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Title:

Safety and Effectiveness of Palivizumab Prophylaxis against Respiratory Syncytial Virus Infection in Children with Immunocompromised Conditions or Down Syndrome: A Multicenter, Post-Marketing Surveillance Study in Japan.

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SUPPLEMENTARY TABLES

Supplementary Table 1 Prior medications and concomitant drugs

Prior Medications and Concomitant Drugs	n (%)
	[N = 304]
Prior medication ^{a,c}	191 (62.8)
Adrenocortical steroids	64 (21.1)
Immunosuppressant	61 (20.1)
Antitumor drugs	45 (14.8)
Biologics	1 (0.3)
Unknown	1 (0.3)
Others	188 (61.8)
Concomitant medications ^{b,c}	245 (80.6)
Others	240 (78.9)
Adrenocortical steroids	85 (28.0)
Immunosuppressant	82 (27.0)
Antitumor drugs	61 (20.1)
Biologics	3 (1.0)
Unknown	1 (0.3)

^aConcomitant drug used during the period from 30 days to 1 day before the first administration

^bConcomitant drug used during the period from first administration to 30 days after the final administration

^cOne subject may be counted more than once

Supplementary Table 2 Adverse events (N=304)

	Adverse events	Serious adverse events
Number of patients (events)	99 (220)	53 (89)
Incidence, %	32.56	17.43
Infections and infestations, n (%)	56 (18.42)	29 (9.54)
Pneumonia	7 (2.30)	6 (1.97)
Bronchitis	6 (1.97)	3 (0.99)
Gastroenteritis ^a	6 (1.97)	3 (0.99)
Influenza	5 (1.64)	2 (0.66)
Respiratory syncytial virus infection ^b	4 (1.32)	2 (0.66)
Bacteremia ^a	3 (0.99)	3 (0.99)
Exanthema subitum	3 (0.99)	
Conjunctivitis ^a	3 (0.99)	
Catheter site infection ^a	3 (0.99)	
Cytomegalovirus infection	2 (0.66)	1 (0.33)
Gastroenteritis viral	2 (0.66)	1 (0.33)
Lower respiratory tract infection ^a	2 (0.66)	2 (0.66)
Pneumonia bacterial	2 (0.66)	2 (0.66)
Nasopharyngitis	2 (0.66)	
Device related infection ^a	2 (0.66)	1 (0.33)
Croup infectious ^a	1 (0.33)	
Epstein-Barr virus infection	1 (0.33)	1 (0.33)
Infection ^a	1 (0.33)	1 (0.33)
Peritonitis ^a	1 (0.33)	1 (0.33)
Cellulitis ^a	1 (0.33)	
Pseudomembranous colitis ^a	1 (0.33)	
Sepsis ^a	1 (0.33)	1 (0.33)
Septic shock ^a	1 (0.33)	1 (0.33)
Sinusitis ^a	1 (0.33)	
Tonsillitis ^a	1 (0.33)	1 (0.33)
Upper respiratory tract infection	1 (0.33)	
Viral pharyngitis	1 (0.33)	
Viral rash	1 (0.33)	
Bronchitis viral	1 (0.33)	1 (0.33)
Enteritis infectious ^a	1 (0.33)	
Clostridial infection ^a	1 (0.33)	
Enterocolitis viral	1 (0.33)	
Viral rhinitis	1 (0.33)	
Enterocolitis bacterial ^a	1 (0.33)	
Metapneumovirus infection	1 (0.33)	
Tinea manuum ^a	1 (0.33)	
Gastroenteritis norovirus	1 (0.33)	
Acute sinusitis ^a	1 (0.33)	
Respiratory, thoracic, and mediastinal disorders, n (%)	36 (11.84)	9 (2.96)
Upper respiratory tract	23 (7.57)	1 (0.33)

