8)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	3 (3.3)
無力症	1 (1.2)	2 (4.8)	0	0	0	0	1 (1.2)	2 (2.2)
胸部不快感	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
悪寒	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
異形成	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態（続き）								
歩行障害	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
全身健康状態悪化	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
注入部位血管外漏出	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	1 (1.2)	2 (2.2)
注入部位血腫	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
注入部位疼痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
注射部位反応	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
倦怠感	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
疼痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ワクチン接種部位刺激感	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
傷害、中毒および処置合併症	6 (7.0)	9 (21.4)	12 (15.0)	13 (33.7)	4 (5.3)	4 (40.8)	19 (22.1)	26 (28.8)
転倒	2 (2.3)	3 (7.1)	1 (1.3)	2 (5.2)	0	0	3 (3.5)	5 (5.5)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
傷害、中毒および処置合併症（続き）								
ワクチン接種合併症	2 (2.3)	3 (7.1)	1 (1.3)	1 (2.6)	0	0	3 (3.5)	4 (4.4)
関節損傷	0	0	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
歯牙破折	0	0	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
胸部損傷	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
歯科修復不成功	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
上顎炎	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
頭部損傷	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
注入に伴う反応	0	0	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	1 (1.2)	2 (2.2)
靱帯断裂	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
腰椎骨折	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
多発骨折	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
橈骨骨折	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
肋骨骨折	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
傷害、中毒および処置合併症（続き）								
脊椎圧迫骨折	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
創傷	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
代謝および栄養障害	15 (17.4)	18 (42.9)	3 (3.8)	3 (7.8)	1 (1.3)	1 (10.2)	19 (22.1)	22 (24.3)
糖尿病	4 (4.7)	4 (9.5)	0	0	1 (1.3)	1 (10.2)	5 (5.8)	5 (5.5)
食欲減退	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
痛風	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
高血糖	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
低血糖	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
低カリウム血症	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
脱水	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
コントロール不良の糖尿病	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
代謝および栄養障害（続き）								
食欲亢進	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
鉄欠乏	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ステロイド糖尿病	1 (1.2)	3 (7.1)	0	0	0	0	1 (1.2)	3 (3.3)
臨床検査	11 (12.8)	21 (50.0)	6 (7.5)	6 (15.5)	2 (2.7)	2 (20.4)	18 (20.9)	29 (32.1)
アラニンアミノトランスフェラーゼ増加	3 (3.5)	3 (7.1)	0	0	0	0	3 (3.5)	3 (3.3)
γ－グルタミルトランスフェラーゼ増加	3 (3.5)	3 (7.1)	0	0	0	0	3 (3.5)	3 (3.3)
アスパラギン酸アミノトランスフェラーゼ増加	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
リンパ球数減少	1 (1.2)	1 (2.4)	0	0	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
白血球数減少	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
血中葉酸減少	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
血中ブドウ糖増加	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
血圧上昇	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
体温上昇	1 (1.2)	2 (4.8)	0	0	0	0	1 (1.2)	2 (2.2)
Ｃ－反応性蛋白増加	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
尿中結晶陽性	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
心電図ＰＲ延長	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
尿中ブドウ糖陽性	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
グリコヘモグロビン増加	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
尿中蛋白陽性	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
赤血球数減少	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
網状赤血球数増加	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
トロポニン増加	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
尿中白血球エステラーゼ陽性	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
尿中ウロビリノーゲン	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
白血球数増加	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
呼吸器、胸郭および縦隔障害	13 (15.1)	23 (54.8)	8 (10.0)	15 (38.9)	1 (1.3)	2 (20.4)	16 (18.6)	40 (44.3)
咳嗽	4 (4.7)	4 (9.5)	1 (1.3)	1 (2.6)	0	0	5 (5.8)	5 (5.5)
呼吸困難	5 (5.8)	6 (14.3)	2 (2.5)	3 (7.8)	0	0	5 (5.8)	9 (10.0)
息詰まり	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
呼吸器、胸郭および縦隔障害（続き）								
労作性呼吸困難	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
低酸素症	0	0	2 (2.5)	2 (5.2)	0	0	2 (2.3)	2 (2.2)
湿性咳嗽	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
慢性気管支炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
喉頭蓋潰瘍	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
肺浸潤	1 (1.2)	4 (9.5)	0	0	0	0	1 (1.2)	4 (4.4)
鼻閉	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
口腔咽頭痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
胸水	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
気道うっ血	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
アレルギー性鼻炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
鼻漏	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
副鼻腔うっ血	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
呼吸器、胸郭および縦隔障害（続き）								
咽喉絞扼感	0	0	1 (1.3)	3 (7.8)	1 (1.3)	2 (20.4)	1 (1.2)	5 (5.5)
皮膚および皮下組織障害	8 (9.3)	8 (19.1)	9 (11.3)	11 (28.5)	0	0	16 (18.6)	19 (21.0)
発疹	2 (2.3)	2 (4.8)	2 (2.5)	2 (5.2)	0	0	4 (4.7)	4 (4.4)
そう痒症	1 (1.2)	1 (2.4)	2 (2.5)	2 (5.2)	0	0	3 (3.5)	3 (3.3)
脱毛症	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
過角化	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
蕁麻疹	0	0	2 (2.5)	2 (5.2)	0	0	2 (2.3)	2 (2.2)
ざ瘡様皮膚炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
薬疹	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
斑状出血	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
皮膚疼痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
皮膚萎縮	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
皮膚および皮下組織障害（続き）								
皮膚病変	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
眼障害	6 (7.0)	6 (14.3)	5 (6.3)	7 (18.1)	3 (4.0)	4 (40.8)	12 (14.0)	17 (18.8)
眼瞼痙攣	0	0	1 (1.3)	1 (2.6)	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
白内障	1 (1.2)	1 (2.4)	2 (2.5)	4 (10.4)	0	0	2 (2.3)	5 (5.5)
複視	1 (1.2)	1 (2.4)	0	0	1 (1.3)	1 (10.2)	2 (2.3)	2 (2.2)
ドライアイ	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
眼瞼下垂	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
緑内障	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
羞明	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
網膜静脈閉塞	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
眼瞼腫脹	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
霧視	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
視力障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
心臓障害	6 (7.0)	7 (16.7)	5 (6.3)	9 (23.3)	2 (2.7)	2 (20.4)	10 (11.6)	18 (19.9)
狭心症	0	0	2 (2.5)	2 (5.2)	1 (1.3)	1 (10.2)	2 (2.3)	3 (3.3)
心房細動	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
動悸	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
頻脈	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
心房頻脈	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
うっ血性心筋症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
冠動脈疾患	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
冠動脈閉塞	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
期外収縮	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
僧帽弁狭窄症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
結節性不整脈	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
心臓障害（続き）								
上室性期外収縮	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
心室性期外収縮	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
血管障害	5 (5.8)	8 (19.1)	4 (5.0)	5 (13.0)	0	0	9 (10.5)	13 (14.4)
高血圧	3 (3.5)	6 (14.3)	1 (1.3)	1 (2.6)	0	0	4 (4.7)	7 (7.7)
深部静脈血栓症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
血腫	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
低血圧	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
血管痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
静脈破裂	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
白衣性高血圧	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
耳および迷路障害	3 (3.5)	6 (14.3)	3 (3.8)	4 (10.4)	0	0	6 (7.0)	10 (11.1)
耳痛	1 (1.2)	1 (2.4)	1 (1.3)	2 (5.2)	0	0	2 (2.3)	3 (3.3)
回転性めまい	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
耳および迷路障害（続き）								
難聴	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
片耳難聴	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
耳不快感	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
耳石症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
耳鳴	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
精神障害	5 (5.8)	5 (11.9)	1 (1.3)	1 (2.6)	0	0	6 (7.0)	6 (6.6)
不眠症	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
抑うつ気分を伴う適応障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
うつ病	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
気分動揺	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
自殺企図	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
腎および尿路障害	3 (3.5)	3 (7.1)	2 (2.5)	2 (5.2)	1 (1.3)	1 (10.2)	6 (7.0)	6 (6.6)
急性腎障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ミクロアルブミン尿	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
腎結石症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
腎尿細管壊死	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
腹圧性尿失禁	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
尿閉	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
血液およびリンパ系障害	0	0	3 (3.8)	4 (10.4)	1 (1.3)	2 (20.4)	4 (4.7)	6 (6.6)
失血性貧血	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
白血球減少症	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
リンパ節症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
リンパ球減少症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
好中球減少症	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
血液およびリンパ系障害（続き）								
血小板減少症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
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 (3.5)	5 (11.9)	1 (1.3)	1 (2.6)	0	0	4 (4.7)	6 (6.6)
前立腺癌	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
皮膚乳頭腫	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
皮膚有棘細胞癌	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
尿管新生物	1 (1.2)	3 (7.1)	0	0	0	0	1 (1.2)	3 (3.3)
生殖系および乳房障害	3 (3.5)	3 (7.1)	1 (1.3)	1 (2.6)	0	0	4 (4.7)	4 (4.4)
乳房腫瘤	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
閉経期障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
生殖系および乳房障害（続き）								
月経障害	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
陰嚢障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
内分泌障害	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
副腎機能不全	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
甲状腺機能亢進症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
先天性、家族性および遺伝性障害	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	1 (1.2)	2 (2.2)
陰嚢水瘤	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	1 (1.2)	2 (2.2)
免疫系障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
薬物過敏症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	64 (77.1)	217 (531.7)	30 (37.5)	57 (544.7)	0	0	68 (81.9)	274 (534.4)
感染症および寄生虫症	26 (31.3)	35 (85.8)	10 (12.5)	10 (95.6)	0	0	31 (37.3)	45 (87.8)
上咽頭炎	7 (8.4)	7 (17.2)	4 (5.0)	4 (38.2)	0	0	10 (12.0)	11 (21.5)
上気道感染	4 (4.8)	4 (9.8)	0	0	0	0	4 (4.8)	4 (7.8)
尿路感染	4 (4.8)	4 (9.8)	0	0	0	0	4 (4.8)	4 (7.8)
口腔カンジダ症	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	2 (3.9)
咽頭炎	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
肺炎	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	2 (3.9)
肛門膿瘍	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
虫垂炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
無症候性ＣＯＶＩＤ－１９	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
骨膿瘍	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
気管支炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
ＣＯＶＩＤ－１９	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	1 (1.2)	2 (3.9)
カンジダ感染	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
丹毒	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
真菌感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮膚真菌感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
帯状疱疹	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
爪感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
歯周炎	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
処置後感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
脂腺感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
副鼻腔炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮膚感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
ＣＯＶＩＤ－１９の疑い	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
ウイルス性発疹	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
胃腸障害	17 (20.5)	27 (66.2)	7 (8.8)	14 (133.8)	0	0	20 (24.1)	41 (80.0)
下痢	6 (7.2)	7 (17.2)	2 (2.5)	2 (19.1)	0	0	7 (8.4)	9 (17.6)
悪心	4 (4.8)	5 (12.3)	2 (2.5)	3 (28.7)	0	0	5 (6.0)	8 (15.6)
腹痛	2 (2.4)	2 (4.9)	2 (2.5)	2 (19.1)	0	0	3 (3.6)	4 (7.8)
上腹部痛	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	2 (3.9)
便秘	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
嚥下障害	1 (1.2)	1 (2.5)	1 (1.3)	2 (19.1)	0	0	2 (2.4)	3 (5.9)
腹部不快感	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
腹部膨満	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
下腹部痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
消化不良	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	1 (1.2)	2 (3.9)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
胃腸障害（続き）								
小腸炎	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
胃腸障害	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
胃食道逆流性疾患	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
血便排泄	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
口唇そう痒症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
口唇潰瘍	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
口腔そう痒症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
嘔吐	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
神経系障害	16 (19.3)	24 (58.8)	6 (7.5)	7 (66.9)	0	0	18 (21.7)	31 (60.5)
頭痛	7 (8.4)	7 (17.2)	0	0	0	0	7 (8.4)	7 (13.7)
片頭痛	2 (2.4)	6 (14.7)	3 (3.8)	3 (28.7)	0	0	4 (4.8)	9 (17.6)
浮動性めまい	3 (3.6)	5 (12.3)	1 (1.3)	1 (9.6)	0	0	3 (3.6)	6 (11.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害（続き）								
重症筋無力症	1 (1.2)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	3 (5.9)
手根管症候群	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
構語障害	0	0	1 (1.3)	2 (19.1)	0	0	1 (1.2)	2 (3.9)
頭部不快感	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
感覚鈍麻	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
安静時振戦	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
一般・全身障害および投与部位の状態	14 (16.9)	19 (46.6)	4 (5.0)	5 (47.8)	0	0	17 (20.5)	24 (46.8)
疲労	3 (3.6)	4 (9.8)	2 (2.5)	2 (19.1)	0	0	5 (6.0)	6 (11.7)
発熱	2 (2.4)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	3 (3.6)	3 (5.9)
インフルエンザ様疾患	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
非心臓性胸痛	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
末梢性浮腫	2 (2.4)	3 (7.4)	0	0	0	0	2 (2.4)	3 (5.9)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態（続き）								
無力症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
胸部不快感	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
胸痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
注射部位硬結	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
倦怠感	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
顔面腫脹	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
全身性炎症反応症候群	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
ワクチン接種部位紅斑	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
筋骨格系および結合組織障害	14 (16.9)	21 (51.5)	6 (7.5)	6 (57.3)	0	0	17 (20.5)	27 (52.7)
背部痛	5 (6.0)	5 (12.3)	1 (1.3)	1 (9.6)	0	0	6 (7.2)	6 (11.7)
関節痛	5 (6.0)	5 (12.3)	1 (1.3)	1 (9.6)	0	0	5 (6.0)	6 (11.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
筋骨格系および結合組織障害（続き）								
筋痙縮	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
筋骨格痛	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
関節拘縮	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
筋緊張	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
筋肉痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
頚部痛	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
変形性関節症	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
四肢痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
乾癬性関節症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
脊椎痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
滑膜炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
腱炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
弾発指	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
傷害、中毒および処置合併症	13 (15.7)	13 (31.9)	2 (2.5)	3 (28.7)	0	0	15 (18.1)	16 (31.2)
転倒	3 (3.6)	3 (7.4)	1 (1.3)	1 (9.6)	0	0	4 (4.8)	4 (7.8)
ワクチン接種合併症	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
節足動物咬傷	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
背部損傷	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
挫傷	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
靱帯捻挫	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
肉離れ	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
処置後合併症	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
ワクチン接種後症候群	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
脊椎圧迫骨折	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
外傷性骨折	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
傷害、中毒および処置合併症（続き）								
創傷	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
呼吸器、胸郭および縦隔障害	12 (14.5)	15 (36.8)	1 (1.3)	1 (9.6)	0	0	13 (15.7)	16 (31.2)
咳嗽	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
喘息	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
呼吸困難	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
鼻出血	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
喀血	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
鼻そう痒症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
口腔咽頭痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
口腔咽頭痙攣	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
咽頭狭窄	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
呼吸不全	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
呼吸器、胸郭および縦隔障害（続き）								
気道うっ血	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
鼻漏	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
副鼻腔うっ血	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
睡眠時無呼吸症候群	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
上気道の炎症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮膚および皮下組織障害	13 (15.7)	16 (39.2)	0	0	0	0	13 (15.7)	16 (31.2)
皮膚病変	3 (3.6)	3 (7.4)	0	0	0	0	3 (3.6)	3 (5.9)
多汗症	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
そう痒症	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
蕁麻疹	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
接触皮膚炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
皮膚および皮下組織障害（続き）								
湿疹	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮脂欠乏性湿疹	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
紅斑	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
点状出血	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮膚色素過剰	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮膚潰瘍	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
臨床検査	9 (10.8)	12 (29.4)	2 (2.5)	2 (19.1)	0	0	10 (12.0)	14 (27.3)
Ｃ－反応性蛋白増加	3 (3.6)	3 (7.4)	1 (1.3)	1 (9.6)	0	0	4 (4.8)	4 (7.8)
活性化部分トロンボプラスチン時間延長	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	1 (1.2)	2 (3.9)
アラニンアミノトランスフェラーゼ増加	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
アスパラギン酸アミノトランスフェラーゼ増加	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
血中クレアチニン増加	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
グリコヘモグロビン増加	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
リンパ球数減少	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
便潜血陽性	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
トランスアミナーゼ上昇	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
体重増加	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
眼障害	5 (6.0)	7 (17.2)	1 (1.3)	1 (9.6)	0	0	6 (7.2)	8 (15.6)
複視	1 (1.2)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	3 (5.9)
白内障	1 (1.2)	2 (4.9)	0	0	0	0	1 (1.2)	2 (3.9)
結膜出血	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
眼痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
