



June 1, 2022

## <u>Launch of DYSVAL® capsules 40mg</u> <u>for Treatment of Tardive Dyskinesia in Japan</u>

Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Hiroaki Ueno; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Holdings Group, announced today that MTPC is launching DYSVAL® capsules 40mg (generic name: valbenazine, DYSVAL) (the vesicular monoamine transporter type 2 (VMAT2) inhibitor) for the treatment of tardive dyskinesia in Japan following the inclusion of DYSVAL in the NHI drug price listing on May 25,2022.

As the first drug approved in Japan for the treatment of tardive dyskinesia, DYSVAL would provide patients with a once-daily treatment option in Japan.

Tardive dyskinesia is a neurologic disorder characterized by involuntary movement. Symptoms include uncontrollable, abnormal and repetitive movements of the tongue, lips, jaw, face, the extremities, and torso. Severe cases can lead to dysphagia or respiratory distress, which can be serious in some patients. 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 wants to help patients who are suffering from tardive dyskinesia symptoms to establish an environment where they can receive treatment for their primary disease and also face treatment for tardive dyskinesia.

MTPC and Janssen Pharmaceutical K.K. (Janssen) with strengths in the neurology area concluded a co-promotion agreement concerning DYSVAL in Japan, in November 2021. Janssen will be responsible for the distribution of DYSVAL, and MTPC, Janssen and Yoshitomiyakuhin Corporation will jointly provide appropriate information to healthcare professionals in Japan.

MTPC Group, in collaboration with Janssen, is committed to contributing to the treatment of patients with tardive dyskinesia by providing prompt, thorough information provision.

Mitsubishi Chemical Holdings Group
Corporate Communications Div.
Osaka Corporate Communications Dept.
Media contacts: [+81] (0)6-6205-5119





Product Name DYSVAL® Capsules 40mg (DYSVAL® capsules)

JAN Valbenazine

Indication Tardive dyskinesia

Dosage Once daily, starting dose is 40mg, and maximum dose is

80mg.

**Packaging** 

40mg 100 capsules [10 capsules (PTP) ×10]

Retail Price 40mg 2331.20yen/one capsule

Approval (Japan) March 28,2022 HVL Listing May 25, 2022 Release (Japan) June 1, 2022

Manufacturer Mitsubishi Tanabe Pharma Corporation

Distributor and Co-Promoter Janssen Pharmaceutical K.K.

Co-Promoter Yoshitomiyakuhin Corporation

## ■About Valbenazine

Valbenazine inhibits VMAT2, 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 in April 2017.

In 2015, MTPC exclusively licensed the development and commercialization rights for Valbenazine in Japan from Neurocrine Biosciences, Inc. (U.S.) and received approval of Valbenazine for the indication of tardive dyskinesia in Singapore, Thailand, South Korea, and Indonesia in May, August, November, and December 2021, respectively, and the application for tardive dyskinesia is currently under review by the authority in Malaysia.