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Results of J-KINECT Study, Phase 2/3 study in Japan of VMAT2 inhibitor MT-5199 in tardive dyskinesia

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director, CEO: Hiroaki Ueno) announces that MTPC has obtained positive results of phase 2/3 clinical study in Japan (J-KINECT study) of MT-5199(generic name: valbenazine), the vesicular monoamine transporter type 2 (VMAT2) inhibitor, in subjects with tardive dyskinesia.

The J-KINECT study is a randomized, double-blind placebo-controlled study to confirm the efficacy and safety of MT-5199 administered once daily for up to 48 weeks in patients with moderate or severe tardive dyskinesia. This 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, MT-5199 was generally well-tolerated.
MTPC plans to publish the detailed data at an upcoming medical conference and journal in a near future.

MTPC also plans to file NDA data package of MT-5199 as a therapeutic medication for tardive dyskinesia in Japan in FY2021.
In Singapore, Thailand, Indonesia, Malaysia and South Korea, where MTPC has the exclusive development and marketing rights, the NDA for tardive dyskinesia was filed in 2020, respectively.

MTPC Group will continue to advance R&D activities so that we can deliver the best possible pharmaceutical products as quickly as possible to many patients fighting against diseases all over the world.

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About tardive dyskinesia

Tardive dyskinesia is a type of involuntary movements arising from the long-term administration of antipsychotic drugs or other drugs. Increased dopamine sensitivity is considered to be a causal factor. Symptoms, which differ by patient, are principally facial, but also in the extremities and torso. Involuntary movements cause psychological and physical burden. Severe cases can lead to dysphagia or respiratory distress. There is currently no approved treatment for tardive dyskinesia in Japan.

About MT-5199

MT-5199 (generic name: valbenazine) inhibits VMAT2 (vesicular monoamine transporter type 2), which is located in nerve endings, thereby reducing the uptake of dopamine and other neurotransmitters into presynaptic vesicles and normalizing the function of dopaminergic neurons associated with occurrence of involuntary movement.

In the U.S., approval for an indication of tardive dyskinesia has been received by Neurocrine Biosciences, Inc., in April 2017.