March 27, 2023

Anti-cytomegalovirus chemotherapeutic agent "Valixa® Dry Syrup 5000mg" Approved for the indication of symptomatic congenital cytomegalovirus infection in Japan

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Hiroaki Ueno; hereinafter, “MTPC”), a member of the Mitsubishi Chemical Group, announced today that MTPC received approval for an additional indication of the anti-cytomegalovirus agent Valixa® Dry Syrup 5000mg (generic name: valganciclovir hydrochloride, hereinafter Valixa® Dry Syrup) for the treatment of symptomatic congenital cytomegalovirus infection.

For this approval, an investigator-initiated clinical trial (VGCV -1) was conducted by a research group of 6 medical institutions (The University of Tokyo Hospital, Nihon University Itabashi Hospital, Nagoya University Hospital, Fujita Health University Hospital, Kobe University Hospital, and Nagasaki University Hospital) in children with symptomatic congenital cytomegalovirus infection. This research was supported by Japan Agency for Medical Research and Development (AMED) grant, “research on treatment of valganciclovir for infants with symptomatic congenital cytomegalovirus infection”, under Project for Baby and Infant in Research of healTH and Development to Adolescent and Young adult – BIRTHDAY. The results showed that administration of Valixa® Dry Syrup for 6 months reduced the amount of cytomegalovirus in the whole blood, and suppressed aggravation of hearing impairment. This is the first approved drug in the world for the treatment of symptomatic congenital cytomegalovirus infection and will provide patients with a new treatment option.

Symptomatic congenital cytomegalovirus infection is a rare disease that develops when cytomegalovirus is transmitted to the fetus via the placenta of a pregnant woman. Approximately 1,700 newborns per year develop the disease in Japan. In neonates with symptomatic congenital cytomegalovirus infection, symptoms such as central nervous system disorders and deafness are often observed at birth, followed by neurological sequelae such as mental retardation. Thus, it is a problem that Patients with the symptomatic congenital cytomegalovirus infection have an impaired growth and development. Currently, there is no approved treatment for neonates/infants with for symptomatic congenital cytomegalovirus infection in Japan or overseas, and therefore, there is an unmet medical need in this patient population.

Valixa® Dry Syrup obtained manufacturing and marketing approval in Japan in 2018. It is approved as a therapeutic drug for cytomegalovirus infection in “acquired immunodeficiency syndrome,” “organ transplantation (including hematopoietic stem cell transplantation),” and “malignant tumors,” and a suppressant for cytomegalovirus infection associated with “organ transplantation (excluding hematopoietic stem cell transplantation).” Orphan drug designation for the treatment of symptomatic congenital cytomegalovirus infection has been granted.

MTPC will continue to advance R&D activities so that we can deliver the new treatment options for diseases with unmet medical needs, including rare diseases.

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