眼障害（続き）								
眼瞼下垂	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
代謝および栄養障害	6 (7.2)	6 (14.7)	0	0	0	0	6 (7.2)	6 (11.7)
食欲減退	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
糖尿病	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
高尿酸血症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
食欲亢進	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
ビタミンD欠乏	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
血管障害	5 (6.0)	5 (12.3)	2 (2.5)	2 (19.1)	0	0	6 (7.2)	7 (13.7)
大動脈障害	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
大動脈狭窄	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	1 (1.2)	2 (3.9)
潮紅	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
高血圧	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
血管障害（続き）								
静脈炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
血管破裂	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
精神障害	2 (2.4)	2 (4.9)	2 (2.5)	2 (19.1)	0	0	4 (4.8)	4 (7.8)
うつ病	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	2 (3.9)
不安	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
パニック発作	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
腎および尿路障害	4 (4.8)	4 (9.8)	1 (1.3)	1 (9.6)	0	0	4 (4.8)	5 (9.8)
頻尿	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
微少病変糸球体腎炎	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	1 (1.2)	2 (3.9)
蛋白尿	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
肝胆道系障害	2 (2.4)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	3 (3.6)	3 (5.9)
胆石症	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
肝胆道系障害（続き）								
肝病変	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
脂肪肝	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
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 (2.4)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	3 (3.6)	3 (5.9)
皮膚血管腫	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
皮膚の新生物	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
皮膚有棘細胞癌	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
血液およびリンパ系障害	2 (2.4)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	3 (5.9)
低色素性貧血	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
好中球減少症	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
血液およびリンパ系障害（続き）								
胸腺腫大	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
心臓障害	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
心房細動	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
動悸	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
耳および迷路障害	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
耳鳴	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
内分泌障害	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
甲状腺腫瘤	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
生殖系および乳房障害	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
子宮内膜肥厚	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	143 (84.6)	574 (693.4)	90 (56.3)	269 (548.3)	23 (30.7)	38 (388.0)	150 (88.8)	881 (622.0)
感染症および寄生虫症	65 (38.5)	100 (120.8)	36 (22.5)	48 (97.8)	7 (9.3)	7 (71.5)	87 (51.5)	155 (109.4)
上咽頭炎	10 (5.9)	10 (12.1)	6 (3.8)	6 (12.2)	1 (1.3)	1 (10.2)	15 (8.9)	17 (12.0)
尿路感染	9 (5.3)	11 (13.3)	5 (3.1)	5 (10.2)	1 (1.3)	1 (10.2)	15 (8.9)	17 (12.0)
ＣＯＶＩＤ－１９	6 (3.6)	6 (7.2)	3 (1.9)	6 (12.2)	1 (1.3)	1 (10.2)	9 (5.3)	13 (9.2)
上気道感染	7 (4.1)	7 (8.5)	2 (1.3)	3 (6.1)	0	0	9 (5.3)	10 (7.1)
帯状疱疹	3 (1.8)	3 (3.6)	3 (1.9)	3 (6.1)	0	0	6 (3.6)	6 (4.2)
咽頭炎	6 (3.6)	6 (7.2)	0	0	0	0	6 (3.6)	6 (4.2)
皮膚真菌感染	3 (1.8)	3 (3.6)	2 (1.3)	2 (4.1)	0	0	5 (3.0)	5 (3.5)
肺炎	3 (1.8)	3 (3.6)	2 (1.3)	3 (6.1)	0	0	5 (3.0)	6 (4.2)
副鼻腔炎	4 (2.4)	4 (4.8)	1 (0.6)	1 (2.0)	0	0	5 (3.0)	5 (3.5)
無症候性ＣＯＶＩＤ－１９	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	3 (1.8)	3 (2.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
気管支炎	2 (1.2)	2 (2.4)	0	0	1 (1.3)	1 (10.2)	3 (1.8)	3 (2.1)
ＣＯＶＩＤ－１９肺炎	2 (1.2)	3 (3.6)	0	0	0	0	2 (1.2)	3 (2.1)
蜂巣炎	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
結膜炎	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
丹毒	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
胃腸炎	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
ウイルス性胃腸炎	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
ウイルス性消化管感染	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
インフルエンザ	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
口腔カンジダ症	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
中耳炎	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
足部白癬	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
膣感染	1 (0.6)	1 (1.2)	0	0	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
肛門膿瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
虫垂炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
細菌性関節炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
骨膿瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
カンジダ感染	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
クロストリジウム・ディフィシレ感染	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
結腸膿瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
爪の皮膚糸状菌症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
憩室炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
耳感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
真菌感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
壊疽	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
消化管感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
膿痂疹	1 (0.6)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	3 (2.1)
感染性皮膚潰瘍	1 (0.6)	2 (2.4)	0	0	0	0	1 (0.6)	2 (1.4)
腎感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
限局性感染	0	0	1 (0.6)	3 (6.1)	0	0	1 (0.6)	3 (2.1)
下気道感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
爪感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
病原体耐性	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
歯周炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
誤嚥性肺炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
ＲＳウイルス肺炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ウイルス性肺炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
処置後感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
術後創感染	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
慢性腎盂腎炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
脂腺感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
皮膚感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ブドウ球菌性敗血症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ＣＯＶＩＤ－１９の疑い	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
歯膿瘍	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
ウイルス性発疹	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
外陰膣真菌感染	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
胃腸障害	46 (27.2)	78 (94.2)	24 (15.0)	38 (77.5)	1 (1.3)	1 (10.2)	61 (36.1)	117 (82.6)
下痢	18 (10.7)	20 (24.2)	6 (3.8)	6 (12.2)	0	0	23 (13.6)	26 (18.4)
悪心	13 (7.7)	18 (21.7)	6 (3.8)	7 (14.3)	0	0	16 (9.5)	25 (17.7)
腹痛	7 (4.1)	8 (9.7)	3 (1.9)	3 (6.1)	0	0	9 (5.3)	11 (7.8)
腹部不快感	2 (1.2)	3 (3.6)	3 (1.9)	4 (8.2)	0	0	4 (2.4)	7 (4.9)
嚥下障害	2 (1.2)	2 (2.4)	2 (1.3)	4 (8.2)	0	0	4 (2.4)	6 (4.2)
嘔吐	2 (1.2)	4 (4.8)	2 (1.3)	2 (4.1)	0	0	4 (2.4)	6 (4.2)
腹部膨満	1 (0.6)	1 (1.2)	2 (1.3)	2 (4.1)	0	0	3 (1.8)	3 (2.1)
便秘	3 (1.8)	3 (3.6)	0	0	0	0	3 (1.8)	3 (2.1)
齲歯	3 (1.8)	3 (3.6)	0	0	0	0	3 (1.8)	3 (2.1)
上腹部痛	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
消化不良	1 (0.6)	1 (1.2)	2 (1.3)	2 (4.1)	0	0	2 (1.2)	3 (2.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
胃腸障害（続き）								
胃炎	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
胃食道逆流性疾患	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
嚥下痛	1 (0.6)	1 (1.2)	0	0	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
下腹部痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
口角口唇炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血性下痢	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
腸憩室	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
口内乾燥	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
小腸炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
軟便	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
排便回数増加	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
胃腸障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
胃腸障害（続き）								
血便排泄	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
痔核	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
口唇そう痒症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
口唇潰瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
口腔知覚不全	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
口腔そう痒症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
歯痛	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
神経系障害	45 (26.6)	68 (82.1)	25 (15.6)	35 (71.3)	4 (5.3)	4 (40.8)	57 (33.7)	107 (75.5)
頭痛	24 (14.2)	27 (32.6)	9 (5.6)	14 (28.5)	2 (2.7)	2 (20.4)	28 (16.6)	43 (30.4)
浮動性めまい	11 (6.5)	14 (16.9)	5 (3.1)	5 (10.2)	0	0	14 (8.3)	19 (13.4)
重症筋無力症	2 (1.2)	5 (6.0)	6 (3.8)	6 (12.2)	0	0	8 (4.7)	11 (7.8)
片頭痛	2 (1.2)	6 (7.2)	3 (1.9)	3 (6.1)	0	0	4 (2.4)	9 (6.4)
失神	2 (1.2)	3 (3.6)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	4 (2.8)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害（続き）								
平衡障害	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
構語障害	0	0	2 (1.3)	4 (8.2)	0	0	2 (1.2)	4 (2.8)
一過性脳虚血発作	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
手根管症候群	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
脳出血	1 (0.6)	2 (2.4)	0	0	0	0	1 (0.6)	2 (1.4)
認知障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
頭部不快感	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
不全片麻痺	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
感覚鈍麻	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肋間神経痛	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
腰仙部神経根障害	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
重症筋無力症クリーゼ	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ヘルペス後神経痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害（続き）								
安静時振戦	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
振戦	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
筋骨格系および結合組織障害	38 (22.5)	61 (73.7)	23 (14.4)	30 (61.2)	3 (4.0)	5 (51.1)	50 (29.6)	96 (67.8)
背部痛	12 (7.1)	12 (14.5)	4 (2.5)	4 (8.2)	0	0	16 (9.5)	16 (11.3)
関節痛	11 (6.5)	13 (15.7)	7 (4.4)	8 (16.3)	2 (2.7)	2 (20.4)	15 (8.9)	23 (16.2)
四肢痛	4 (2.4)	5 (6.0)	2 (1.3)	2 (4.1)	1 (1.3)	1 (10.2)	7 (4.1)	8 (5.6)
筋痙縮	4 (2.4)	6 (7.2)	2 (1.3)	2 (4.1)	0	0	6 (3.6)	8 (5.6)
椎間板突出	1 (0.6)	1 (1.2)	2 (1.3)	2 (4.1)	1 (1.3)	1 (10.2)	4 (2.4)	4 (2.8)
頚部痛	2 (1.2)	2 (2.4)	2 (1.3)	2 (4.1)	0	0	4 (2.4)	4 (2.8)
筋肉痛	3 (1.8)	3 (3.6)	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	3 (1.8)	5 (3.5)
腱炎	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
筋骨格系および結合組織障害（続き）								
筋力低下	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
筋骨格痛	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
筋骨格硬直	0	0	2 (1.3)	2 (4.1)	0	0	2 (1.2)	2 (1.4)
変形性関節症	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
滑膜炎	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
尾骨痛	1 (0.6)	2 (2.4)	0	0	0	0	1 (0.6)	2 (1.4)
単径部痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
出血性関節症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
関節拘縮	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
筋緊張	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
筋攣縮	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
筋骨格系胸痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
結節性変形性関節症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
筋骨格系および結合組織障害（続き）								
骨減少症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
骨粗鬆症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
乾癬性関節症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肩回旋筋腱板症候群	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
脊椎痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
弾発指	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
一般・全身障害および投与部位の状態	37 (21.9)	51 (61.6)	18 (11.3)	19 (38.7)	3 (4.0)	3 (30.6)	47 (27.8)	73 (51.5)
疲労	10 (5.9)	12 (14.5)	6 (3.8)	6 (12.2)	1 (1.3)	1 (10.2)	16 (9.5)	19 (13.4)
末梢性浮腫	5 (3.0)	7 (8.5)	2 (1.3)	2 (4.1)	0	0	7 (4.1)	9 (6.4)
発熱	3 (1.8)	3 (3.6)	2 (1.3)	2 (4.1)	1 (1.3)	1 (10.2)	6 (3.6)	6 (4.2)
インフルエンザ様疾患	4 (2.4)	4 (4.8)	1 (0.6)	1 (2.0)	0	0	5 (3.0)	5 (3.5)
非心臓性胸痛	5 (3.0)	5 (6.0)	0	0	0	0	5 (3.0)	5 (3.5)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態（続き）								
胸痛	2 (1.2)	3 (3.6)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	4 (2.8)
無力症	2 (1.2)	3 (3.6)	0	0	0	0	2 (1.2)	3 (2.1)
胸部不快感	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
倦怠感	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
ワクチン接種部位反応	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	3 (2.1)
悪寒	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
異形成	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
歩行障害	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
全身健康状態悪化	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
注入部位血管外漏出	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	2 (1.4)
注入部位血腫	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
注入部位疼痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態（続き）								
注射部位硬結	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
注射部位反応	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
疼痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
顔面腫脹	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
全身性炎症反応症候群	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
ワクチン接種部位紅斑	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ワクチン接種部位刺激感	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
傷害、中毒および処置合併症	19 (11.2)	22 (26.6)	14 (8.8)	16 (32.6)	4 (5.3)	4 (40.8)	34 (20.1)	42 (29.7)
転倒	5 (3.0)	6 (7.2)	2 (1.3)	3 (6.1)	0	0	7 (4.1)	9 (6.4)
ワクチン接種合併症	4 (2.4)	5 (6.0)	1 (0.6)	1 (2.0)	0	0	5 (3.0)	6 (4.2)
関節損傷	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
傷害、中毒および処置合併症（続き）								
脊椎圧迫骨折	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
歯牙破折	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
創傷	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
節足動物咬傷	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
背部損傷	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
胸部損傷	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
挫傷	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
歯科修復不成功	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
上顎炎	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
頭部損傷	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
注入に伴う反応	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	1 (0.6)	2 (1.4)
靱帯断裂	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
靱帯捻挫	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
傷害、中毒および処置合併症（続き）								
腰椎骨折	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
多発骨折	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肉離れ	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
処置後合併症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
ワクチン接種後症候群	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
橈骨骨折	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
肋骨骨折	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
外傷性骨折	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
呼吸器、胸郭および縦隔障害	25 (14.8)	38 (45.9)	9 (5.6)	16 (32.6)	1 (1.3)	2 (20.4)	29 (17.2)	56 (39.5)
咳嗽	6 (3.6)	6 (7.2)	1 (0.6)	1 (2.0)	0	0	7 (4.1)	7 (4.9)
呼吸困難	6 (3.6)	7 (8.5)	2 (1.3)	3 (6.1)	0	0	6 (3.6)	10 (7.1)
息詰まり	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
呼吸器、胸郭および縦隔障害（続き）								
労作性呼吸困難	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
低酸素症	0	0	2 (1.3)	2 (4.1)	0	0	2 (1.2)	2 (1.4)
口腔咽頭痛	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
湿性咳嗽	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
気道うっ血	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
鼻漏	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
副鼻腔うっ血	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
喘息	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
慢性気管支炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
喉頭蓋潰瘍	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
鼻出血	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
喀血	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肺浸潤	1 (0.6)	4 (4.8)	0	0	0	0	1 (0.6)	4 (2.8)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
呼吸器、胸郭および縦隔障害（続き）								
鼻閉	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
鼻そう痒症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
口腔咽頭痙攣	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
咽頭狭窄	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
胸水	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
呼吸不全	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
アレルギー性鼻炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
睡眠時無呼吸症候群	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
咽喉絞扼感	0	0	1 (0.6)	3 (6.1)	1 (1.3)	2 (20.4)	1 (0.6)	5 (3.5)
上気道の炎症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
皮膚および皮下組織障害	21 (12.4)	24 (29.0)	9 (5.6)	11 (22.4)	0	0	29 (17.2)	35 (24.7)
そう痒症	3 (1.8)	3 (3.6)	2 (1.3)	2 (4.1)	0	0	5 (3.0)	5 (3.5)
発疹	2 (1.2)	2 (2.4)	2 (1.3)	2 (4.1)	0	0	4 (2.4)	4 (2.8)
皮膚病変	4 (2.4)	4 (4.8)	0	0	0	0	4 (2.4)	4 (2.8)
蕁麻疹	2 (1.2)	2 (2.4)	2 (1.3)	2 (4.1)	0	0	4 (2.4)	4 (2.8)
脱毛症	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
多汗症	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
過角化	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
ざ瘡様皮膚炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
接触皮膚炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
薬疹	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
斑状出血	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
湿疹	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
皮脂欠乏性湿疹	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
皮膚および皮下組織障害（続き）								
紅斑	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
皮膚疼痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
点状出血	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
皮膚萎縮	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
皮膚色素過剰	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
皮膚潰瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
臨床検査	20 (11.8)	33 (39.9)	8 (5.0)	8 (16.3)	2 (2.7)	2 (20.4)	28 (16.6)	43 (30.4)
C－反応性蛋白増加	4 (2.4)	4 (4.8)	1 (0.6)	1 (2.0)	0	0	5 (3.0)	5 (3.5)
アラニンアミノトランスフェラーゼ増加	4 (2.4)	4 (4.8)	0	0	0	0	4 (2.4)	4 (2.8)
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.8)	3 (3.6)	0	0	0	0	3 (1.8)	3 (2.1)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
γ－グルタミルトランスフェラーゼ増加	3 (1.8)	3 (3.6)	0	0	0	0	3 (1.8)	3 (2.1)
リンパ球数減少	2 (1.2)	2 (2.4)	0	0	1 (1.3)	1 (10.2)	3 (1.8)	3 (2.1)
グリコヘモグロビン増加	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
白血球数減少	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
活性化部分トロンボプラスチン時間延長	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	2 (1.4)
血中クレアチニン増加	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血中葉酸減少	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血中ブドウ糖増加	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
血圧上昇	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
体温上昇	1 (0.6)	2 (2.4)	0	0	0	0	1 (0.6)	2 (1.4)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
尿中結晶陽性	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
心電図ＰＲ延長	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
尿中ブドウ糖陽性	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
便潜血陽性	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
尿中蛋白陽性	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
赤血球数減少	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
網状赤血球数増加	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
トランスアミナーゼ上昇	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
トロポニン増加	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
尿中白血球エステラーゼ陽性	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
尿中ウロビリノーゲン	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
体重増加	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
白血球数増加	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
代謝および栄養障害	21 (12.4)	24 (29.0)	3 (1.9)	3 (6.1)	1 (1.3)	1 (10.2)	25 (14.8)	28 (19.8)
糖尿病	5 (3.0)	5 (6.0)	0	0	1 (1.3)	1 (10.2)	6 (3.6)	6 (4.2)
食欲減退	4 (2.4)	4 (4.8)	0	0	0	0	4 (2.4)	4 (2.8)
痛風	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
高血糖	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
低血糖	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
低カリウム血症	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
食欲亢進	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

