March 28, 2022

Regulatory Approval of DYSVAL®capsules 40mg for Treatment of Tardive Dyskinesia in Japan

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) obtained the regulatory approval of the vesicular monoamine transporter type 2 (VMAT2) inhibitor, DYSVAL® capsules 40mg (DYSVAL, development code: MT-5199, generic name: valbenazine) for the treatment of tardive dyskinesia from the Ministry of Health, Labour and Welfare on March 28, 2022.
As the first drug approved in Japan for the treatment of tardive dyskinesia, MTPC believes that DYSVAL offers a new treatment option for tardive dyskinesia.

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.

In 2015, MTPC exclusively licensed the development and commercialization rights for this product in Japan and certain other Asian countries from Neurocrine Biosciences, Inc. (U.S.). MTPC conducted the phase 2/3 clinical study (J-KINECT study: MT-5199-J02) in Japan from June 2017 to confirm the efficacy and safety of DYSVAL. J-KINECT 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 DYSVAL compared to placebo. The persistence of efficacy was also shown in the AIMS total score at Week 48. In addition, DYSVAL was generally well-tolerated.

MTPC received approval of this product 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.

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 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.

After MTPC obtains regulatory approval for this product in Japan, Janssen Pharmaceutical K.K. will be responsible for distribution. Both companies will jointly promote it (press release dated December 3, 2021).

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* and uterine fibroids*, as well as over a dozen mid-to-late-stage clinical programs in multiple therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn. (*in collaboration with AbbVie).