

European CHMP Issues Positive Opinion for Cariprazine for the Treatment of Schizophrenia

Budapest, Hungary – 19 May 2017 – Gedeon Richter Plc. (“Richter”) announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion on the company’s application for cariprazine, a novel antipsychotic for the treatment of schizophrenia in adult patients. The marketing authorization application has been submitted to EMA in March 2016. Subject to approval by the European Commission, Richter is expected to receive in two months a marketing authorization for cariprazine valid for all European Union Member States.

Cariprazine was discovered by Richter scientists and is licensed to Allergan (earlier Forest / Actavis), in the U.S. and Canada. Following its FDA approval in September 2015, the product was launched in the U.S. in March 2016 under the trademark of VRAYLAR™ for the treatment of both schizophrenia and bipolar mania. In August 2016 Richter and Recordati signed an exclusive license agreement to commercialize cariprazine in Western Europe, in Algeria, in Tunisia and in Turkey.

The European application for the treatment of schizophrenia includes results from three short-term, placebo and partly active controlled positive trials in over 1,800 patients and one long-term trial, using the change from baseline in the scale, assessing the severity of schizophrenia symptoms, i.e. the Positive and Negative Syndrome Scale (PANSS) total score and the time to relapse as primary efficacy endpoints, respectively. A clinical trial with positive results was also carried out in patients suffering from predominant negative symptoms of schizophrenia.

“We are very pleased with the CHMP positive opinion of cariprazine, which is considered as a significant milestone for Richter’s original research programme,” said Erik Bogsch, Managing Director of Gedeon Richter Plc. “Although there are various treatment options available for patients living with schizophrenia, medical needs persist, therefore we remain committed to offer an additional treatment option for patients suffering from this complex condition.”

About Schizophrenia

Schizophrenia is a chronic and disabling disorder that has a worldwide prevalence approaching 1%. It imposes significant burden on patients, their families, and society. Symptoms fall into three broad categories: positive symptoms (hallucinations, delusions, thought disorders, and movement disorders), negative symptoms (such as loss of motivation and social withdrawal), and cognitive symptoms (problems with executive functioning, focusing, and working memory).

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 Allergan (earlier Forest / Actavis) and Richter and was approved by

FDA in both indications in 2015. Ongoing clinical developments of cariprazine are being currently managed by Allergan (earlier Forest / Actavis) and Richter for bipolar depression (BD) and as adjunctive therapy for major depressive disorder (MDD) in the US. Additionally, Mitsubishi-Tanabe Pharma Corporation (MTPC) is developing cariprazine for the treatment of schizophrenia in Japan and in other Asian countries.

About Gedeon Richter Plc.

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 3.7 billion (US\$ 3.9 billion) by the end of 2016, Richter's consolidated sales were approximately EUR 1.3 billion (US\$ 1.4 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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