表 2.7.6-5　TEAE の内訳（RCP，As-treated 集団）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
Subjects with at least one event	37 (71.2%)	117 (72.7%)	4 (100%)	8 (61.5%)	41 (73.2%)	125 (71.8%)
Blood and lymphatic system disorders	4 (7.7%)	12 (7.5%)	0	0	4 (7.1%)	12 (6.9%)
Anaemia	2 (3.8%)	6 (3.7%)	0	0	2 (3.6%)	6 (3.4%)
Iron deficiency anaemia	1 (1.9%)	0	0	0	1 (1.8%)	0
Leukocytosis	0	2 (1.2%)	0	0	0	2 (1.1%)
Leukopenia	0	1 (0.6%)	0	0	0	1 (0.6%)
Lymphadenopathy	1 (1.9%)	0	0	0	1 (1.8%)	0
Lymphopenia	0	3 (1.9%)	0	0	0	3 (1.7%)
Neutropenia	0	4 (2.5%)	0	0	0	4 (2.3%)
Neutrophilia	0	1 (0.6%)	0	0	0	1 (0.6%)
Cardiac disorders	3 (5.8%)	1 (0.6%)	0	0	3 (5.4%)	1 (0.6%)
Arrhythmia	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Sinus bradycardia	1 (1.9%)	0	0	0	1 (1.8%)	0
Sinus tachycardia	1 (1.9%)	0	0	0	1 (1.8%)	0
Ear and labyrinth disorders	1 (1.9%)	4 (2.5%)	0	0	1 (1.8%)	4 (2.3%)
Ear pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Ear pruritus	0	1 (0.6%)	0	0	0	1 (0.6%)
Tinnitus	0	1 (0.6%)	0	0	0	1 (0.6%)
Vertigo	0	2 (1.2%)	0	0	0	2 (1.1%)
Vertigo positional	1 (1.9%)	0	0	0	1 (1.8%)	0
Endocrine disorders	0	2 (1.2%)	0	1 (7.7%)	0	3 (1.7%)
Adrenal insufficiency	0	1 (0.6%)	0	0	0	1 (0.6%)
Hyperthyroidism	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Eye disorders	7 (13.5%)	9 (5.6%)	0	1 (7.7%)	7 (12.5%)	10 (5.7%)
Blepharitis	1 (1.9%)	0	0	0	1 (1.8%)	0
Blepharospasm	1 (1.9%)	0	0	0	1 (1.8%)	0
Eye inflammation	0	0	0	1 (7.7%)	0	1 (0.6%)
Eye irritation	0	2 (1.2%)	0	0	0	2 (1.1%)
Eye pain	1 (1.9%)	5 (3.1%)	0	0	1 (1.8%)	5 (2.9%)
Eye pruritus	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Ocular discomfort	1 (1.9%)	0	0	0	1 (1.8%)	0
Ocular hyperaemia	1 (1.9%)	0	0	0	1 (1.8%)	0
Photophobia	1 (1.9%)	0	0	0	1 (1.8%)	0
Vision blurred	0	2 (1.2%)	0	1 (7.7%)	0	3 (1.7%)
Visual acuity reduced	1 (1.9%)	0	0	0	1 (1.8%)	0
Gastrointestinal disorders	11 (21.2%)	24 (14.9%)	1 (25.0%)	1 (7.7%)	12 (21.4%)	25 (14.4%)
Abdominal discomfort	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Abdominal distension	1 (1.9%)	0	0	0	1 (1.8%)	0
Abdominal pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Abdominal pain lower	0	1 (0.6%)	0	0	0	1 (0.6%)
Abdominal pain upper	0	1 (0.6%)	0	0	0	1 (0.6%)
Constipation	2 (3.8%)	0	0	0	2 (3.6%)	0
Dental caries	0	1 (0.6%)	0	0	0	1 (0.6%)
Diarrhoea	3 (5.8%)	7 (4.3%)	0	1 (7.7%)	3 (5.4%)	8 (4.6%)
Dry mouth	0	1 (0.6%)	0	0	0	1 (0.6%)
Dyspepsia	0	1 (0.6%)	0	0	0	1 (0.6%)
Enteritis	0	1 (0.6%)	0	0	0	1 (0.6%)
Enterocolitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Gastritis	1 (1.9%)	0	0	0	1 (1.8%)	0
Gastrooesophageal reflux disease	1 (1.9%)	0	0	0	1 (1.8%)	0
Ileus	0	1 (0.6%)	0	0	0	1 (0.6%)
