



February 28, 2018

Valixa[®] Tablet 450 mg

**Public knowledge-based application for an additional pediatric indication
for the prevention of CMV disease in organ transplant patients
as well as application for an additional dosage form of dry syrup**

Mitsubishi Tanabe Pharma Corporation (President and Representative Director: Masayuki Mitsuka; hereafter “the Company”) announced that on February 28 the Company filed a public knowledge-based application for an additional pediatric indication for the prevention of cytomegalovirus (CMV) disease in organ transplant patients (excluding haematopoietic stem cell transplantation) for Valixa[®] Tablets 450mg (hereafter “Valixa”, generic name: valganciclovir hydrochloride). In addition, the Company filed an application for an additional dosage form of dry syrup.

At the “33rd Review Committee on Unapproved Drugs and Indications with High Medical Needs” held on December 22, 2017, Valixa was evaluated as an agent eligible for a public knowledge-based application for a pediatric indication for the prevention of CMV disease in organ transplant patients (excluding haematopoietic stem cell transplantation). Subsequently, at a meeting of the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on February 2, 2018, a decision was made not to oppose the public knowledge-based application, and the filing was implemented. In addition, the Company also filed an application for an additional dosage form of dry syrup for administration to pediatric patients.

Valganciclovir was discovered by F. Hoffmann-La Roche Ltd. (Basel / Switzerland), and in Japan the Company received approval and began sales in 2004. Subsequently, in 2016 the Company obtained approval for an indication of prevention of CMV disease in organ transplant patients (excluding haematopoietic stem cell transplantation) in adult patients.

Moving forward, Mitsubishi Tanabe Pharma Corporation will continue working to advance the research, development, and sales of drugs that address unmet medical

needs and striving to contribute to a high quality of life for patients.

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