



August 8, 2019

Regulatory Approval for Marketing Cariprazine (MP-214)
for the Treatment of Schizophrenia
in Part of the ASEAN (Singapore and Thailand)

Mitsubishi Tanabe Pharma Corporation (MTPC, Chuo-ku, Osaka, Japan; President & Representative Director, CEO: Masayuki Mitsuka) announced today that MTPC's subsidiaries in ASEAN obtained the regulatory approval of cariprazine (generic name; development code: MP-214; dopamine D3/D2 receptor partial agonist) for the treatment of schizophrenia in Singapore from the Singaporean Health Sciences Authority on July 11, and from Food and Drug Administration Thailand in Thailand on July 22, following the completion of the approval application procedure in both countries.

In Singapore, Mitsubishi Tanabe Pharma Singapore Pte. Ltd., the locally based subsidiary of MTPC, will market as the Marketing Authorization Holder (MHA) cariprazine under the name SYMVENU[®]. In Thailand, Mitsubishi Tanabe Pharma (Thailand) Co., Ltd., will market as the MAH the product under the name REAGILA[®].

While the mechanism of action of cariprazine is unknown, it has been confirmed that cariprazine produces few extrapyramidal adverse reactions such as parkinsonian symptoms (tremors in the limbs, muscle stiffness, and/or lack of calmness), and has improving effects on negative symptoms such as lowered motivation and blunted and/or flat affect.

Schizophrenia is a mental disorder, causes have not yet been accurately identified. The symptoms of schizophrenia are broadly classified into three types: positive symptoms (including delusions and hallucinations), negative symptoms, and cognitive dysfunctions (abnormalities in the abilities to concentrate on, memorize, or plan things, or solve problems). Patients differ in terms of the type and level of their symptoms. It is estimated that there are approximately 30,000 patients suffering from schizophrenia in Singapore, and approximately 360,000 in Thailand.

MTPC has been developing cariprazine for the Asian market under the license that its right has been granted by Gedeon Richter Plc. (Budapest, Hungary). This product has already been launched by Gedeon Richter Plc. and its partner in Europe and the U.S.

The symptoms of schizophrenia pose many difficulties for many patients in their everyday lives in Asian countries.

MTPC will strive to provide this product to patients who are forced to experience difficulties in their lives due to schizophrenia, in order to improve their quality of life (QOL).

**Mitsubishi Tanabe Pharma Corporation
Corporate Communications Department**

Media contacts: TEL:+81 6 6205 5119

Investor contacts: TEL:+81 6 6205 5110

■ **About Cariprazine (MP-214)**

Cariprazine is an oral, once daily atypical antipsychotic approved by FDA and EMA for the treatment of schizophrenia in adults (1.5 to 6 mg/day). While the mechanism of action of cariprazine is unknown, the efficacy of cariprazine could be mediated through a combination of partial agonist activity at central dopamine D₂ and serotonin 5-HT_{1A} receptors and antagonist activity at serotonin 5-HT_{2A} receptors. Pharmacodynamic studies with cariprazine have shown that it acts as a partial agonist with high binding affinity at dopamine D₃, dopamine D₂, and serotonin 5-HT_{1A} receptors.

■ **About Mitsubishi Tanabe Pharma Singapore Pte. Ltd.**

Mitsubishi Tanabe Pharma Singapore Pte. Ltd. was founded as a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (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, the company carries out its operations, including development, in order to promptly provide patients in ASEAN countries with our innovative pharmaceutical products that can satisfy local unmet medical needs. Future Symvenu[®] will be promoted by itself.

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

Mitsubishi Tanabe Pharma (Thailand) Co., Ltd. was founded as a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC) in Thailand in 2016. In Thailand, which has one of the largest pharmaceutical market in ASEAN region, the company sells drugs for cardiovascular diseases, such as HERBESSER[®]. Future Reagila[®] will be promoted by itself.