

News Release

October 8, 2021

Top-line data of J-KINECT Study, Phase 2/3 study in Japan of VMAT2 inhibitor MT-5199 in TD, presented at the 31st annual meeting of the Japanese Society of Clinical Neuropsychopharmacology

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) presented top-line data 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 (TD) at the 31st annual meeting of the Japanese Society of Clinical Neuropsychopharmacology from October 7 to October 8, 2021.

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 TD, and 253 patients received either MT-5199 or placebo. In this presentation, the results from the placebo-controlled double-blind period (up to 6 weeks of administration) were presented as top-line data.

Title: Topline results of J-KINECT study, Phase 2/3 study of vesicular monoamine transporter 2 (VMAT2) inhibitor MT-5199 in Japanese tardive dyskinesia patients

- Primary Endpoint: The mean change from baseline in the Abnormal Involuntary Movement Scale (AIMS) total score at Week 6 showed significant improvement in the MT-5199 group compared to the placebo group.
- Secondary endpoints: The proportion of subjects achieving $\geq 50\%$ improvement from baseline in AIMS total score at Week 6 was significantly higher in the MT-5199 group than that in the placebo group. The MT-5199 group showed a significant improvement in the Clinical Global Impression of Change-Tardive Dyskinesia (CGI-TD) score at Week 6 compared with the placebo group.
- Safety: In the placebo-controlled double-blind period, the MT-5199 group was generally well tolerated. Adverse events that occurred at a $\geq 5\%$ higher incidence in the MT-5199 group than in the placebo group were somnolence, salivary hypersecretion, malaise, schizophrenia, and tremor.

These results indicate that MT-5199 is generally well tolerated and improves TD symptoms. The efficacy and safety results for 48 weeks treatment period in this study will be presented at an academic conference in the near future.

In 2015, MTPC exclusively licensed the development and commercialization rights for MT-5199 in Japan and certain other Asian countries from Neurocrine Biosciences Inc. (U.S.), and since then, MTPC has been conducting development activities for MT-5199 within the licensed region.

In Japan, MTPC filed an application for marketing authorization of MT-5199 for the treatment of TD with the Ministry of Health, Labour and Welfare in April 2021. Moreover, in Singapore and Thailand, MT-5199 was approved in May 2021 and August 2021, respectively, and the applications have been filed and are currently under review in Indonesia, Malaysia, and South Korea.

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 (TD) 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 TD 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.