

Richter extends existing licensing agreement with AbbVie

Budapest, Hungary – 02 June 2021 – Gedeon Richter Plc. (“Richter”) announces that it extended its existing licensing agreement with AbbVie, originally dated 2004, for the development and commercialization of its own-developed molecule, cariprazine. The initial agreement covered the territories of the USA and Canada and was extended in 2019 to include certain countries in Latin America. The present agreement further expands the geographic scope of the co-operation to include Japan and Taiwan.

Under the terms of the agreement, AbbVie is responsible for development and commercialization of cariprazine for certain neuropsychiatry indications in Japan. Richter is eligible to receive a regulatory related milestone payment, which would be due to Richter upon the approval of marketing authorization in Japan, along with subsequent tiered royalties combined with sales related milestone payments.

About cariprazine

Cariprazine is an orally active and potent dopamine D₃/D₂ receptor partial agonist with preferential binding to D₃ receptors and partial agonist at serotonin 5-HT_{1A} receptors. Cariprazine was discovered by Richter, having been developed for the treatment of schizophrenia and bipolar mania jointly by AbbVie / Allergan (earlier Forest / Actavis) and Richter and was approved by FDA in both indications in 2015. The product is marketed in the USA by AbbVie under the name Vraylar®. In 2019 FDA approved a supplemental New Drug Application (sNDA) for Vraylar® for expanded use to treat depressive episodes associated with bipolar I disorder (bipolar depression) in adults. Vraylar® is currently under development by AbbVie / Richter in the USA as an adjunctive treatment to antidepressant therapy in adults with major depressive disorder (MDD) who failed to adequately respond to antidepressant monotherapy. Cariprazine is also marketed across the EU, other European and CIS countries, certain MENA countries, Singapore, Thailand, Malaysia and Israel under the name Reagila® by Richter or its license partners.

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 capitalization of EUR 3.8 billion (USD 4.5 billion) by the end of 2020, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.8 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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