

## **Gedeon Richter and Actavis Announce FDA Receipt of NDA Resubmission for Cariprazine**

*-- Potential Treatment of Both Schizophrenia and Manic or Mixed Episodes Associated with  
Bipolar I Disorder --*

**BUDAPEST, HUNGARY & DUBLIN, IRELAND — January 6, 2015** — Gedeon Richter Plc. and Actavis plc (NYSE: ACT) today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of Actavis' New Drug Application (NDA) resubmission for its atypical antipsychotic, cariprazine, a potent dopamine D<sub>3</sub>/D<sub>2</sub> receptor partial agonist with preferential binding to D<sub>3</sub> receptors. The Prescription Drug User Fee Act (PDUFA) date is expected to be in the second quarter of 2015.

“We believe the resubmission of the cariprazine NDA includes the necessary data to address FDA’s comments and continue the review of this innovative treatment option,” said David Nicholson, Actavis Senior Vice President, Global Brands R&D. “We are committed to the mental health community and this promising treatment option to address patients’ medical needs.”

“We are pleased that the resubmission procedure occurred according to the originally established timeline,” added Dr. István Greiner, Research Director of Gedeon Richter Plc. “We continue to provide all the necessary clinical and regulatory support to Actavis to bring cariprazine to the market.”

### **About Cariprazine**

Cariprazine, an investigational drug, is an atypical antipsychotic for the treatment of patients with schizophrenia and for patients with manic or mixed episodes associated with bipolar I disorder. The safety and efficacy of cariprazine was studied in a clinical trial program of more than 2,700 patients. In addition, cariprazine is being investigated for the treatment of bipolar depression and as adjunctive treatment for major depressive disorder in adults. Cariprazine is protected by a composition-of-matter patent that expires in 2027.

### **About Schizophrenia**

Schizophrenia is a chronic and disabling disorder that affects more than 2 million people in the U.S. 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 Bipolar I Disorder**

Bipolar disorder, which encompasses bipolar I and bipolar II disorders, affects approximately 5.7 million people in the U.S. Bipolar I disorder, also known as manic-depressive illness, is characterized by unusual shifts in mood, energy, activity levels, and the ability to carry out day-to-day tasks. Patients experience "mood episodes" that manifest as either a manic episode (overexcited, extreme irritability, racing thoughts, and difficulties with sleep) or a depressive episode (extreme sadness, fatigue or hopelessness) or a combination of both.

### **About Actavis**

Actavis plc (NYSE:ACT), headquartered in Dublin, Ireland, is a unique specialty pharmaceutical company focused on developing, manufacturing and commercializing high quality affordable generic and innovative branded pharmaceutical products for patients around the world.

Actavis markets a broad portfolio of branded and generic pharmaceuticals and develops innovative medicines for patients suffering from diseases principally in the central nervous system, gastroenterology, women's health, urology, cardiovascular, respiratory and anti-infective therapeutic categories. The Company is an industry leader in product research and development, with one of the broadest brand development pipelines in the pharmaceutical industry, and a leading position in the submission of generic product applications. Actavis has commercial operations in more than 60 countries and operates more than 30 manufacturing and distribution facilities around the world.

For more information, visit Actavis' website at [www.actavis.com](http://www.actavis.com).

### **Actavis Forward-Looking Statement**

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Actavis' current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Actavis disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Actavis' current expectations depending upon a number of factors affecting Actavis' business. These factors include, among others, the difficulty of predicting the timing or outcome of EMA approvals or actions, if any; the impact of competitive products and

pricing; market acceptance of and continued demand for Actavis' products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Actavis' periodic public filings with the Securities and Exchange Commission, including but not limited to Actavis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. Except as expressly required by law, Actavis disclaims any intent or obligation to update these forward-looking statements.

### **About Gedeon Richter**

Gedeon Richter ([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. Richter's consolidated sales were approximately EUR1.2 billion (US\$1.6 billion) while its market capitalization amounted to EUR2.8 billion (US\$3.8 billion) in 2013. The product portfolio of Richter covers almost all 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.

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