

July 31, 2023

**Launch of REMLEAS® capsules 40mg for Treatment of Tardive Dyskinesia
in three ASEAN countries**

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, “MTPC”), a member of the Mitsubishi Chemical Group, announced today that MTPC’s group company has launched REMLEAS® (Japan product name: DYSVAL®, generic name: valbenazine, the vesicular monoamine transporter type 2 inhibitor) for the treatment of tardive dyskinesia in Thailand on July 31, 2023. REMLEAS® was launched in Singapore in January 2023 and in Indonesia in May 2023.

As the first drug approved in Thailand, Singapore, and Indonesia for the treatment of tardive dyskinesia, REMLEAS® would provide a new treatment option for patients with tardive dyskinesia in these countries.

In these three countries, the marketing subsidiaries of MTPC, Mitsubishi Tanabe Pharma (Thailand) Co., Ltd., Mitsubishi Tanabe Pharma Singapore Pte. Ltd., and PT Mitsubishi Tanabe Pharma Indonesia are the marketing authorization holders, marketing valbenazine under the product name REMLEAS®.

Tardive dyskinesia is a neurologic disorder characterized by involuntary movements, including uncontrollable, abnormal and repetitive movements of the tongue, lips, jaw, face, extremities, and torso. It may cause difficulty in activities of daily living and, in severe cases, dysphagia or respiratory distress. Tardive dyskinesia arises from the long-term administration of antipsychotic drugs or other drugs. Increased sensitivity of dopamine receptors is considered to be a causal factor.

MTPC obtained the regulatory approval of DYSVAL® in March 2022 in Japan and launched in June the same year.

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 is a vesicular monoamine transporter type 2 (VMAT2) inhibitor licensed in from Neurocrine Biosciences, Inc. (U.S.). 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 movement.

In the U.S., Neurocrine Biosciences, Inc. obtained an approval of valbenazine for the indication of tardive dyskinesia in April 2017, and it is marketed under the product name INGREZZA®.

■ About Mitsubishi Tanabe Pharma (Thailand) Co., Ltd. (MTTH)

Mitsubishi Tanabe Pharma (Thailand) Co., Ltd. (MTTH) was founded as a wholly-owned subsidiary of MTPC in Thailand in 2016. Along with Indonesia, Thailand has one of the largest pharmaceutical markets in the ASEAN region. MTTH sells REAGILA®, a medication for schizophrenia and bipolar disorder, in addition to many products for lifestyle-related diseases such as HERBESSER®, TANATRIL® and TENELIA®. MTTH will expand its central nervous system (CNS) pipeline with REMLEAS®.

■ About Mitsubishi Tanabe Pharma Singapore Pte. Ltd. (MTSG)

Mitsubishi Tanabe Pharma Singapore Pte. Ltd. (MTSG) was founded as a wholly-owned subsidiary of MTPC in Singapore in 2016. As a company in charge of supervising the ASEAN region, where the economies and pharmaceutical markets have been rapidly growing, MTSG carries out its operations, including development, in order to promptly provide patients in ASEAN countries with innovative pharmaceutical products that can satisfy unmet needs. MTSG sells SYMVENU®, a medication for schizophrenia and bipolar disorder. MTSG will expand its CNS pipeline with REMLEAS®.

■ About PT Mitsubishi Tanabe Pharma Indonesia (MTID)

PT Mitsubishi Tanabe Pharma Indonesia (MTID) was founded as a wholly-owned subsidiary of MTPC in 1970. It has its headquarters in Jakarta, 13 sales bases in Indonesia and a manufacturing base in Bandung. MTID sells SYMVENU®, a medication for schizophrenia and bipolar disorder, as well as many products for lifestyle-related diseases such as HERBESSER®, TANAPRESS® (Japan product name: TANATRIL®), and LIVALO®. MTID will expand its CNS pipeline with REMLEAS®. As the manufacturing base in Southeast and South Asia, MTID supplies products not only to Indonesia but also to ASEAN countries, Sri Lanka, Pakistan, and Hong Kong, etc.