Irritable bowel syndrome	0	1 (0.6%)	0	0	0	1 (0.6%)
Nausea	2 (3.8%)	6 (3.7%)	1 (25.0%)	0	3 (5.4%)	6 (3.4%)
Oral mucosal blistering	1 (1.9%)	0	0	0	1 (1.8%)	0
Pancreatitis acute	0	1 (0.6%)	0	0	0	1 (0.6%)
Proctalgia	1 (1.9%)	0	0	0	1 (1.8%)	0
Sensitivity of teeth	0	1 (0.6%)	0	0	0	1 (0.6%)
Toothache	0	1 (0.6%)	0	0	0	1 (0.6%)
Vomiting	4 (7.7%)	1 (0.6%)	0	0	4 (7.1%)	1 (0.6%)

表 2.7.6-5　TEAE の内訳（RCP，As-treated 集団）（続き）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
General disorders and administration site conditions	5 (9.6%)	17 (10.6%)	1 (25.0%)	1 (7.7%)	6 (10.7%)	18 (10.3%)
Asthenia	0	2 (1.2%)	0	0	0	2 (1.1%)
Chest discomfort	0	1 (0.6%)	0	0	0	1 (0.6%)
Chest pain	1 (1.9%)	0	0	0	1 (1.8%)	0
Chills	0	2 (1.2%)	0	0	0	2 (1.1%)
Discomfort	0	1 (0.6%)	0	0	0	1 (0.6%)
Drug intolerance	0	1 (0.6%)	0	0	0	1 (0.6%)
Facial pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Fatigue	1 (1.9%)	3 (1.9%)	0	0	1 (1.8%)	3 (1.7%)
Gait disturbance	0	1 (0.6%)	0	0	0	1 (0.6%)
Influenza like illness	2 (3.8%)	3 (1.9%)	0	0	2 (3.6%)	3 (1.7%)
Malaise	0	1 (0.6%)	0	0	0	1 (0.6%)
Non-cardiac chest pain	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Oedema peripheral	0	2 (1.2%)	0	0	0	2 (1.1%)
Pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Peripheral swelling	0	3 (1.9%)	0	0	0	3 (1.7%)
Pyrexia	1 (1.9%)	2 (1.2%)	1 (25.0%)	0	2 (3.6%)	2 (1.1%)
Hepatobiliary disorders	1 (1.9%)	4 (2.5%)	0	0	1 (1.8%)	4 (2.3%)
Cholangitis acute	0	1 (0.6%)	0	0	0	1 (0.6%)
Cholecystitis acute	0	1 (0.6%)	0	0	0	1 (0.6%)
Hepatic function abnormal	0	2 (1.2%)	0	0	0	2 (1.1%)
Hepatic steatosis	0	1 (0.6%)	0	0	0	1 (0.6%)
Hepatitis	1 (1.9%)	0	0	0	1 (1.8%)	0
Immune system disorders	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Seasonal allergy	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Infections and infestations	23 (44.2%)	63 (39.1%)	0	3 (23.1%)	23 (41.1%)	66 (37.9%)
Abscess limb	0	1 (0.6%)	0	0	0	1 (0.6%)
Atypical pneumonia	0	1 (0.6%)	0	0	0	1 (0.6%)
Bacterial vaginosis	0	1 (0.6%)	0	0	0	1 (0.6%)
Bacteriuria	0	0	0	1 (7.7%)	0	1 (0.6%)
Beta haemolytic streptococcal infection	0	1 (0.6%)	0	0	0	1 (0.6%)
Breast abscess	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Bronchitis	2 (3.8%)	3 (1.9%)	0	0	2 (3.6%)	3 (1.7%)
Conjunctivitis	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Conjunctivitis viral	0	1 (0.6%)	0	0	0	1 (0.6%)
Cystitis	0	4 (2.5%)	0	1 (7.7%)	0	5 (2.9%)
Fungal skin infection	0	1 (0.6%)	0	0	0	1 (0.6%)
Gastroenteritis viral	0	1 (0.6%)	0	0	0	1 (0.6%)
Gastrointestinal infection	1 (1.9%)	0	0	0	1 (1.8%)	0
Gingivitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Herpes zoster	1 (1.9%)	0	0	0	1 (1.8%)	0
Hordeolum	0	3 (1.9%)	0	0	0	3 (1.7%)
Influenza	2 (3.8%)	4 (2.5%)	0	0	2 (3.6%)	4 (2.3%)