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Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
代謝および栄養障害（続き）								
脱水	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
コントロール不良の糖尿病	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
高尿酸血症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
鉄欠乏	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ステロイド糖尿病	1 (0.6)	3 (3.6)	0	0	0	0	1 (0.6)	3 (2.1)
ビタミンD欠乏	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
眼障害	11 (6.5)	13 (15.7)	6 (3.8)	8 (16.3)	3 (4.0)	4 (40.8)	18 (10.7)	25 (17.7)
複視	2 (1.2)	3 (3.6)	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	4 (2.4)	5 (3.5)
白内障	2 (1.2)	3 (3.6)	2 (1.3)	4 (8.2)	0	0	3 (1.8)	7 (4.9)
眼瞼痙攣	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
眼瞼下垂	1 (0.6)	1 (1.2)	0	0	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
結膜出血	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
眼障害（続き）								
ドライアイ	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
眼痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
緑内障	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
羞明	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
網膜静脈閉塞	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
眼瞼腫脹	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
霧視	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
視力障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血管障害	10 (5.9)	13 (15.7)	6 (3.8)	7 (14.3)	0	0	15 (8.9)	20 (14.1)
高血圧	3 (1.8)	6 (7.2)	2 (1.3)	2 (4.1)	0	0	5 (3.0)	8 (5.6)
大動脈障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
大動脈狭窄	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	2 (1.4)
深部静脈血栓症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
血管障害（続き）								
潮紅	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血腫	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
低血圧	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
静脈炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血管痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血管破裂	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
静脈破裂	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
白衣性高血圧	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
心臓障害	8 (4.7)	9 (10.9)	5 (3.1)	9 (18.3)	2 (2.7)	2 (20.4)	12 (7.1)	20 (14.1)
心房細動	3 (1.8)	3 (3.6)	0	0	0	0	3 (1.8)	3 (2.1)
動悸	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
狭心症	0	0	2 (1.3)	2 (4.1)	1 (1.3)	1 (10.2)	2 (1.2)	3 (2.1)
頻脈	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
心臓障害（続き）								
心房頻脈	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
うっ血性心筋症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
冠動脈疾患	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
冠動脈閉塞	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
期外収縮	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
僧帽弁狭窄症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
結節性不整脈	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
上室性期外収縮	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
心室性期外収縮	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
精神障害	7 (4.1)	7 (8.5)	3 (1.9)	3 (6.1)	0	0	10 (5.9)	10 (7.1)
うつ病	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
不眠症	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
精神障害（続き）								
抑うつ気分を伴う適応障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
不安	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
気分動揺	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
パニック発作	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
自殺企図	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
腎および尿路障害	7 (4.1)	7 (8.5)	3 (1.9)	3 (6.1)	1 (1.3)	1 (10.2)	10 (5.9)	11 (7.8)
頻尿	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
急性腎障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
微少病変糸球体腎炎	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	2 (1.4)
ミクロアルブミン尿	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
腎結石症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
腎および尿路障害（続き）								
蛋白尿	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
腎尿細管壊死	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
腹圧性尿失禁	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
尿閉	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
耳および迷路障害	4 (2.4)	7 (8.5)	3 (1.9)	4 (8.2)	0	0	7 (4.1)	11 (7.8)
耳痛	1 (0.6)	1 (1.2)	1 (0.6)	2 (4.1)	0	0	2 (1.2)	3 (2.1)
耳鳴	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
回転性めまい	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
難聴	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
片耳難聴	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
耳不快感	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
耳石症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
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 (3.0)	7 (8.5)	2 (1.3)	2 (4.1)	0	0	7 (4.1)	9 (6.4)
皮膚有棘細胞癌	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
皮膚血管腫	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
皮膚の新生物	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
前立腺癌	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
皮膚乳頭腫	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
尿管新生物	1 (0.6)	3 (3.6)	0	0	0	0	1 (0.6)	3 (2.1)
血液およびリンパ系障害	2 (1.2)	2 (2.4)	4 (2.5)	5 (10.2)	1 (1.3)	2 (20.4)	6 (3.6)	9 (6.4)
好中球減少症	0	0	1 (0.6)	1 (2.0)	1 (1.3)	1 (10.2)	2 (1.2)	2 (1.4)
失血性貧血	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
血液およびリンパ系障害（続き）								
低色素性貧血	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
白血球減少症	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
リンパ節症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
リンパ球減少症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
血小板減少症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
胸腺腫大	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
生殖系および乳房障害	4 (2.4)	4 (4.8)	1 (0.6)	1 (2.0)	0	0	5 (3.0)	5 (3.5)
乳房腫瘤	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
子宮内膜肥厚	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
閉経期障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
月経障害	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
陰嚢障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope
Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
内分泌障害	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
副腎機能不全	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
甲状腺機能亢進症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
甲状腺腫瘤	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肝胆道系障害	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
胆石症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
肝病変	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
脂肪肝	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
先天性、家族性および遺伝性障害	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	2 (1.4)
陰嚢水瘤	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	1 (0.6)	2 (1.4)
免疫系障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
薬物過敏症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.
Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.
Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.
Note: AEs are coded using MedDRA 24.1
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=6) PY = 2.9		>6 to 12 months (N=5) PY = 2.5		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=6) PY = 6.1	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	5 (83.3)	23 (793.9)	2 (40.0)	3 (120.0)	0	0	6 (100.0)	26 (427.8)
胃腸障害	3 (50.0)	5 (172.6)	0	0	0	0	3 (50.0)	5 (82.3)
下痢	2 (33.3)	3 (103.5)	0	0	0	0	2 (33.3)	3 (49.4)
口角口唇炎	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
齲歯	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
代謝および栄養障害	2 (33.3)	5 (172.6)	1 (20.0)	1 (40.0)	0	0	3 (50.0)	6 (98.7)
脱水	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
コントロール不良の糖尿病	0	0	1 (20.0)	1 (40.0)	0	0	1 (16.7)	1 (16.5)
低血糖	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
ステロイド糖尿病	1 (16.7)	3 (103.5)	0	0	0	0	1 (16.7)	3 (49.4)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=6) PY = 2.9		>6 to 12 months (N=5) PY = 2.5		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=6) PY = 6.1	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
筋骨格系および結合組織障害	2 (33.3)	2 (69.0)	1 (20.0)	1 (40.0)	0	0	3 (50.0)	3 (49.4)
結節性変形性関節症	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
四肢痛	0	0	1 (20.0)	1 (40.0)	0	0	1 (16.7)	1 (16.5)
腱炎	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
感染症および寄生虫症	2 (33.3)	3 (103.5)	0	0	0	0	2 (33.3)	3 (49.4)
爪の皮膚糸状菌症	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
咽頭炎	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
足部白癬	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
神経系障害	2 (33.3)	3 (103.5)	0	0	0	0	2 (33.3)	3 (49.4)
脳出血	1 (16.7)	2 (69.0)	0	0	0	0	1 (16.7)	2 (32.9)
浮動性めまい	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
眼障害	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
網膜静脈閉塞	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=6) PY = 2.9		>6 to 12 months (N=5) PY = 2.5		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=6) PY = 6.1	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態	1 (16.7)	1 (34.5)	1 (20.0)	1 (40.0)	0	0	1 (16.7)	2 (32.9)
ワクチン接種部位反応	1 (16.7)	1 (34.5)	1 (20.0)	1 (40.0)	0	0	1 (16.7)	2 (32.9)
臨床検査	1 (16.7)	3 (103.5)	0	0	0	0	1 (16.7)	3 (49.4)
アラニンアミノトランスフェラーゼ増加	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
アスパラギン酸アミノトランスフェラーゼ増加	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
γ－グルタミルトランスフェラーゼ増加	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=5) PY = 2.5		>6 to 12 months (N=5) PY = 0.7		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=5) PY = 3.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	5 (100.0)	13 (520.0)	2 (40.0)	2 (305.9)	0	0	5 (100.0)	15 (475.6)
感染症および寄生虫症	1 (20.0)	1 (40.0)	2 (40.0)	2 (305.9)	0	0	3 (60.0)	3 (95.1)
上咽頭炎	1 (20.0)	1 (40.0)	2 (40.0)	2 (305.9)	0	0	3 (60.0)	3 (95.1)
代謝および栄養障害	2 (40.0)	2 (80.0)	0	0	0	0	2 (40.0)	2 (63.4)
食欲減退	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
高尿酸血症	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
皮膚および皮下組織障害	2 (40.0)	2 (80.0)	0	0	0	0	2 (40.0)	2 (63.4)
接触皮膚炎	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
皮脂欠乏性湿疹	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
心臓障害	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
動悸	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=5) PY = 2.5		>6 to 12 months (N=5) PY = 0.7		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=5) PY = 3.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
倦怠感	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
臨床検査	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
血中クレアチニン増加	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
筋骨格系および結合組織障害	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
背部痛	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
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）	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
皮膚の新生物	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=5) PY = 2.5		>6 to 12 months (N=5) PY = 0.7		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=5) PY = 3.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
頭部不快感	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
腎および尿路障害	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
蛋白尿	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
呼吸器、胸郭および縦隔障害	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)
咽頭狭窄	1 (20.0)	1 (40.0)	0	0	0	0	1 (20.0)	1 (31.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=11) PY = 5.4		>6 to 12 months (N=10) PY = 3.2		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=11) PY = 9.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	10 (90.9)	36 (667.0)	4 (40.0)	5 (158.5)	0	0	11 (100.0)	41 (444.1)
感染症および寄生虫症	3 (27.3)	4 (74.1)	2 (20.0)	2 (63.4)	0	0	5 (45.5)	6 (65.0)
上咽頭炎	1 (9.1)	1 (18.5)	2 (20.0)	2 (63.4)	0	0	3 (27.3)	3 (32.5)
爪の皮膚糸状菌症	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
咽頭炎	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
足部白癬	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
代謝および栄養障害	4 (36.4)	7 (129.7)	1 (10.0)	1 (31.7)	0	0	5 (45.5)	8 (86.7)
食欲減退	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
脱水	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
コントロール不良の糖尿病	0	0	1 (10.0)	1 (31.7)	0	0	1 (9.1)	1 (10.8)
高尿酸血症	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=11) PY = 5.4		>6 to 12 months (N=10) PY = 3.2		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=11) PY = 9.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
代謝および栄養障害（続き）								
低血糖	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
ステロイド糖尿病	1 (9.1)	3 (55.6)	0	0	0	0	1 (9.1)	3 (32.5)
筋骨格系および結合組織障害	3 (27.3)	3 (55.6)	1 (10.0)	1 (31.7)	0	0	4 (36.4)	4 (43.3)
背部痛	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
結節性変形性関節症	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
四肢痛	0	0	1 (10.0)	1 (31.7)	0	0	1 (9.1)	1 (10.8)
腱炎	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
胃腸障害	3 (27.3)	5 (92.6)	0	0	0	0	3 (27.3)	5 (54.2)
下痢	2 (18.2)	3 (55.6)	0	0	0	0	2 (18.2)	3 (32.5)
口角口唇炎	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
齲歯	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=11) PY = 5.4		>6 to 12 months (N=10) PY = 3.2		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=11) PY = 9.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害	3 (27.3)	4 (74.1)	0	0	0	0	3 (27.3)	4 (43.3)
脳出血	1 (9.1)	2 (37.1)	0	0	0	0	1 (9.1)	2 (21.7)
浮動性めまい	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
頭部不快感	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
一般・全身障害および投与部位の状態	2 (18.2)	2 (37.1)	1 (10.0)	1 (31.7)	0	0	2 (18.2)	3 (32.5)
倦怠感	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
ワクチン接種部位反応	1 (9.1)	1 (18.5)	1 (10.0)	1 (31.7)	0	0	1 (9.1)	2 (21.7)
臨床検査	2 (18.2)	4 (74.1)	0	0	0	0	2 (18.2)	4 (43.3)
アラニンアミノトランスフェラーゼ増加	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
アスパラギン酸アミノトランスフェラーゼ増加	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
血中クレアチニン増加	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=11) PY = 5.4		>6 to 12 months (N=10) PY = 3.2		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=11) PY = 9.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
臨床検査（続き）								
γ－グルタミルトランスフェラーゼ増加	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
皮膚および皮下組織障害	2 (18.2)	2 (37.1)	0	0	0	0	2 (18.2)	2 (21.7)
接触皮膚炎	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
皮脂欠乏性湿疹	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
心臓障害	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
動悸	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
眼障害	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
網膜静脈閉塞	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.2.4.J

