

Mitsubishi received regulatory approval for Cariprazine in part of ASEAN (Singapore and Thailand)

Budapest, Hungary – 08 August 2019 – Gedeon Richter Plc (“Richter”) today announced that Mitsubishi Tanabe Pharma Corporation’s (“MTPC”) subsidiaries in ASEAN obtained the regulatory approval of cariprazine for the treatment of schizophrenia. Current approvals have been granted in Singapore and in Thailand.

Under the terms of the agreement, Richter will be responsible for product supply and MTPC through its subsidiaries will be responsible for the commercialisation of the product in the above markets. Richter is entitled to regulatory related milestone payments and sales related royalties.

“We are pleased with this very recent regulatory development, which by taking cariprazine to ASEAN represents a further step down the road of making cariprazine available worldwide for those who are suffering from schizophrenia” said Mr Gábor Orbán, Chief Executive Officer of Richter.

About Schizophrenia

Schizophrenia is a severe and highly disabling chronic mental illness involving disordered thought and perception. Its characteristic onset in late adolescence / early adulthood is often associated with a marked, lifelong impact on social and role functioning. The prevalence of schizophrenia is about 1% in the general population worldwide.

About cariprazine

Cariprazine is an oral, once daily atypical antipsychotic approved by FDA for the acute treatment of adults with manic or mixed episodes associated with bipolar I disorder (3 to 6 mg/day) and for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults (1.5 or 3 mg/day). Cariprazine is also approved by FDA 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. Cariprazine demonstrated up to ~8-fold greater *in vitro* affinity for dopamine D₃ vs D₂ receptors. Cariprazine also acts as an antagonist at serotonin 5-HT_{2B} and 5-HT_{2A} receptors with high and moderate binding affinity, respectively as well as it binds to the histamine H₁ receptors.

Cariprazine shows lower binding affinity to the serotonin 5-HT_{2C} and α_{1A} -adrenergic receptors and has no appreciable affinity for cholinergic muscarinic receptors. The clinical significance of these *in vitro* data is unknown. Cariprazine was discovered and co-developed by Gedeon Richter Plc and is licensed by Allergan, in the U.S. and in Canada. For more than a decade both companies have conducted over 50 clinical trials enrolling thousands of patients worldwide to evaluate the efficacy and safety of cariprazine for people living with a broad range of mental health illnesses.

Apart from being available in the US for more than 3 years cariprazine is also approved in the EU in schizophrenia indication and has already been marketed in 18 European countries.

About Richter

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China and in Latin America. Having reached a market capitalisation of EUR 3.2 billion (USD 3.6 billion) by the end of 2018, Richter's consolidated sales were approximately EUR 1.4 billion (USD 1.6 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's Healthcare field worldwide. Richter is also active in biosimilar product development.

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