Laryngitis	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Meningitis viral	1 (1.9%)	0	0	0	1 (1.8%)	0
Muscle abscess	0	1 (0.6%)	0	0	0	1 (0.6%)
Myelitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Nasopharyngitis	6 (11.5%)	12 (7.5%)	0	1 (7.7%)	6 (10.7%)	13 (7.5%)
Onychomycosis	1 (1.9%)	0	0	0	1 (1.8%)	0
Oral herpes	3 (5.8%)	1 (0.6%)	0	0	3 (5.4%)	1 (0.6%)
Otitis externa	0	1 (0.6%)	0	0	0	1 (0.6%)
Paronychia	0	1 (0.6%)	0	0	0	1 (0.6%)
Periodontitis	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Pharyngitis	0	2 (1.2%)	0	0	0	2 (1.1%)
Pharyngitis streptococcal	0	1 (0.6%)	0	0	0	1 (0.6%)
Pneumonia	1 (1.9%)	0	0	0	1 (1.8%)	0
Pyelocystitis	1 (1.9%)	0	0	0	1 (1.8%)	0
Rash pustular	0	1 (0.6%)	0	0	0	1 (0.6%)
Respiratory tract infection	0	1 (0.6%)	0	0	0	1 (0.6%)
Respiratory tract infection viral	0	3 (1.9%)	0	0	0	3 (1.7%)
Retinitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Rhinitis	0	3 (1.9%)	0	0	0	3 (1.7%)

表 2.7.6-5　TEAE の内訳（RCP，As-treated 集団）（続き）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
Salpingitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Septic shock	1 (1.9%)	0	0	0	1 (1.8%)	0
Sinusitis	0	3 (1.9%)	0	0	0	3 (1.7%)
Soft tissue infection	0	1 (0.6%)	0	0	0	1 (0.6%)
Tinea cruris	0	1 (0.6%)	0	0	0	1 (0.6%)
Tracheitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Upper respiratory tract infection	3 (5.8%)	5 (3.1%)	0	0	3 (5.4%)	5 (2.9%)
Urinary tract infection	5 (9.6%)	18 (11.2%)	0	2 (15.4%)	5 (8.9%)	20 (11.5%)
Urinary tract infection staphylococcal	0	1 (0.6%)	0	0	0	1 (0.6%)
Viral infection	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Viral pharyngitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Viral rhinitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Viral upper respiratory tract infection	0	1 (0.6%)	0	0	0	1 (0.6%)
Injury, poisoning and procedural complications	10 (19.2%)	26 (16.1%)	1 (25.0%)	1 (7.7%)	11 (19.6%)	27 (15.5%)
Arthropod bite	0	2 (1.2%)	0	0	0	2 (1.1%)
Burns third degree	0	1 (0.6%)	0	0	0	1 (0.6%)
Eye contusion	0	1 (0.6%)	0	0	0	1 (0.6%)
Fall	1 (1.9%)	7 (4.3%)	0	1 (7.7%)	1 (1.8%)	8 (4.6%)
Femur fracture	0	1 (0.6%)	0	0	0	1 (0.6%)
Infusion related reaction	5 (9.6%)	15 (9.3%)	1 (25.0%)	1 (7.7%)	6 (10.7%)	16 (9.2%)
Laceration	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Ligament injury	0	1 (0.6%)	0	0	0	1 (0.6%)
Ligament sprain	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Multiple injuries	1 (1.9%)	0	0	0	1 (1.8%)	0
Post-traumatic pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Procedural anxiety	1 (1.9%)	0	0	0	1 (1.8%)	0
Procedural nausea	0	1 (0.6%)	0	0	0	1 (0.6%)
Road traffic accident	0	2 (1.2%)	0	0	0	2 (1.1%)