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=11) PY = 5.4		>6 to 12 months (N=10) PY = 3.2		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=11) PY = 9.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
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）	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
皮膚の新生物	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
腎および尿路障害	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
蛋白尿	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
呼吸器、胸郭および縦隔障害	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
咽頭狭窄	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
Patients with Treatment-Emergent Adverse Events	21 (25.3)	47 (56.6)	37 (43.0)	45 (52.3)	58 (34.3)	92 (54.4)
血液およびリンパ系障害	0	2 (2.4)	1 (1.2)	3 (3.5)	1 (0.6)	5 (3.0)
失血性貧血	0	0	0	1 (1.2)	0	1 (0.6)
低色素性貧血	0	1 (1.2)	0	0	0	1 (0.6)
白血球減少症	0	0	1 (1.2)	0	1 (0.6)	0
リンパ節症	0	0	0	1 (1.2)	0	1 (0.6)
リンパ球減少症	0	0	0	1 (1.2)	0	1 (0.6)
好中球減少症	0	1 (1.2)	1 (1.2)	0	1 (0.6)	1 (0.6)
血小板減少症	0	0	0	1 (1.2)	0	1 (0.6)
胸腺腫大	0	1 (1.2)	0	0	0	1 (0.6)
心臓障害	1 (1.2)	1 (1.2)	1 (1.2)	9 (10.5)	2 (1.2)	10 (5.9)
狭心症	0	0	0	2 (2.3)	0	2 (1.2)
心房細動	0	1 (1.2)	0	2 (2.3)	0	3 (1.8)
心房頻脈	0	0	0	1 (1.2)	0	1 (0.6)
うっ血性心筋症	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
心臓障害（続き）						
冠動脈疾患	0	0	0	1 (1.2)	0	1 (0.6)
冠動脈閉塞	0	0	0	1 (1.2)	0	1 (0.6)
期外収縮	0	0	0	1 (1.2)	0	1 (0.6)
僧帽弁狭窄症	0	0	1 (1.2)	0	1 (0.6)	0
結節性不整脈	0	0	0	1 (1.2)	0	1 (0.6)
動悸	1 (1.2)	0	0	2 (2.3)	1 (0.6)	2 (1.2)
上室性期外収縮	0	0	0	1 (1.2)	0	1 (0.6)
頻脈	0	0	0	2 (2.3)	0	2 (1.2)
心室性期外収縮	0	0	0	1 (1.2)	0	1 (0.6)
先天性、家族性および遺伝性障害	0	0	0	1 (1.2)	0	1 (0.6)
陰嚢水瘤	0	0	0	1 (1.2)	0	1 (0.6)
耳および迷路障害	0	1 (1.2)	0	6 (7.0)	0	7 (4.1)
難聴	0	0	0	1 (1.2)	0	1 (0.6)
片耳難聴	0	0	0	1 (1.2)	0	1 (0.6)
耳不快感	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
耳および迷路障害（続き）						
耳痛	0	0	0	2 (2.3)	0	2 (1.2)
耳石症	0	0	0	1 (1.2)	0	1 (0.6)
耳鳴	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
回転性めまい	0	0	0	2 (2.3)	0	2 (1.2)
内分泌障害	0	1 (1.2)	0	2 (2.3)	0	3 (1.8)
副腎機能不全	0	0	0	1 (1.2)	0	1 (0.6)
甲状腺機能亢進症	0	0	0	1 (1.2)	0	1 (0.6)
甲状腺腫瘤	0	1 (1.2)	0	0	0	1 (0.6)
眼障害	0	6 (7.2)	0	12 (14.0)	0	18 (10.7)
眼瞼痙攣	0	0	0	2 (2.3)	0	2 (1.2)
白内障	0	1 (1.2)	0	2 (2.3)	0	3 (1.8)
結膜出血	0	1 (1.2)	0	0	0	1 (0.6)
複視	0	2 (2.4)	0	2 (2.3)	0	4 (2.4)
ドライアイ	0	0	0	1 (1.2)	0	1 (0.6)
眼痛	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
眼障害（続き）						
眼瞼下垂	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
緑内障	0	0	0	1 (1.2)	0	1 (0.6)
羞明	0	0	0	1 (1.2)	0	1 (0.6)
網膜静脈閉塞	0	0	0	1 (1.2)	0	1 (0.6)
眼瞼腫脹	0	0	0	1 (1.2)	0	1 (0.6)
霧視	0	0	0	1 (1.2)	0	1 (0.6)
視力障害	0	0	0	1 (1.2)	0	1 (0.6)
胃腸障害	7 (8.4)	13 (15.7)	14 (16.3)	27 (31.4)	21 (12.4)	40 (23.7)
腹部不快感	0	1 (1.2)	0	3 (3.5)	0	4 (2.4)
腹部膨満	1 (1.2)	0	0	2 (2.3)	1 (0.6)	2 (1.2)
腹痛	0	3 (3.6)	1 (1.2)	5 (5.8)	1 (0.6)	8 (4.7)
下腹部痛	0	1 (1.2)	0	0	0	1 (0.6)
上腹部痛	0	2 (2.4)	0	0	0	2 (1.2)
口角口唇炎	0	0	1 (1.2)	0	1 (0.6)	0
便秘	0	2 (2.4)	0	1 (1.2)	0	3 (1.8)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
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Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
胃腸障害（続き）						
齲歯	0	0	0	3 (3.5)	0	3 (1.8)
下痢	1 (1.2)	6 (7.2)	6 (7.0)	10 (11.6)	7 (4.1)	16 (9.5)
血性下痢	0	0	0	1 (1.2)	0	1 (0.6)
腸憩室	0	0	0	1 (1.2)	0	1 (0.6)
口内乾燥	0	0	0	1 (1.2)	0	1 (0.6)
消化不良	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
嚥下障害	0	2 (2.4)	1 (1.2)	1 (1.2)	1 (0.6)	3 (1.8)
小腸炎	0	1 (1.2)	0	0	0	1 (0.6)
軟便	0	0	0	1 (1.2)	0	1 (0.6)
排便回数増加	0	0	0	1 (1.2)	0	1 (0.6)
胃炎	0	0	0	2 (2.3)	0	2 (1.2)
胃腸障害	1 (1.2)	0	0	0	1 (0.6)	0
胃食道逆流性疾患	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
血便排泄	0	1 (1.2)	0	0	0	1 (0.6)
痔核	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

