Mitsubishi Tanabe Pharma Press Release

August 26, 2016

Press release

Mitsubishi Tanabe Pharma Corporation

Valixa® Tablet 450 mg
Approval for Additional Indication in Japan for the Prevention of CMV disease in organ transplant patients

Osaka, Japan, August 26, 2016—Mitsubishi Tanabe Pharma Corporation (President and Representative Director: Masayuki Mitsuka) has announced today that it has received approval for an additional indication of the prevention of cytomegalovirus (CMV) disease in organ transplant patients (excluding haematopoietic 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. This public knowledge-based application 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, and was approved for the additional indication.

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

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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