

Richter and Actavis Announce Positive Phase III Results for Cariprazine in the Prevention of Relapse in Patients with Schizophrenia

BUDAPEST, HUNGARY and DUBLIN, IRELAND — January 20, 2015 — Gedeon Richter Plc. and Actavis plc (NYSE: ACT) today announced positive results from a Phase III trial evaluating the efficacy and safety of cariprazine in the prevention of relapse in patients with schizophrenia.

There were 101 patients randomized to cariprazine 3 to 9 mg per day and 99 randomized to placebo. The primary efficacy measure was time to first relapse during the double-blind period. There were 25 relapses (24.8%) in the cariprazine group versus 47 relapses (47.5%) in the placebo group. Treatment with cariprazine was associated with a 55% reduction in risk of relapse versus placebo (hazard ratio 0.45, 95% CI [0.28, 0.73] p=0.0010).

“We are pleased with the long-term efficacy results demonstrated in this trial. Cariprazine has the potential to provide patients suffering with schizophrenia a treatment that can reduce the risk of relapse associated with this serious illness,” said David Nicholson, Actavis Executive Vice President, Global Brands R&D.

“We are encouraged by the positive top line results shown in this study, which are considered as a further milestone in the process of making this promising treatment option available for patients suffering from schizophrenia,” added Dr. István Greiner, Research Director of Gedeon Richter Plc.

About this Phase III Study

This 97 week study was a multi-national, multi-center, randomized, double-blind, placebo-controlled clinical trial in adult patients with schizophrenia. The study included a 20-week open-label phase where patients with schizophrenia were treated with cariprazine 3, 6 or 9 mg per day. Patients who responded and met the stabilization criteria during the open-label period were then randomized to continue their cariprazine dose (3, 6 or 9 mg per day) or switched to placebo for up to 72 weeks or until a relapse occurred. The primary endpoint was time to first symptom relapse during the double blind phase.

In the double-blind phase, there were no cariprazine adverse events $\geq 10\%$. Across the cariprazine treated group, the most common adverse events (incidence $\geq 5\%$ and greater than placebo) were nasopharyngitis, tremor, extrapyramidal disorder, akathisia, back pain, and blood creatine phosphokinase increased.

About Cariprazine

Cariprazine, an investigational drug, is a potent dopamine D₃/D₂ receptor partial agonist atypical antipsychotic with preferential binding to D₃ receptors for the treatment of patients with schizophrenia and for adult 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 adult 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 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.

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

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About Gedeon Richter

Gedeon Richter (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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