inflammation		
Asthma ^a	5 (1.64)	4 (1.32)
Rhinorrhea	2 (0.66)	
Acute pulmonary edema ^a	1 (0.33)	1 (0.33)
Cough	1 (0.33)	
Hypoxia ^a	1 (0.33)	1 (0.33)
Interstitial lung disease ^a	1 (0.33)	
Pulmonary hypertension ^a	1 (0.33)	1 (0.33)
Respiratory arrest ^a	1 (0.33)	1 (0.33)
Respiratory disorder ^a	1 (0.33)	1 (0.33)
Respiratory failure ^a	1 (0.33)	1 (0.33)
Allergic rhinitis ^a	1 (0.33)	
Fibrinous bronchitis	1 (0.33)	
Blood and lymphatic system disorders, n (%)	16 (5.26)	8 (2.63)
Febrile neutropenia	11 (3.62)	2 (0.66)
Bone marrow failure ^a	3 (0.99)	3 (0.99)
Anemia ^a	2 (0.66)	1 (0.33)
Histiocytosis hematophagic ^a	2 (0.66)	1 (0.33)
Disseminated intravascular coagulation ^a	2 (0.66)	2 (0.66)
Hemolysis ^a	1 (0.33)	1 (0.33)
Pancytopenia ^a	1 (0.33)	1 (0.33)
Coagulopathy ^a	1 (0.33)	1 (0.33)
Gastrointestinal disorders, n (%)	10 (3.29)	1 (0.33)
Diarrhea	6 (1.97)	
Abdominal pain ^a	1 (0.33)	
Ascites ^a	1 (0.33)	
Constipation ^a	1 (0.33)	
Enterocolitis ^a	1 (0.33)	
Nausea ^a	1 (0.33)	
Stomatitis ^a	1 (0.33)	
Vomiting	1 (0.33)	1 (0.33)
Hepatobiliary disorders, n (%)	9 (2.96)	5 (1.64)
Hepatic function abnormal ^a	3 (0.99)	1 (0.33)
Liver disorder ^a	3 (0.99)	1 (0.33)
Cholangitis ^a	1 (0.33)	1 (0.33)
Hepatic failure ^a	1 (0.33)	1 (0.33)
Drug-induced liver injury ^a	1 (0.33)	1 (0.33)
General disorders and administration site conditions, n (%)	8 (2.63)	3 (0.99)
Pyrexia	6 (1.97)	2 (0.66)
Condition aggravated ^a	1 (0.33)	1 (0.33)
Pain	1 (0.33)	
Investigations, n (%)	8 (2.63)	2 (0.66)
Neutrophil count decreased	3 (0.99)	1 (0.33)
Alanine aminotransferase increased	1 (0.33)	
Blood culture positive ^a	1 (0.33)	

White blood cell count decreased	1 (0.33)	
Antithrombin III decreased ^a	1 (0.33)	
Norovirus test positive	1 (0.33)	1 (0.33)
Aspergillus test positive ^a	1 (0.33)	
Immune system disorders, n (%)	6 (1.97)	2 (0.66)
Hypogammaglobulinemia ^a	2 (0.66)	
Chronic graft versus host disease ^a	2 (0.66)	2 (0.66)
Engraftment syndrome ^a	1 (0.33)	
Graft versus host disease ^a	1 (0.33)	
Hypersensitivity ^a	1 (0.33)	
Metabolism and nutrition disorders, n (%)	5 (1.64)	2 (0.66)
Hypoalbuminemia ^a	1 (0.33)	1 (0.33)
Hypokalemia ^a	1 (0.33)	
Hyponatremia ^a	1 (0.33)	
Lactose intolerance ^a	1 (0.33)	
Hypophagia ^a	1 (0.33)	1 (0.33)
Nervous system disorders	4 (1.32)	3 (0.99)
Febrile convulsion ^a	2 (0.66)	2 (0.66)
Epilepsy ^a	1 (0.33)	
Neurological symptom ^a	1 (0.33)	1 (0.33)
Injury, poisoning and procedural complications, n (%)	4 (1.32)	
Femur fracture ^a	1 (0.33)	
Frostbite ^a	1 (0.33)	
Vaccination complication ^a	1 (0.33)	
Postoperative ileus ^a	1 (0.33)	
Skin and subcutaneous tissue disorders, n (%)	4 (1.32)	1 (0.33)
Rash	2 (0.66)	1 (0.33)
Dermatitis ^a	1 (0.33)	
Penile ulceration ^a	1 (0.33)	
Skin ulcer ^a	1 (0.33)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps), n (%)	3 (0.99)	3 (0.99)
Brain neoplasm malignant ^a	1 (0.33)	1 (0.33)
Nephroblastoma ^a	1 (0.33)	1 (0.33)
Malignant neoplasm progression ^a	1 (0.33)	1 (0.33)
Cardiac disorders, n (%)	3 (0.99)	3 (0.99)
Cardiac failure ^a	2 (0.66)	2 (0.66)
Bradycardia	1 (0.33)	1 (0.33)
Renal and urinary disorders, n (%)	3 (0.99)	2 (0.66)
Renal impairment ^a	2 (0.66)	2 (0.66)
Nephrotic syndrome ^a	1 (0.33)	
Congenital, familial and genetic disorders, n (%)	3 (0.99)	3 (0.99)
Anal atresia ^a	1 (0.33)	1 (0.33)
X-linked lymphoproliferative syndrome ^a	1 (0.33)	1 (0.33)
Omenn syndrome ^a	1 (0.33)	1 (0.33)

Eye disorders, n (%)	2 (0.66)	1 (0.33)
Eyelid edema ^a	1 (0.33)	1 (0.33)
Uveitis ^a	1 (0.33)	
Vascular disorders, n (%)	2 (0.66)	1 (0.33)
Hypertension ^a	2 (0.66)	1 (0.33)
Endocrine disorders, n (%)	2 (0.66)	1 (0.33)
Adrenal disorder ^a	1 (0.33)	1 (0.33)
Adrenal insufficiency ^a	1 (0.33)	

^aAdverse reactions/infections not expected based on PRECAUTIONS of the package insert

^bIn one case, RSV was detected on the day palivizumab was administered, and so it was not recorded as an AE. Hence only 4 RSV infections were recorded as AEs.

Adverse events were classified using Medical Dictionary for Regulatory Activities/Japanese Version 18.1.