EMA started the evaluation of Richter's marketing authorisation application for cariprazine for the treatment of schizophrenia

Budapest, **29 March 2016** – Gedeon Richter Plc. ("Richter") today announced that the European Medicines Agency (EMA) has accepted Richter's regulatory submission for cariprazine, a novel antipsychotic for the treatment of schizophrenia in adult patients. 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 has been recently launched in the USA under the trademark of VRAYLAR™ for the treatment of both schizophrenia and bipolar mania.

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 Positive and Negative Syndrome Scale (PANSS) total score and the time to relapse as primary efficacy endpoints. A clinical trial with positive results was also carried out in patients suffering from predominant negative symptoms of schizophrenia.

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 D_3/D_2 receptor partial agonist with preferential binding to D_3 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. Currently it is under development by Richter in the EU for the treatment of schizophrenia and for the treatment of schizophrenia with predominant negative symptoms while ongoing clinical developments of cariprazine are being 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 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. Having reached a market capitalisation of EUR 3.3 billion (US$ 3.6 billion) by the end of 2015, Richter's consolidated sales were approximately EUR 1.2 billion (US$ 1.3 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including gynaecology, 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 female healthcare field worldwide. Richter is also active in biosimilar product development.

For further information:

Investors:	Katalin Ördög	+36 1 431 5680
Media:	Zsuzsa Beke	+36 1 431 4888