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Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
胃腸障害（続き）						
口唇そう痒症	1 (1.2)	0	0	0	1 (0.6)	0
口唇潰瘍	0	1 (1.2)	0	0	0	1 (0.6)
悪心	4 (4.8)	1 (1.2)	7 (8.1)	4 (4.7)	11 (6.5)	5 (3.0)
嚥下痛	0	0	0	2 (2.3)	0	2 (1.2)
口腔知覚不全	0	0	0	1 (1.2)	0	1 (0.6)
口腔そう痒症	1 (1.2)	0	0	0	1 (0.6)	0
歯痛	0	0	0	1 (1.2)	0	1 (0.6)
嘔吐	0	1 (1.2)	0	3 (3.5)	0	4 (2.4)
一般・全身障害および投与部位の状態	4 (4.8)	13 (15.7)	4 (4.7)	26 (30.2)	8 (4.7)	39 (23.1)
無力症	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
胸部不快感	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
胸痛	0	1 (1.2)	0	2 (2.3)	0	3 (1.8)
悪寒	0	0	0	1 (1.2)	0	1 (0.6)
異形成	0	0	0	1 (1.2)	0	1 (0.6)
疲労	3 (3.6)	2 (2.4)	2 (2.3)	9 (10.5)	5 (3.0)	11 (6.5)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
一般・全身障害および投与部位の状態（続き）						
歩行障害	0	0	0	1 (1.2)	0	1 (0.6)
全身健康状態悪化	0	0	0	1 (1.2)	0	1 (0.6)
インフルエンザ様疾患	0	2 (2.4)	0	3 (3.5)	0	5 (3.0)
注入部位血管外漏出	0	0	1 (1.2)	0	1 (0.6)	0
注入部位血腫	0	0	0	1 (1.2)	0	1 (0.6)
注入部位疼痛	0	0	1 (1.2)	0	1 (0.6)	0
注射部位硬結	0	1 (1.2)	0	0	0	1 (0.6)
注射部位反応	0	0	0	1 (1.2)	0	1 (0.6)
倦怠感	1 (1.2)	0	0	1 (1.2)	1 (0.6)	1 (0.6)
非心臓性胸痛	0	2 (2.4)	0	3 (3.5)	0	5 (3.0)
末梢性浮腫	0	2 (2.4)	0	5 (5.8)	0	7 (4.1)
疼痛	0	0	0	1 (1.2)	0	1 (0.6)
発熱	0	3 (3.6)	0	3 (3.5)	0	6 (3.6)
顔面腫脹	0	1 (1.2)	0	0	0	1 (0.6)
全身性炎症反応症候群	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

