



July 27, 2017

Notice regarding the initiation of a phase 2/3 clinical trial in Japan for tardive dyskinesia patients for VMAT2 inhibitor MT-5199

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director: Masayuki Mitsuka) announced today that it has started a phase 2/3 clinical trial in Japan (J-KINECT trial) for tardive dyskinesia patients for MT-5199 (generic name: valbenazine), which is a vesicular monoamine transporter type 2 (VMAT2) inhibitor.

The J-KINECT trial is a randomized, double-blind placebo-controlled trial of the efficacy and safety of MT-5199 for patients with moderate to severe tardive dyskinesia, with once-daily administration for a maximum of 48 weeks. This trial has a placebo-controlled period (6 weeks) and an MT-5199 extended administration period (42 weeks). The primary outcome of efficacy will be the amount of change in the Abnormal Involuntary Movements Scale (AIMS) score; after 6 weeks of administration, the change in the AIMS score from the baseline will be compared with placebo to evaluate the efficacy of MT-5199 treatment for tardive dyskinesia symptoms.

MT-5199 is a VMAT2 inhibitor that the Company in-licensed from Neurocrine Biosciences, Inc., of the U.S. (San Diego). On March 31, 2015, Mitsubishi Tanabe Pharma and Neurocrine Biosciences signed a licensing agreement related to exclusive development and sales rights for MT-5199 in Japan and Asia.

Under the Medium-Term Management Plan 16-20: Open Up the Future, Mitsubishi Tanabe Pharma identified four strategic priorities. One of those priorities is "Maximizing Pipeline Value," and to that end the Company has established the objective of discovering 10 late-stage drug candidates during the period covered by the plan. During fiscal 2017, the Company was able to advance MT-5199 to the development stage as a late-stage drug candidate. In addition, tardive dyskinesia, which is the focus of this trial, is a central nervous system disease, which is one of the Company's strategic areas. Moving forward, Mitsubishi Tanabe Pharma will aggressively work to develop new drugs that address unmet medical needs, centered on its strategic areas.

⟨⟨For Details, Contact the Following Section⟩⟩

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◆Reference◆

About tardive dyskinesia

Tardive dyskinesia is a type of involuntary movement 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 common in the extremities and torso. Severe cases can lead to dysphagia or respiratory distress.

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.