March 22, 2016

Press release

Mitsubishi Tanabe Pharma Corporation

Valixa® Tablet 450 mg
Application for Additional Indication in Japan for the Prevention of CMV disease in organ transplant patients
Public Knowledge-based Application

Osaka, Japan, March 22, 2016—Mitsubishi Tanabe Pharma Corporation (President and Representative Director: Masayuki Mitsuka) has announced today that the company filed public knowledge-based application for additional indication of the prevention of cytomegalovirus (CMV) disease in organ transplant patients (excluding hematogenic stem cell transplantation) for Valixa® Tablets 450mg (hereinafter Valixa, generic name: valganciclovir hydrochloride) in Japan.

Valixa was evaluated as the agent applicable "public knowledge-based application" at the "26th Review Committee on Unapproved Drugs and Indications with High Medical Needs" held on February 3, 2016. The filing was made based on the decision at the meeting of the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on February 26, 2016.

Valganciclovir was discovered by F. Hoffmann-La Roche Ltd. (Basel / Switzeland), and has been distributed to more than 100 countries for this indication. On the other hands, in Japan, Mitsubishi Tanabe Pharma obtained approval on 2004 for the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS), and approval for an additional indication on 2009 for cytomegalovirus infection in organ transplantation (including hematogenic stem cell transplantation, but not including its prevention).

Mitsubishi Tanabe Pharma will aggressively work to develop new drugs that address unmet medical needs and will contribute to a higher quality of life for patients.

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