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一般・全身障害および投与部位の状態（続き）						
ワクチン接種部位紅斑	0	1 (1.2)	0	0	0	1 (0.6)
ワクチン接種部位刺激感	0	0	0	1 (1.2)	0	1 (0.6)
ワクチン接種部位反応	0	0	0	2 (2.3)	0	2 (1.2)
肝胆道系障害	0	3 (3.6)	0	0	0	3 (1.8)
胆石症	0	1 (1.2)	0	0	0	1 (0.6)
肝病変	0	1 (1.2)	0	0	0	1 (0.6)
脂肪肝	0	1 (1.2)	0	0	0	1 (0.6)
免疫系障害	0	0	0	1 (1.2)	0	1 (0.6)
薬物過敏症	0	0	0	1 (1.2)	0	1 (0.6)
感染症および寄生虫症	4 (4.8)	27 (32.5)	13 (15.1)	43 (50.0)	17 (10.1)	70 (41.4)
肛門膿瘍	0	1 (1.2)	0	0	0	1 (0.6)
虫垂炎	0	1 (1.2)	0	0	0	1 (0.6)
細菌性関節炎	0	0	0	1 (1.2)	0	1 (0.6)
無症候性ＣＯＶＩＤ－１９	0	1 (1.2)	1 (1.2)	1 (1.2)	1 (0.6)	2 (1.2)
骨膿瘍	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
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感染症および寄生虫症（続き）						
気管支炎	0	1 (1.2)	2 (2.3)	0	2 (1.2)	1 (0.6)
ＣＯＶＩＤ－１９	0	1 (1.2)	0	8 (9.3)	0	9 (5.3)
ＣＯＶＩＤ－１９肺炎	0	0	0	2 (2.3)	0	2 (1.2)
カンジダ感染	0	1 (1.2)	0	0	0	1 (0.6)
蜂巣炎	0	0	1 (1.2)	1 (1.2)	1 (0.6)	1 (0.6)
クロストリジウム・ディフィシレ感染	0	0	0	1 (1.2)	0	1 (0.6)
結腸膿瘍	0	0	0	1 (1.2)	0	1 (0.6)
結膜炎	0	0	0	2 (2.3)	0	2 (1.2)
爪の皮膚糸状菌症	0	0	0	1 (1.2)	0	1 (0.6)
憩室炎	0	0	0	1 (1.2)	0	1 (0.6)
耳感染	0	0	0	1 (1.2)	0	1 (0.6)
丹毒	1 (1.2)	0	0	1 (1.2)	1 (0.6)	1 (0.6)
真菌感染	0	1 (1.2)	0	0	0	1 (0.6)
皮膚真菌感染	1 (1.2)	0	1 (1.2)	3 (3.5)	2 (1.2)	3 (1.8)
壊疽	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
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Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
感染症および寄生虫症（続き）						
胃腸炎	0	0	0	2 (2.3)	0	2 (1.2)
ウイルス性胃腸炎	0	0	0	2 (2.3)	0	2 (1.2)
消化管感染	0	0	0	1 (1.2)	0	1 (0.6)
ウイルス性消化管感染	0	0	0	2 (2.3)	0	2 (1.2)
帯状疱疹	0	1 (1.2)	2 (2.3)	3 (3.5)	2 (1.2)	4 (2.4)
膿痂疹	0	0	0	1 (1.2)	0	1 (0.6)
感染性皮膚潰瘍	0	0	0	1 (1.2)	0	1 (0.6)
インフルエンザ	0	0	1 (1.2)	1 (1.2)	1 (0.6)	1 (0.6)
腎感染	0	0	0	1 (1.2)	0	1 (0.6)
限局性感染	0	0	0	1 (1.2)	0	1 (0.6)
下気道感染	0	0	0	1 (1.2)	0	1 (0.6)
爪感染	0	1 (1.2)	0	0	0	1 (0.6)
上咽頭炎	0	10 (12.0)	1 (1.2)	4 (4.7)	1 (0.6)	14 (8.3)
口腔カンジダ症	0	2 (2.4)	0	0	0	2 (1.2)
中耳炎	0	0	1 (1.2)	1 (1.2)	1 (0.6)	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
感染症および寄生虫症（続き）						
病原体耐性	0	0	0	1 (1.2)	0	1 (0.6)
歯周炎	0	1 (1.2)	0	0	0	1 (0.6)
咽頭炎	0	2 (2.4)	0	4 (4.7)	0	6 (3.6)
肺炎	0	2 (2.4)	1 (1.2)	2 (2.3)	1 (0.6)	4 (2.4)
誤嚥性肺炎	0	0	0	1 (1.2)	0	1 (0.6)
ＲＳウイルス肺炎	0	0	0	1 (1.2)	0	1 (0.6)
ウイルス性肺炎	0	0	0	1 (1.2)	0	1 (0.6)
処置後感染	0	1 (1.2)	0	0	0	1 (0.6)
術後創感染	0	0	0	1 (1.2)	0	1 (0.6)
慢性腎盂腎炎	0	0	0	1 (1.2)	0	1 (0.6)
脂腺感染	1 (1.2)	0	0	0	1 (0.6)	0
副鼻腔炎	0	1 (1.2)	0	4 (4.7)	0	5 (3.0)
皮膚感染	1 (1.2)	0	0	0	1 (0.6)	0
ブドウ球菌性敗血症	0	0	0	1 (1.2)	0	1 (0.6)
ＣＯＶＩＤ－１９の疑い	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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感染症および寄生虫症（続き）						
足部白癬	0	0	0	2 (2.3)	0	2 (1.2)
歯膿瘍	0	0	0	1 (1.2)	0	1 (0.6)
上気道感染	0	4 (4.8)	2 (2.3)	3 (3.5)	2 (1.2)	7 (4.1)
尿路感染	0	4 (4.8)	2 (2.3)	9 (10.5)	2 (1.2)	13 (7.7)
腟感染	0	0	0	2 (2.3)	0	2 (1.2)
ウイルス性発疹	0	1 (1.2)	0	0	0	1 (0.6)
外陰腟真菌感染	0	0	0	1 (1.2)	0	1 (0.6)
傷害、中毒および処置合併症	1 (1.2)	14 (16.9)	3 (3.5)	16 (18.6)	4 (2.4)	30 (17.8)
節足動物咬傷	0	1 (1.2)	0	0	0	1 (0.6)
背部損傷	0	1 (1.2)	0	0	0	1 (0.6)
胸部損傷	0	0	0	1 (1.2)	0	1 (0.6)
挫傷	0	1 (1.2)	0	0	0	1 (0.6)
歯科修復不成功	0	0	0	1 (1.2)	0	1 (0.6)
上顎炎	0	0	0	1 (1.2)	0	1 (0.6)
転倒	0	4 (4.8)	1 (1.2)	2 (2.3)	1 (0.6)	6 (3.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
傷害、中毒および処置合併症（続き）						
頭部損傷	0	0	1 (1.2)	0	1 (0.6)	0
注入に伴う反応	0	0	1 (1.2)	0	1 (0.6)	0
関節損傷	0	0	0	2 (2.3)	0	2 (1.2)
靱帯断裂	0	0	0	1 (1.2)	0	1 (0.6)
靱帯捻挫	0	1 (1.2)	0	0	0	1 (0.6)
腰椎骨折	0	0	0	1 (1.2)	0	1 (0.6)
多発骨折	0	0	0	1 (1.2)	0	1 (0.6)
肉離れ	1 (1.2)	0	0	0	1 (0.6)	0
処置後合併症	0	1 (1.2)	0	0	0	1 (0.6)
ワクチン接種後症候群	0	1 (1.2)	0	0	0	1 (0.6)
橈骨骨折	0	0	0	1 (1.2)	0	1 (0.6)
肋骨骨折	0	0	0	1 (1.2)	0	1 (0.6)
脊椎圧迫骨折	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
歯牙破折	0	0	0	2 (2.3)	0	2 (1.2)
外傷性骨折	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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傷害、中毒および処置合併症（続き）						
ワクチン接種合併症	0	2 (2.4)	0	3 (3.5)	0	5 (3.0)
創傷	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
臨床検査	1 (1.2)	9 (10.8)	3 (3.5)	15 (17.4)	4 (2.4)	24 (14.2)
活性化部分トロンボプラスチン時間延長	0	1 (1.2)	0	0	0	1 (0.6)
アラニンアミノトランスフェラーゼ増加	1 (1.2)	0	1 (1.2)	2 (2.3)	2 (1.2)	2 (1.2)
アスパラギン酸アミノトランスフェラーゼ増加	1 (1.2)	0	0	2 (2.3)	1 (0.6)	2 (1.2)
血中クレアチニン増加	0	1 (1.2)	0	0	0	1 (0.6)
血中葉酸減少	0	0	0	1 (1.2)	0	1 (0.6)
血中ブドウ糖増加	0	0	1 (1.2)	0	1 (0.6)	0
血圧上昇	0	0	0	1 (1.2)	0	1 (0.6)
体温上昇	0	0	1 (1.2)	0	1 (0.6)	0
Ｃ－反応性蛋白増加	0	4 (4.8)	0	1 (1.2)	0	5 (3.0)
尿中結晶陽性	0	0	0	1 (1.2)	0	1 (0.6)
心電図ＰＲ延長	0	0	0	1 (1.2)	0	1 (0.6)
γ－グルタミルトランスフェラーゼ増加	0	0	0	3 (3.5)	0	3 (1.8)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
臨床検査（続き）						
尿中ブドウ糖陽性	0	0	0	1 (1.2)	0	1 (0.6)
グリコヘモグロビン増加	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
リンパ球数減少	0	1 (1.2)	0	2 (2.3)	0	3 (1.8)
便潜血陽性	0	1 (1.2)	0	0	0	1 (0.6)
尿中蛋白陽性	0	0	0	1 (1.2)	0	1 (0.6)
赤血球数減少	0	0	0	1 (1.2)	0	1 (0.6)
網状赤血球数増加	0	0	0	1 (1.2)	0	1 (0.6)
トランスアミナーゼ上昇	0	1 (1.2)	0	0	0	1 (0.6)
トロポニン増加	0	0	0	1 (1.2)	0	1 (0.6)
尿中白血球エステラーゼ陽性	0	0	0	1 (1.2)	0	1 (0.6)
尿中ウロビリノーゲン	0	0	0	1 (1.2)	0	1 (0.6)
体重増加	0	1 (1.2)	0	0	0	1 (0.6)
白血球数減少	0	0	0	2 (2.3)	0	2 (1.2)
白血球数増加	0	0	0	1 (1.2)	0	1 (0.6)
代謝および栄養障害	2 (2.4)	4 (4.8)	2 (2.3)	17 (19.8)	4 (2.4)	21 (12.4)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
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Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
代謝および栄養障害（続き）						
食欲減退	1 (1.2)	1 (1.2)	2 (2.3)	0	3 (1.8)	1 (0.6)
脱水	0	0	0	1 (1.2)	0	1 (0.6)
糖尿病	0	1 (1.2)	0	5 (5.8)	0	6 (3.6)
コントロール不良の糖尿病	0	0	0	1 (1.2)	0	1 (0.6)
痛風	0	0	0	2 (2.3)	0	2 (1.2)
高血糖	0	0	0	2 (2.3)	0	2 (1.2)
高尿酸血症	0	1 (1.2)	0	0	0	1 (0.6)
低血糖	0	0	0	2 (2.3)	0	2 (1.2)
低カリウム血症	0	0	0	2 (2.3)	0	2 (1.2)
食欲亢進	1 (1.2)	0	0	1 (1.2)	1 (0.6)	1 (0.6)
鉄欠乏	0	0	0	1 (1.2)	0	1 (0.6)
ステロイド糖尿病	0	0	0	1 (1.2)	0	1 (0.6)
ビタミンD欠乏	0	1 (1.2)	0	0	0	1 (0.6)
筋骨格系および結合組織障害	2 (2.4)	15 (18.1)	9 (10.5)	24 (27.9)	11 (6.5)	39 (23.1)
関節痛	1 (1.2)	4 (4.8)	4 (4.7)	6 (7.0)	5 (3.0)	10 (5.9)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
筋骨格系および結合組織障害（続き）						
背部痛	1 (1.2)	5 (6.0)	0	10 (11.6)	1 (0.6)	15 (8.9)
尾骨痛	0	0	1 (1.2)	0	1 (0.6)	0
単径部痛	0	0	0	1 (1.2)	0	1 (0.6)
出血性関節症	0	0	0	1 (1.2)	0	1 (0.6)
椎間板突出	0	0	0	4 (4.7)	0	4 (2.4)
関節拘縮	0	1 (1.2)	0	0	0	1 (0.6)
筋痙縮	0	2 (2.4)	0	4 (4.7)	0	6 (3.6)
筋緊張	0	1 (1.2)	0	0	0	1 (0.6)
筋攣縮	0	0	0	1 (1.2)	0	1 (0.6)
筋力低下	0	0	0	2 (2.3)	0	2 (1.2)
筋骨格系胸痛	0	0	0	1 (1.2)	0	1 (0.6)
筋骨格痛	0	2 (2.4)	0	0	0	2 (1.2)
筋骨格硬直	0	0	0	2 (2.3)	0	2 (1.2)
筋肉痛	0	1 (1.2)	2 (2.3)	0	2 (1.2)	1 (0.6)
頚部痛	0	1 (1.2)	1 (1.2)	2 (2.3)	1 (0.6)	3 (1.8)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
筋骨格系および結合組織障害（続き）						
結節性変形性関節症	0	0	0	1 (1.2)	0	1 (0.6)
変形性関節症	0	1 (1.2)	1 (1.2)	0	1 (0.6)	1 (0.6)
骨減少症	0	0	0	1 (1.2)	0	1 (0.6)
骨粗鬆症	0	0	0	1 (1.2)	0	1 (0.6)
四肢痛	0	1 (1.2)	0	6 (7.0)	0	7 (4.1)
乾癬性関節症	0	1 (1.2)	0	0	0	1 (0.6)
肩回旋筋腱板症候群	0	0	1 (1.2)	0	1 (0.6)	0
脊椎痛	0	1 (1.2)	0	0	0	1 (0.6)
滑膜炎	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
腱炎	0	1 (1.2)	1 (1.2)	1 (1.2)	1 (0.6)	2 (1.2)
弾発指	0	1 (1.2)	0	0	0	1 (0.6)
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	3 (3.6)	1 (1.2)	3 (3.5)	1 (0.6)	6 (3.6)
皮膚血管腫	0	1 (1.2)	0	0	0	1 (0.6)
皮膚の新生物	0	1 (1.2)	0	0	0	1 (0.6)
前立腺癌	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
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Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
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）（続き）						
皮膚乳頭腫	0	0	1 (1.2)	0	1 (0.6)	0
皮膚有棘細胞癌	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
尿管新生物	0	0	0	1 (1.2)	0	1 (0.6)
神経系障害	6 (7.2)	12 (14.5)	13 (15.1)	26 (30.2)	19 (11.2)	38 (22.5)
平衡障害	0	0	0	2 (2.3)	0	2 (1.2)
手根管症候群	0	1 (1.2)	0	0	0	1 (0.6)
脳出血	0	0	0	1 (1.2)	0	1 (0.6)
認知障害	0	0	0	1 (1.2)	0	1 (0.6)
浮動性めまい	1 (1.2)	2 (2.4)	3 (3.5)	8 (9.3)	4 (2.4)	10 (5.9)
構語障害	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
頭部不快感	1 (1.2)	0	0	0	1 (0.6)	0
頭痛	4 (4.8)	3 (3.6)	11 (12.8)	10 (11.6)	15 (8.9)	13 (7.7)
不全片麻痺	0	0	0	1 (1.2)	0	1 (0.6)
感覚鈍麻	0	1 (1.2)	0	0	0	1 (0.6)
肋間神経痛	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
神経系障害（続き）						
腰仙部神経根障害	0	0	0	1 (1.2)	0	1 (0.6)
片頭痛	0	4 (4.8)	0	0	0	4 (2.4)
重症筋無力症	1 (1.2)	1 (1.2)	0	6 (7.0)	1 (0.6)	7 (4.1)
重症筋無力症クリーゼ	0	0	0	1 (1.2)	0	1 (0.6)
ヘルペス後神経痛	0	0	0	1 (1.2)	0	1 (0.6)
安静時振戦	0	1 (1.2)	0	0	0	1 (0.6)
失神	0	0	0	3 (3.5)	0	3 (1.8)
一過性脳虚血発作	0	0	0	2 (2.3)	0	2 (1.2)
振戦	0	0	0	1 (1.2)	0	1 (0.6)
精神障害	0	4 (4.8)	0	6 (7.0)	0	10 (5.9)
抑うつ気分を伴う適応障害	0	0	0	1 (1.2)	0	1 (0.6)
不安	0	1 (1.2)	0	0	0	1 (0.6)
うつ病	0	2 (2.4)	0	1 (1.2)	0	3 (1.8)
不眠症	0	0	0	2 (2.3)	0	2 (1.2)
気分動揺	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
精神障害（続き）						
パニック発作	0	1 (1.2)	0	0	0	1 (0.6)
自殺企図	0	0	0	1 (1.2)	0	1 (0.6)
腎および尿路障害	1 (1.2)	3 (3.6)	0	6 (7.0)	1 (0.6)	9 (5.3)
急性腎障害	0	0	0	1 (1.2)	0	1 (0.6)
微少病変糸球体腎炎	0	1 (1.2)	0	0	0	1 (0.6)
ミクロアルブミン尿	0	0	0	1 (1.2)	0	1 (0.6)
腎結石症	0	0	0	1 (1.2)	0	1 (0.6)
頻尿	1 (1.2)	1 (1.2)	0	0	1 (0.6)	1 (0.6)
蛋白尿	0	1 (1.2)	0	0	0	1 (0.6)
腎尿細管壊死	0	0	0	1 (1.2)	0	1 (0.6)
腹圧性尿失禁	0	0	0	1 (1.2)	0	1 (0.6)
尿閉	0	0	0	1 (1.2)	0	1 (0.6)
生殖系および乳房障害	0	1 (1.2)	1 (1.2)	3 (3.5)	1 (0.6)	4 (2.4)
乳房腫瘤	0	0	0	1 (1.2)	0	1 (0.6)
子宮内膜肥厚	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
生殖系および乳房障害（続き）						
閉経期障害	0	0	0	1 (1.2)	0	1 (0.6)
月経障害	0	0	1 (1.2)	0	1 (0.6)	0
陰嚢障害	0	0	0	1 (1.2)	0	1 (0.6)
呼吸器、胸郭および縦隔障害	0	13 (15.7)	3 (3.5)	13 (15.1)	3 (1.8)	26 (15.4)
喘息	0	1 (1.2)	0	0	0	1 (0.6)
慢性気管支炎	0	0	0	1 (1.2)	0	1 (0.6)
息詰まり	0	0	0	2 (2.3)	0	2 (1.2)
咳嗽	0	2 (2.4)	0	5 (5.8)	0	7 (4.1)
呼吸困難	0	1 (1.2)	0	5 (5.8)	0	6 (3.6)
労作性呼吸困難	0	0	0	2 (2.3)	0	2 (1.2)
喉頭蓋潰瘍	0	0	1 (1.2)	0	1 (0.6)	0
鼻出血	0	1 (1.2)	0	0	0	1 (0.6)
喀血	0	1 (1.2)	0	0	0	1 (0.6)
低酸素症	0	0	0	2 (2.3)	0	2 (1.2)
肺浸潤	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
呼吸器、胸郭および縦隔障害（続き）						
鼻閉	0	0	0	1 (1.2)	0	1 (0.6)
鼻そう痒症	0	1 (1.2)	0	0	0	1 (0.6)
口腔咽頭痛	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
口腔咽頭痙攣	0	1 (1.2)	0	0	0	1 (0.6)
咽頭狭窄	0	1 (1.2)	0	0	0	1 (0.6)
胸水	0	0	0	1 (1.2)	0	1 (0.6)
湿性咳嗽	0	0	0	2 (2.3)	0	2 (1.2)
呼吸不全	0	1 (1.2)	0	0	0	1 (0.6)
気道うっ血	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
アレルギー性鼻炎	0	0	0	1 (1.2)	0	1 (0.6)
鼻漏	0	1 (1.2)	1 (1.2)	0	1 (0.6)	1 (0.6)
副鼻腔うっ血	0	1 (1.2)	0	1 (1.2)	0	2 (1.2)
睡眠時無呼吸症候群	0	1 (1.2)	0	0	0	1 (0.6)
咽喉絞扼感	0	0	1 (1.2)	0	1 (0.6)	0
上気道の炎症	0	1 (1.2)	0	0	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
皮膚および皮下組織障害	3 (3.6)	10 (12.0)	5 (5.8)	11 (12.8)	8 (4.7)	21 (12.4)
脱毛症	0	0	1 (1.2)	1 (1.2)	1 (0.6)	1 (0.6)
ざ瘡様皮膚炎	0	0	1 (1.2)	0	1 (0.6)	0
接触皮膚炎	0	1 (1.2)	0	0	0	1 (0.6)
薬疹	0	0	0	1 (1.2)	0	1 (0.6)
斑状出血	0	0	0	1 (1.2)	0	1 (0.6)
湿疹	0	1 (1.2)	0	0	0	1 (0.6)
皮脂欠乏性湿疹	0	1 (1.2)	0	0	0	1 (0.6)
紅斑	0	1 (1.2)	0	0	0	1 (0.6)
多汗症	0	2 (2.4)	0	0	0	2 (1.2)
過角化	0	0	0	2 (2.3)	0	2 (1.2)
皮膚疼痛	0	0	0	1 (1.2)	0	1 (0.6)
点状出血	1 (1.2)	0	0	0	1 (0.6)	0
そう痒症	1 (1.2)	1 (1.2)	2 (2.3)	1 (1.2)	3 (1.8)	2 (1.2)
発疹	0	0	2 (2.3)	2 (2.3)	2 (1.2)	2 (1.2)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
皮膚および皮下組織障害（続き）						
皮膚萎縮	0	0	0	1 (1.2)	0	1 (0.6)
皮膚色素過剰	1 (1.2)	0	0	0	1 (0.6)	0
皮膚病変	0	3 (3.6)	0	1 (1.2)	0	4 (2.4)
皮膚潰瘍	0	1 (1.2)	0	0	0	1 (0.6)
蕁麻疹	1 (1.2)	1 (1.2)	0	2 (2.3)	1 (0.6)	3 (1.8)
血管障害	1 (1.2)	5 (6.0)	1 (1.2)	8 (9.3)	2 (1.2)	13 (7.7)
大動脈障害	0	1 (1.2)	0	0	0	1 (0.6)
大動脈狭窄	0	1 (1.2)	0	0	0	1 (0.6)
深部静脈血栓症	0	0	0	1 (1.2)	0	1 (0.6)
潮紅	1 (1.2)	0	0	0	1 (0.6)	0
血腫	0	0	0	1 (1.2)	0	1 (0.6)
高血圧	0	1 (1.2)	0	4 (4.7)	0	5 (3.0)
低血圧	0	0	0	1 (1.2)	0	1 (0.6)
静脈炎	0	1 (1.2)	0	0	0	1 (0.6)
血管痛	0	0	1 (1.2)	0	1 (0.6)	0