Skin abrasion	0	1 (0.6%)	0	0	0	1 (0.6%)
Thermal burn	1 (1.9%)	0	0	0	1 (1.8%)	0
Investigations	4 (7.7%)	12 (7.5%)	1 (25.0%)	1 (7.7%)	5 (8.9%)	13 (7.5%)
Alanine aminotransferase increased	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Aspartate aminotransferase increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Bacterial test positive	0	1 (0.6%)	0	0	0	1 (0.6%)
Blood bilirubin increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Blood cholesterol increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Blood folate decreased	0	1 (0.6%)	0	0	0	1 (0.6%)
Blood glucose fluctuation	0	1 (0.6%)	0	0	0	1 (0.6%)
Blood sodium decreased	0	0	1 (25.0%)	0	1 (1.8%)	0
Body temperature increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Crystal urine present	0	0	0	1 (7.7%)	0	1 (0.6%)
Electrocardiogram T wave abnormal	1 (1.9%)	0	0	0	1 (1.8%)	0
Eosinophil percentage increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Gamma-glutamyltransferase increased	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Hepatic enzyme increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Liver function test increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Lymphocyte count decreased	0	2 (1.2%)	0	0	0	2 (1.1%)
Lymphocyte count increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Neutrophil count increased	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Nuclear magnetic resonance imaging abnormal	0	1 (0.6%)	0	0	0	1 (0.6%)
Weight decreased	0	1 (0.6%)	0	0	0	1 (0.6%)
White blood cell count increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Metabolism and nutrition disorders	4 (7.7%)	3 (1.9%)	0	1 (7.7%)	4 (7.1%)	4 (2.3%)
Hypercholesterolaemia	0	1 (0.6%)	0	0	0	1 (0.6%)
Hyperlipidaemia	0	2 (1.2%)	0	0	0	2 (1.1%)
Hypertriglyceridaemia	1 (1.9%)	0	0	1 (7.7%)	1 (1.8%)	1 (0.6%)
Hypoalbuminaemia	1 (1.9%)	0	0	0	1 (1.8%)	0
Hypocalcaemia	1 (1.9%)	0	0	0	1 (1.8%)	0
Hypoglycaemia	1 (1.9%)	0	0	0	1 (1.8%)	0
Hypokalaemia	1 (1.9%)	0	0	0	1 (1.8%)	0

表 2.7.6-5　TEAE の内訳（RCP，As-treated 集団）（続き）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
Musculoskeletal and connective tissue disorders	11 (21.2%)	36 (22.4%)	1 (25.0%)	2 (15.4%)	12 (21.4%)	38 (21.8%)
Arthralgia	2 (3.8%)	16 (9.9%)	0	1 (7.7%)	2 (3.6%)	17 (9.8%)
Arthritis	0	1 (0.6%)	0	0	0	1 (0.6%)
Back pain	2 (3.8%)	11 (6.8%)	0	2 (15.4%)	2 (3.6%)	13 (7.5%)
Bone deformity	0	1 (0.6%)	0	0	0	1 (0.6%)
Coccydynia	0	1 (0.6%)	0	0	0	1 (0.6%)
Costochondritis	1 (1.9%)	0	0	0	1 (1.8%)	0
Flank pain	0	0	0	1 (7.7%)	0	1 (0.6%)
Groin pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Ligament laxity	0	1 (0.6%)	0	0	0	1 (0.6%)
Limb discomfort	0	1 (0.6%)	0	0	0	1 (0.6%)
