

## **Richter and Recordati signed a license agreement for marketing cariprazine in Western Europe**

**Budapest, Hungary – Milan, Italy** - 02 August 2016 – Gedeon Richter Plc. (hereinafter: "Richter") and Recordati today announced the signing of an exclusive license agreement to commercialize cariprazine, a novel atypical antipsychotic in Western Europe and in Algeria, in Tunisia and in Turkey.

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 USA in March 2016 under the trademark of VRAYLAR™ for the treatment of both bipolar mania and schizophrenia. The European Medicines Agency (EMA) started the evaluation of Richter's marketing authorisation application for cariprazine for the treatment of schizophrenia in March 2016.

Under the terms of the agreement Recordati shall make an upfront payment upon signature of the contract, and further milestone payments shall be made depending on the progress of both the regulatory procedure and the commercialization of the product. In addition, further sales related royalties will become payable to Richter following the launch of the product.

In line with the agreement Richter shall be responsible for conducting Pediatric Clinical Studies according to the Pediatric Investigation Plan, as required by the European Medicines Agency's PDCO (Paediatric Committee) and it shall be co-financed with Recordati.

"We are pleased having Recordati as our marketing partner in Western-Europe, given our long standing relationship and their approach of successfully managing the company for many decades. Their experience and well established international sales network are reflected in a proven track record of introducing successfully new products on the markets. This partnership is aligned with Richter's strategy to bring cariprazine to the market for the millions of people living with schizophrenia and are seeking an effective new treatment option", stated Erik Bogsch, Managing Director of Gedeon Richter Plc.

"We are very pleased with the addition of this innovative treatment for schizophrenia to our corporate pipeline", stated Giovanni Recordati, Chairman and CEO. "The central nervous system therapeutic sector represents a further area of growth for the group. We believe that the overall high quality of our sales organization together with specific experience matured in some countries in the area of mental health will enable us to create the necessary awareness in our territories for the adoption of this important new treatment for schizophrenia, a serious invalidating mental 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 D<sub>3</sub>/D<sub>2</sub> receptor partial agonist with preferential binding to D<sub>3</sub> receptors and partial agonist at serotonin 5-HT<sub>1A</sub> receptors. Cariprazine was discovered by Richter, having been developed for the treatment of bipolar mania and schizophrenia 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](http://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.

### **About Recordati**

Recordati, established in 1926, is an international pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of around 4,000, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations in the main European countries, in Russia, in other Central and Eastern European countries, in Turkey, in North Africa and in the United States of America. An efficient field force of medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses for its territories. Recordati is committed to the research and development of new specialties within the urogenital therapeutic area and of treatments for rare diseases. Consolidated revenue for 2015 was EUR 1,047.7 million, operating income was EUR 278.5 million and net income was € 198.8 million.

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