

Richter and Allergan amended their license agreement for the commercialisation of cariprazine to include Latin America

Budapest – 21 June 2019 – Gedeon Richter Plc (“Richter”) today announced the amendment of its existing license agreement with Allergan Plc. (“Allergan”) for cariprazine to include major markets in Latin America (Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Peru and Venezuela).

Under the terms of the amended agreement Allergan will be responsible for the registration of the compound in the newly licensed territories. Allergan will also pay tiered net sales related royalties to Richter.

“We are very pleased to further increase the geographic coverage of cariprazine for schizophrenia, bipolar I disorder and bipolar depression, providing an innovative treatment for patients suffering of such a complex condition as the spectrum disease”, said Gábor Orbán, Chief Executive Officer of Richter.

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 15 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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