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4

Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship

Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=83) Related n (%)	 Not Related n (%)	Ravulizumab to Ravulizumab (N=86) Related n (%)	 Not Related n (%)	Total (N=169) Related n (%)	 Not Related n (%)
血管障害（続き）						
血管破裂	0	1 (1.2)	0	0	0	1 (0.6)
静脈破裂	0	0	0	1 (1.2)	0	1 (0.6)
白衣性高血圧	0	0	0	1 (1.2)	0	1 (0.6)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4.J
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship (Japanese)
Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=5)		Ravulizumab to Ravulizumab (N=6)		Total (N=11)	
	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)
Patients with Treatment-Emergent Adverse Events	2 (40.0)	3 (60.0)	2 (33.3)	4 (66.7)	4 (36.4)	7 (63.6)
心臓障害	1 (20.0)	0	0	0	1 (9.1)	0
動悸	1 (20.0)	0	0	0	1 (9.1)	0
眼障害	0	0	0	1 (16.7)	0	1 (9.1)
網膜静脈閉塞	0	0	0	1 (16.7)	0	1 (9.1)
胃腸障害	0	0	2 (33.3)	1 (16.7)	2 (18.2)	1 (9.1)
口角口唇炎	0	0	1 (16.7)	0	1 (9.1)	0
齲歯	0	0	0	1 (16.7)	0	1 (9.1)
下痢	0	0	1 (16.7)	1 (16.7)	1 (9.1)	1 (9.1)
一般・全身障害および投与部位の状態	1 (20.0)	0	0	1 (16.7)	1 (9.1)	1 (9.1)
倦怠感	1 (20.0)	0	0	0	1 (9.1)	0
ワクチン接種部位反応	0	0	0	1 (16.7)	0	1 (9.1)
感染症および寄生虫症	0	3 (60.0)	0	2 (33.3)	0	5 (45.5)
爪の皮膚糸状菌症	0	0	0	1 (16.7)	0	1 (9.1)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4.J
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship (Japanese)
Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=5)		Ravulizumab to Ravulizumab (N=6)		Total (N=11)	
	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)
感染症および寄生虫症（続き）						
上咽頭炎	0	3 (60.0)	0	0	0	3 (27.3)
咽頭炎	0	0	0	1 (16.7)	0	1 (9.1)
足部白癬	0	0	0	1 (16.7)	0	1 (9.1)
臨床検査	0	1 (20.0)	0	1 (16.7)	0	2 (18.2)
アラニンアミノトランスフェラーゼ増加	0	0	0	1 (16.7)	0	1 (9.1)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	1 (16.7)	0	1 (9.1)
血中クレアチニン増加	0	1 (20.0)	0	0	0	1 (9.1)
γ－グルタミルトランスフェラーゼ増加	0	0	0	1 (16.7)	0	1 (9.1)
代謝および栄養障害	1 (20.0)	1 (20.0)	0	3 (50.0)	1 (9.1)	4 (36.4)
食欲減退	1 (20.0)	0	0	0	1 (9.1)	0
脱水	0	0	0	1 (16.7)	0	1 (9.1)
コントロール不良の糖尿病	0	0	0	1 (16.7)	0	1 (9.1)
高尿酸血症	0	1 (20.0)	0	0	0	1 (9.1)
低血糖	0	0	0	1 (16.7)	0	1 (9.1)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4.J
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship (Japanese)
Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=5)		Ravulizumab to Ravulizumab (N=6)		Total (N=11)	
	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)
代謝および栄養障害（続き）						
ステロイド糖尿病	0	0	0	1 (16.7)	0	1 (9.1)
筋骨格系および結合組織障害	0	1 (20.0)	1 (16.7)	2 (33.3)	1 (9.1)	3 (27.3)
背部痛	0	1 (20.0)	0	0	0	1 (9.1)
結節性変形性関節症	0	0	0	1 (16.7)	0	1 (9.1)
四肢痛	0	0	0	1 (16.7)	0	1 (9.1)
腱炎	0	0	1 (16.7)	0	1 (9.1)	0
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	1 (20.0)	0	0	0	1 (9.1)
皮膚の新生物	0	1 (20.0)	0	0	0	1 (9.1)
神経系障害	1 (20.0)	0	0	2 (33.3)	1 (9.1)	2 (18.2)
脳出血	0	0	0	1 (16.7)	0	1 (9.1)
浮動性めまい	0	0	0	1 (16.7)	0	1 (9.1)
頭部不快感	1 (20.0)	0	0	0	1 (9.1)	0
腎および尿路障害	0	1 (20.0)	0	0	0	1 (9.1)
蛋白尿	0	1 (20.0)	0	0	0	1 (9.1)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.4.4.J
Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope, by Highest Relationship (Japanese)
Ravulizumab Treated Set

System Organ Class Preferred term	Placebo to Ravulizumab (N=5)		Ravulizumab to Ravulizumab (N=6)		Total (N=11)	
	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)
呼吸器、胸郭および縦隔障害	0	1 (20.0)	0	0	0	1 (9.1)
咽頭狭窄	0	1 (20.0)	0	0	0	1 (9.1)
皮膚および皮下組織障害	0	2 (40.0)	0	0	0	2 (18.2)
接触皮膚炎	0	1 (20.0)	0	0	0	1 (9.1)
皮脂欠乏性湿疹	0	1 (20.0)	0	0	0	1 (9.1)

Note: % = n/N*100.
Note: Treatment emergent AEs are AEs with a start date on or after first ravulizumab infusion date.
Note: In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.
Note: Highest relationship for each patient per SOC/PT is summarized.
Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.
Note: AEs are coded using MedDRA 24.1

