April 22, 2021

Notification of Marketing Authorization Application of Valbenazine (MT-5199) for the Treatment of Tardive Dyskinesia in Japan

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director, CEO: Hiroaki Ueno) announced today that MTPC has filed an application for marketing authorization of valbenazine (MT-5199) for the treatment of tardive dyskinesia with the Ministry of Health, Labour and Welfare.

MTPC conducted a phase 2/3 clinical study (J-KINECT study) in Japan from June 2017 to confirm the efficacy and safety of valbenazine. J-KINECT study showed a significant improvement in the primary efficacy endpoint of the mean change from baseline in the Abnormal Involuntary Movement Rating Scale (AIMS) total score at Week 6 of treatment with MT-5199 compared to placebo. In addition, there was no trend that was significantly different from the safety profile of valbenazine reported so far.

Tardive dyskinesia is a type of involuntary movement arising from the long-term administration of antipsychotic drugs or other drugs. Increased sensitivity of dopamine receptors is considered to be a causal factor. Symptoms, which differ by patient, are principally facial, but also in the extremities and torso. Severe cases can lead to dysphagia or respiratory distress, which can be serious in some patients. Since there is currently no approved treatment for tardive dyskinesia in Japan, MTPC would like to bring valbenazine to patients as soon as possible after obtaining regulatory approval.
In Singapore, Thailand, Indonesia, Malaysia and South Korea, where MTPC has the exclusive development and marketing rights, the application was filed in 2020.

MTPC Group will continue to advance R & D activities so that we can deliver the best pharmaceutical products for diseases with unmet needs as soon as possible.

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About valbenazine

Valbenazine (MT-5199) is a VMAT2 inhibitor licensed in from Neurocrine Biosciences, Inc. (San Diego, USA). By inhibiting VMAT2 existing in nerve terminals, it reduces the uptake of neurotransmitters such as dopamine into synaptic vesicles and normalizes the function of the dopamine nervous system which is involved in the expression of involuntary movements.

In the U.S., valbenazine was the first product to be approved for the treatment of adults with tardive dyskinesia in April 2017. INGREZZA® (valbenazine) is commercialized in the US by Neurocrine Biosciences and is contributing to the treatment of patients with tardive dyskinesia.