Muscle spasms	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Muscular weakness	0	3 (1.9%)	0	0	0	3 (1.7%)
Musculoskeletal chest pain	1 (1.9%)	0	0	0	1 (1.8%)	0
Musculoskeletal pain	1 (1.9%)	3 (1.9%)	0	0	1 (1.8%)	3 (1.7%)
Musculoskeletal stiffness	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Myalgia	2 (3.8%)	1 (0.6%)	0	0	2 (3.6%)	1 (0.6%)
Neck pain	1 (1.9%)	4 (2.5%)	0	0	1 (1.8%)	4 (2.3%)
Pain in extremity	4 (7.7%)	1 (0.6%)	0	0	4 (7.1%)	1 (0.6%)
Spinal pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Sympathetic posterior cervical syndrome	0	0	1 (25.0%)	0	1 (1.8%)	0
Tendon pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (1.2%)	0	0	0	2 (1.1%)
Benign ovarian tumour	0	1 (0.6%)	0	0	0	1 (0.6%)
Pituitary tumour benign	0	1 (0.6%)	0	0	0	1 (0.6%)
Nervous system disorders	12 (23.1%)	30 (18.6%)	0	2 (15.4%)	12 (21.4%)	32 (18.4%)
Allodynia	0	1 (0.6%)	0	0	0	1 (0.6%)
Balance disorder	0	1 (0.6%)	0	0	0	1 (0.6%)
Cognitive disorder	0	1 (0.6%)	0	0	0	1 (0.6%)
Dizziness	1 (1.9%)	4 (2.5%)	0	0	1 (1.8%)	4 (2.3%)
Dysaesthesia	0	3 (1.9%)	0	0	0	3 (1.7%)
Epilepsy	0	0	0	1 (7.7%)	0	1 (0.6%)
Facial paralysis	0	1 (0.6%)	0	0	0	1 (0.6%)
Headache	4 (7.7%)	13 (8.1%)	0	0	4 (7.1%)	13 (7.5%)
Hypersomnia	0	1 (0.6%)	0	0	0	1 (0.6%)
Hypertonia	1 (1.9%)	0	0	0	1 (1.8%)	0
Hypoaesthesia	1 (1.9%)	5 (3.1%)	0	1 (7.7%)	1 (1.8%)	6 (3.4%)
Hypokinesia	0	1 (0.6%)	0	0	0	1 (0.6%)
Intercostal neuralgia	0	1 (0.6%)	0	0	0	1 (0.6%)
Migraine	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Migraine with aura	0	1 (0.6%)	0	0	0	1 (0.6%)
Monoparesis	0	1 (0.6%)	0	0	0	1 (0.6%)
Muscle spasticity	0	1 (0.6%)	0	0	0	1 (0.6%)
Myasthenia gravis	0	1 (0.6%)	0	0	0	1 (0.6%)
Neuromyelitis optica spectrum disorder	1 (1.9%)	0	0	0	1 (1.8%)	0
Paraesthesia	0	4 (2.5%)	0	0	0	4 (2.3%)
Post-traumatic headache	0	1 (0.6%)	0	0	0	1 (0.6%)
Sacral radiculopathy	1 (1.9%)	0	0	0	1 (1.8%)	0
Seizure	1 (1.9%)	0	0	0	1 (1.8%)	0
Somnolence	0	1 (0.6%)	0	0	0	1 (0.6%)
Syncope	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Tension headache	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Tremor	0	1 (0.6%)	0	0	0	1 (0.6%)
Psychiatric disorders	7 (13.5%)	11 (6.8%)	1 (25.0%)	1 (7.7%)	8 (14.3%)	12 (6.9%)
Abnormal dreams	0	1 (0.6%)	0	0	0	1 (0.6%)
Adjustment disorder with depressed mood	0	1 (0.6%)	0	0	0	1 (0.6%)
Anxiety	0	2 (1.2%)	0	0	0	2 (1.1%)
Depressed mood	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Depression	5 (9.6%)	4 (2.5%)	0	0	5 (8.9%)	4 (2.3%)
Depressive symptom	0	0	1 (25.0%)	0	1 (1.8%)	0
Insomnia	1 (1.9%)	3 (1.9%)	0	1 (7.7%)	1 (1.8%)	4 (2.3%)

表 2.7.6-5　TEAE の内訳（RCP，As-treated 集団）（続き）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
Restlessness	0	1 (0.6%)	0	0	0	1 (0.6%)
