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Anti-cytomegalovirus chemotherapeutic agents "Valixa® Dry Syrup 5000mg" Notification of application for additional indication of symptomatic congenital cytomegalovirus infection in Japan

Mitsubishi Tanabe Pharma Corporation

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

An investigator-initiated trial evaluating the efficacy and safety of Valixa® in children with symptomatic congenital cytomegalovirus infection (VGCV-1) showed improvement of symptoms, and therefore MTPC, the manufacturer and distributor of Valixa® in Japan, filed an application using the results of VGCV-1 trial. VGCV-1 trial has been done an investigator-initiated clinical trial conducted by a research group at a total of 6 medical institutions including The University of Tokyo Hospital, Nihon University Itabashi Hospital, Nagoya University Hospital, Fujita Health University Hospital, Kobe University Hospital, and Nagasaki University Hospital.
Valixa® has been granted Orphan Drug Designation for the treatment of symptomatic congenital cytomegalovirus infection. If approved for symptomatic congenital cytomegalovirus infection, it would be the first treatment in the world.

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).”

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

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<Reference>

■Investigator-initiated clinical trial

An investigator-initiated clinical trial is a clinical trial conducted by a doctor who plans/draws up a clinical trial by himself/herself and submits a clinical trial plan notification. It is a clinical trial in which the doctor himself/herself has responsibility for not only the “conduct of the clinical trial” but also the entire clinical trial such as “preparation for the clinical trial” and “management of the clinical trial”.