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	20 (23.3)	35 (83.4)	14 (17.5)	20 (51.8)	2 (2.7)	2 (20.4)	29 (33.7)	57 (63.1)
感染症および寄生虫症	7 (8.1)	11 (26.2)	6 (7.5)	7 (18.1)	0	0	13 (15.1)	18 (19.9)
ＣＯＶＩＤ－１９	0	0	2 (2.5)	3 (7.8)	0	0	2 (2.3)	3 (3.3)
ＣＯＶＩＤ－１９肺炎	2 (2.3)	3 (7.1)	0	0	0	0	2 (2.3)	3 (3.3)
細菌性関節炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
憩室炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
丹毒	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
壊疽	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ウイルス性胃腸炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
帯状疱疹	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
感染性皮膚潰瘍	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
限局性感染	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
肺炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
ＲＳウイルス肺炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
ウイルス性肺炎	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
ブドウ球菌性敗血症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
神経系障害	5 (5.8)	6 (14.3)	3 (3.8)	3 (7.8)	1 (1.3)	1 (10.2)	9 (10.5)	10 (11.1)
重症筋無力症	0	0	3 (3.8)	3 (7.8)	0	0	3 (3.5)	3 (3.3)
一過性脳虚血発作	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
脳出血	1 (1.2)	2 (4.8)	0	0	0	0	1 (1.2)	2 (2.2)
肋間神経痛	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)
重症筋無力症クリーゼ	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
失神	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
心臓障害	1 (1.2)	1 (2.4)	2 (2.5)	2 (5.2)	1 (1.3)	1 (10.2)	4 (4.7)	4 (4.4)
狭心症	0	0	0	0	1 (1.3)	1 (10.2)	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
心臓障害（続き）								
うっ血性心筋症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
冠動脈閉塞	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
僧帽弁狭窄症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
呼吸器、胸郭および縦隔障害	3 (3.5)	3 (7.1)	1 (1.3)	1 (2.6)	0	0	4 (4.7)	4 (4.4)
呼吸困難	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
労作性呼吸困難	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
肺浸潤	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
一般・全身障害および投与部位の状態	2 (2.3)	3 (7.1)	1 (1.3)	1 (2.6)	0	0	3 (3.5)	4 (4.4)
無力症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
胸痛	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
一般・全身障害および投与部位の状態（続き）								
全身健康状態悪化	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
非心臓性胸痛	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
筋骨格系および結合組織障害	3 (3.5)	3 (7.1)	0	0	0	0	3 (3.5)	3 (3.3)
椎間板突出	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
結節性変形性関節症	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
腱炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
眼障害	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
白内障	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
視力障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
胃腸障害	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
嚥下障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
胃腸障害（続き）								
悪心	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
傷害、中毒および処置合併症	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
腰椎骨折	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
多発骨折	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
代謝および栄養障害	1 (1.2)	1 (2.4)	1 (1.3)	1 (2.6)	0	0	2 (2.3)	2 (2.2)
コントロール不良の糖尿病	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
ステロイド糖尿病	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
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 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
皮膚有棘細胞癌	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
尿管新生物	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
血管障害	0	0	2 (2.5)	2 (5.2)	0	0	2 (2.3)	2 (2.2)
低血圧	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
静脈破裂	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
精神障害	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
自殺企図	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
皮膚および皮下組織障害	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
蕁麻疹	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	10 (12.0)	13 (31.9)	4 (5.0)	5 (47.8)	0	0	12 (14.5)	18 (35.1)
感染症および寄生虫症	6 (7.2)	6 (14.7)	2 (2.5)	2 (19.1)	0	0	7 (8.4)	8 (15.6)
肛門膿瘍	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
虫垂炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
ＣＯＶＩＤ－１９	1 (1.2)	1 (2.5)	1 (1.3)	1 (9.6)	0	0	1 (1.2)	2 (3.9)
丹毒	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
肺炎	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
ＣＯＶＩＤ－１９の疑い	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
尿路感染	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
一般・全身障害および投与部位の状態	3 (3.6)	3 (7.4)	0	0	0	0	3 (3.6)	3 (5.9)
発熱	2 (2.4)	2 (4.9)	0	0	0	0	2 (2.4)	2 (3.9)
疲労	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害	2 (2.4)	2 (4.9)	1 (1.3)	1 (9.6)	0	0	2 (2.4)	3 (5.9)
構語障害	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
頭痛	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
重症筋無力症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
胃腸障害	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
嚥下障害	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
傷害、中毒および処置合併症	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
外傷性骨折	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
筋骨格系および結合組織障害	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)
滑膜炎	1 (1.2)	1 (2.5)	0	0	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Placebo to Ravulizumab

System Organ Class Preferred term	0 - 6 months (N=83) PY = 40.8		>6 to 12 months (N=80) PY = 10.5		>12 to 18 months (N=0) PY = 0.0		0 to cutoff (N=83) PY = 51.3	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
精神障害	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)
パニック発作	0	0	1 (1.3)	1 (9.6)	0	0	1 (1.2)	1 (2.0)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	30 (17.8)	48 (58.0)	18 (11.3)	25 (51.0)	2 (2.7)	2 (20.4)	41 (24.3)	75 (53.0)
感染症および寄生虫症	13 (7.7)	17 (20.5)	8 (5.0)	9 (18.3)	0	0	20 (11.8)	26 (18.4)
ＣＯＶＩＤ－１９	1 (0.6)	1 (1.2)	3 (1.9)	4 (8.2)	0	0	3 (1.8)	5 (3.5)
ＣＯＶＩＤ－１９肺炎	2 (1.2)	3 (3.6)	0	0	0	0	2 (1.2)	3 (2.1)
丹毒	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
肺炎	0	0	2 (1.3)	2 (4.1)	0	0	2 (1.2)	2 (1.4)
肛門膿瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
虫垂炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
細菌性関節炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
憩室炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
壊疽	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ウイルス性胃腸炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
帯状疱疹	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
感染症および寄生虫症（続き）								
感染性皮膚潰瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
限局性感染	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
ＲＳウイルス肺炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ウイルス性肺炎	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
ブドウ球菌性敗血症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
ＣＯＶＩＤ－１９の疑い	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
尿路感染	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
神経系障害	7 (4.1)	8 (9.7)	4 (2.5)	4 (8.2)	1 (1.3)	1 (10.2)	11 (6.5)	13 (9.2)
重症筋無力症	1 (0.6)	1 (1.2)	3 (1.9)	3 (6.1)	0	0	4 (2.4)	4 (2.8)
一過性脳虚血発作	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
脳出血	1 (0.6)	2 (2.4)	0	0	0	0	1 (0.6)	2 (1.4)
構語障害	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
神経系障害（続き）								
頭痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肋間神経痛	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
重症筋無力症クリーゼ	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
失神	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
一般・全身障害および投与部位の状態	5 (3.0)	6 (7.2)	1 (0.6)	1 (2.0)	0	0	6 (3.6)	7 (4.9)
発熱	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
無力症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
胸痛	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
疲労	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
全身健康状態悪化	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
非心臓性胸痛	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
心臓障害	1 (0.6)	1 (1.2)	2 (1.3)	2 (4.1)	1 (1.3)	1 (10.2)	4 (2.4)	4 (2.8)
狭心症	0	0	0	0	1 (1.3)	1 (10.2)	1 (0.6)	1 (0.7)
うっ血性心筋症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
冠動脈閉塞	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
僧帽弁狭窄症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
筋骨格系および結合組織障害	4 (2.4)	4 (4.8)	0	0	0	0	4 (2.4)	4 (2.8)
椎間板突出	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
結節性変形性関節症	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
滑膜炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
腱炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
呼吸器、胸郭および縦隔障害	3 (1.8)	3 (3.6)	1 (0.6)	1 (2.0)	0	0	4 (2.4)	4 (2.8)
呼吸困難	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
労作性呼吸困難	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
肺浸潤	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
胃腸障害	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
嚥下障害	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
悪心	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
傷害、中毒および処置合併症	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
腰椎骨折	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
多発骨折	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
外傷性骨折	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
眼障害	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
白内障	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
視力障害	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
代謝および栄養障害	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
コントロール不良の糖尿病	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
ステロイド糖尿病	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
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 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
皮膚有棘細胞癌	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
尿管新生物	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
精神障害	1 (0.6)	1 (1.2)	1 (0.6)	1 (2.0)	0	0	2 (1.2)	2 (1.4)
パニック発作	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
自殺企図	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
血管障害	0	0	2 (1.3)	2 (4.1)	0	0	2 (1.2)	2 (1.4)
低血圧	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
静脈破裂	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
皮膚および皮下組織障害	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
蕁麻疹	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4.J

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=6) PY = 2.9		>6 to 12 months (N=5) PY = 2.5		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=6) PY = 6.1	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	4 (66.7)	5 (172.6)	1 (20.0)	1 (40.0)	0	0	5 (83.3)	6 (98.7)
代謝および栄養障害	1 (16.7)	1 (34.5)	1 (20.0)	1 (40.0)	0	0	2 (33.3)	2 (32.9)
コントロール不良の糖尿病	0	0	1 (20.0)	1 (40.0)	0	0	1 (16.7)	1 (16.5)
ステロイド糖尿病	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
筋骨格系および結合組織障害	2 (33.3)	2 (69.0)	0	0	0	0	2 (33.3)	2 (32.9)
結節性変形性関節症	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
腱炎	1 (16.7)	1 (34.5)	0	0	0	0	1 (16.7)	1 (16.5)
神経系障害	1 (16.7)	2 (69.0)	0	0	0	0	1 (16.7)	2 (32.9)
脳出血	1 (16.7)	2 (69.0)	0	0	0	0	1 (16.7)	2 (32.9)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.3.4.J

Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope (Japanese)

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 – 6 months (N=11) PY = 5.4		>6 to 12 months (N=10) PY = 3.2		>12 to 18 months (N=5) PY = 0.7		0 to cutoff (N=11) PY = 9.2	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	4 (36.4)	5 (92.6)	1 (10.0)	1 (31.7)	0	0	5 (45.5)	6 (65.0)
代謝および栄養障害	1 (9.1)	1 (18.5)	1 (10.0)	1 (31.7)	0	0	2 (18.2)	2 (21.7)
コントロール不良の糖尿病	0	0	1 (10.0)	1 (31.7)	0	0	1 (9.1)	1 (10.8)
ステロイド糖尿病	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
筋骨格系および結合組織障害	2 (18.2)	2 (37.1)	0	0	0	0	2 (18.2)	2 (21.7)
結節性変形性関節症	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
腱炎	1 (9.1)	1 (18.5)	0	0	0	0	1 (9.1)	1 (10.8)
神経系障害	1 (9.1)	2 (37.1)	0	0	0	0	1 (9.1)	2 (21.7)
脳出血	1 (9.1)	2 (37.1)	0	0	0	0	1 (9.1)	2 (21.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.6.4

Treatment-Emergent Adverse Events Leading to Withdrawal of Study Drug, by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Ravulizumab to Ravulizumab

System Organ Class Preferred term	0 – 6 months (N=86) PY = 42.0		>6 to 12 months (N=80) PY = 38.6		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=86) PY = 90.4	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	2 (2.3)	2 (4.8)	1 (1.3)	1 (2.6)	0	0	3 (3.5)	3 (3.3)
感染症および寄生虫症	2 (2.3)	2 (4.8)	0	0	0	0	2 (2.3)	2 (2.2)
ＣＯＶＩＤ－１９肺炎	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
感染性皮膚潰瘍	1 (1.2)	1 (2.4)	0	0	0	0	1 (1.2)	1 (1.1)
神経系障害	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)
重症筋無力症	0	0	1 (1.3)	1 (2.6)	0	0	1 (1.2)	1 (1.1)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.

Table 14.3.3.1.6.4

Treatment-Emergent Adverse Events Leading to Withdrawal of Study Drug, by MedDRA System Organ Class and Preferred Term During the Ravulizumab Treatment Period up to Data Cutoff Date per Scope

Ravulizumab Treated Set

Total

System Organ Class Preferred term	0 - 6 months (N=169) PY = 82.8		>6 to 12 months (N=160) PY = 49.1		>12 to 18 months (N=75) PY = 9.8		0 to cutoff (N=169) PY = 141.6	
	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)	n (%)	E (rate)
Any Adverse Event (AE)	2 (1.2)	2 (2.4)	1 (0.6)	1 (2.0)	0	0	3 (1.8)	3 (2.1)
感染症および寄生虫症	2 (1.2)	2 (2.4)	0	0	0	0	2 (1.2)	2 (1.4)
ＣＯＶＩＤ－１９肺炎	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
感染性皮膚潰瘍	1 (0.6)	1 (1.2)	0	0	0	0	1 (0.6)	1 (0.7)
神経系障害	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)
重症筋無力症	0	0	1 (0.6)	1 (2.0)	0	0	1 (0.6)	1 (0.7)

Note: PY=Patient Year.

Note: Percentages are based on the number of patients in each column, i.e., % = n/N*100. E=number of events and rate=rate of AE adjusted by patient-years of exposure, defined as (number of events)/100 patient years. In summarizing n (%), if a patient had multiple events for a particular SOC or PT, he/she is counted only once for that SOC or PT.

Note: Treatment emergent AEs are AEs with a start date and start time on or after the date and time of the first ravulizumab infusion date.

Results were sorted by '0 to cutoff' column in descending order of SOC patient percentage and then PT within SOC.

Note: AEs are coded using MedDRA 24.1

Note: The Ravulizumab Treated Set consists of all patients who received at least 1 dose of ravulizumab either in the Randomized-Controlled Period (RCP) or the Open-label Extension Period. Data up to Week 60 at data cut-off are included.