Renal and urinary disorders	1 (1.9%)	4 (2.5%)	0	1 (7.7%)	1 (1.8%)	5 (2.9%)
Dysuria	1 (1.9%)	0	0	0	1 (1.8%)	0
Leukocyturia	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Nocturia	0	3 (1.9%)	0	0	0	3 (1.7%)
Reproductive system and breast disorders	2 (3.8%)	4 (2.5%)	0	0	2 (3.6%)	4 (2.3%)
Benign prostatic hyperplasia	0	1 (0.6%)	0	0	0	1 (0.6%)
Fibrocystic breast disease	0	1 (0.6%)	0	0	0	1 (0.6%)
Menorrhagia	0	1 (0.6%)	0	0	0	1 (0.6%)
Menstrual disorder	0	1 (0.6%)	0	0	0	1 (0.6%)
Metrorrhagia	1 (1.9%)	0	0	0	1 (1.8%)	0
Vaginal haemorrhage	1 (1.9%)	0	0	0	1 (1.8%)	0
Respiratory, thoracic and mediastinal disorders	3 (5.8%)	10 (6.2%)	0	0	3 (5.4%)	10 (5.7%)
Asthma	0	1 (0.6%)	0	0	0	1 (0.6%)
Atelectasis	1 (1.9%)	0	0	0	1 (1.8%)	0
Chronic obstructive pulmonary disease	0	1 (0.6%)	0	0	0	1 (0.6%)
Cough	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Dyspnoea	1 (1.9%)	0	0	0	1 (1.8%)	0
Hiccups	0	1 (0.6%)	0	0	0	1 (0.6%)
Oropharyngeal pain	1 (1.9%)	4 (2.5%)	0	0	1 (1.8%)	4 (2.3%)
Productive cough	1 (1.9%)	0	0	0	1 (1.8%)	0
Rhinorrhoea	0	1 (0.6%)	0	0	0	1 (0.6%)
Yawning	0	1 (0.6%)	0	0	0	1 (0.6%)
Skin and subcutaneous tissue disorders	10 (19.2%)	22 (13.7%)	0	1 (7.7%)	10 (17.9%)	23 (13.2%)
Acne	0	2 (1.2%)	0	0	0	2 (1.1%)
Alopecia	2 (3.8%)	1 (0.6%)	0	0	2 (3.6%)	1 (0.6%)
Blister	0	1 (0.6%)	0	0	0	1 (0.6%)
Dermatitis contact	1 (1.9%)	0	0	0	1 (1.8%)	0
Drug eruption	0	1 (0.6%)	0	0	0	1 (0.6%)
Dry skin	0	2 (1.2%)	0	0	0	2 (1.1%)
Eczema	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Erythema	0	1 (0.6%)	0	0	0	1 (0.6%)
Hidradenitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Hyperhidrosis	0	0	0	1 (7.7%)	0	1 (0.6%)
Miliaria	0	1 (0.6%)	0	0	0	1 (0.6%)
Night sweats	0	1 (0.6%)	0	0	0	1 (0.6%)
Onychoclasis	0	1 (0.6%)	0	0	0	1 (0.6%)
Pruritus	5 (9.6%)	1 (0.6%)	0	0	5 (8.9%)	1 (0.6%)
Psoriasis	0	1 (0.6%)	0	0	0	1 (0.6%)
Rash	0	4 (2.5%)	0	0	0	4 (2.3%)
Rash maculo-papular	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Skin disorder	1 (1.9%)	0	0	0	1 (1.8%)	0
Skin exfoliation	0	2 (1.2%)	0	0	0	2 (1.1%)
Skin hyperpigmentation	0	1 (0.6%)	0	0	0	1 (0.6%)
Urticaria	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Surgical and medical procedures	0	1 (0.6%)	0	0	0	1 (0.6%)
Tooth extraction	0	1 (0.6%)	0	0	0	1 (0.6%)
Vascular disorders	5 (9.6%)	3 (1.9%)	0	0	5 (8.9%)	3 (1.7%)
Deep vein thrombosis	1 (1.9%)	0	0	0	1 (1.8%)	0
Hyperaemia	1 (1.9%)	0	0	0	1 (1.8%)	0
Hypertension	2 (3.8%)	3 (1.9%)	0	0	2 (3.6%)	3 (1.7%)
Hypotension	1 (1.9%)	0	0	0	1 (1.8%)	0

TEAE = treatment-emergent adverse event; MEDI551 = Inebilizumab.
As-Treated 集団は少なくとも治験薬が 1 回投与された被験者とした.
a 被験者は事象の回数にかかわらず，SOC 及び PT 別に 1 件として計上した.
Source: Table 14.3.1.2.2.1，1155 CSR.