

RECORDATI: THE EUROPEAN COMMISSION APPROVES REAGILA® (CARIPRAZINE) FOR THE TREATMENT OF SCHIZOPHRENIA

Milan, 19 July 2017 – Recordati announces that Gedeon Richter Plc. was granted marketing authorization from the European Commission for Reagila® (cariprazine), a novel antipsychotic for the treatment of schizophrenia in adult patients, valid for all European Union Member States. In August 2016 Richter and Recordati signed an exclusive license agreement to commercialize cariprazine in Western Europe, Algeria, Tunisia and Turkey.

The European application for the treatment of schizophrenia included results from three 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. The high relevance of these results is the base for a publication in *The Lancet* (Cariprazine versus risperidone monotherapy for treatment of predominant negative symptoms in patients with schizophrenia: a randomised, double-blind, controlled trial; *The Lancet* Volume 389, No. 10074, p1103–1113, 18 March 2017).

“We are very pleased with the European Commission’s decision to authorize the marketing of cariprazine, a novel antipsychotic which represents an additional treatment option for patients suffering from schizophrenia, a complex condition for which a medical need for new treatment options persists”, declared Andrea Recordati, Vice Chairman and Chief Executive Officer. “We are extremely pleased to enter the segment dedicated to treatments for central nervous system disorders in which there is a continuing need for new and differentiated therapeutic solutions. Recordati has an established and efficient pan-European sales organization as well as an effective coverage of the pharmaceutical market in Turkey, Tunisia and Algeria and I am confident that Reagila® will quickly be accepted as an important new medication for the management of schizophrenia by the specialized medical community in all territories.”

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 more than 4,100, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations in the main European countries, in Russia, other Central and Eastern European countries, Turkey, North Africa, the United States of America, Canada, Mexico and in some South American countries. 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 with a focus on treatments for rare diseases. Consolidated revenue for 2016 was € 1,153.9 million, operating income was € 327.4 million and net income was € 237.4 million.

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