



February 28, 2025
Mitsubishi Tanabe Pharma Corporation

Regulatory Approval of Cariprazine (MP-214)
For Adjunctive therapy for major depressive disorder in Thailand

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura, "MTPC"), a member of the Mitsubishi Chemical Group, announced that Mitsubishi Tanabe Pharma (Thailand) Co., Ltd., which is a consolidated subsidiary of MTPC, has obtained the regulatory approval of cariprazine (generic name; development code: MP-214; dopamine D3/D2 receptor partial agonist; trademark in Thailand: Reagila®) for the treatment of adjunctive therapy to antidepressants for the treatment of major depressive disorder in Thailand on January 31.

Major depressive disorder, commonly referred to as depression, is a mental disorder characterized by a persistently depressed mood and a loss of interest or pleasure in daily activities. Treatment typically involves medications (antidepressants) and psychological treatment.

Adjunctive therapy to antidepressants for the treatment of major depressive disorder refers to a therapy to be performed in addition to antidepressants to improve symptoms when antidepressants alone do not sufficiently work.

MTPC markets this drug for the indications of schizophrenia and bipolar disorder in MTPC's territory* under license from Gedeon Richter Plc., Hungary. For this indication, which was recently approved in Thailand, an application of additional indication is currently under review by the authorities in other countries in the territory.

MTPC will continue to advance research and development so that we can deliver the best pharmaceutical product to patients with unmet need as soon as possible.

* For the treatment of schizophrenia in MTPC's territory, the regulatory approval was obtained in Singapore and Thailand in July 2019, in Malaysia in August 2020, and in Indonesia in July 2021. For the treatment of bipolar disorder, the regulatory approval was obtained in Singapore in January 2022, in Thailand in February 2022, in Malaysia in August 2022 (depression) and June 2023 (mania), and in Indonesia in February 2023.

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■ About cariprazine (MP-214)

MTPC has been developed cariprazine, which is licensed from Gedeon Richter Plc. in Hungary, in some Asian countries. Cariprazine is an oral atypical antipsychotic. While some 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 (Thailand) Co., Ltd.

Mitsubishi Tanabe Pharma (Thailand) Co., Ltd. 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 ASEAN. The company is marketing REMLEAS[®], a treatment for tardive dyskinesia, and Reagila[®], a treatment for schizophrenia and bipolar disorder, in addition to a number of products for lifestyle-related diseases such as HERBESSER[®], TANATRIL[®] and TENELIA[®].