Gedeon Richter Plc. and Forest Laboratories, Inc. Announce Positive Phase IIb Topline Results for Cariprazine for the Treatment of Bipolar Depression
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Gedeon Richter Plc. and Forest Laboratories, Inc. (NYSE: FRX) announced positive topline results from a Phase IIb trial evaluating the efficacy and safety of the investigational antipsychotic **cariprazine in patients with bipolar depression.**
The trial consisted of four treatment groups: cariprazine 0.75 mg/day, 1.5 mg/day, 3.0 mg/day, and placebo. Statistically significant improvements were observed in the cariprazine 1.5 mg/day group relative to placebo at 6 weeks for the primary endpoint, the Montgomery-Asberg Depression Rating Scale (MADRS) total score and the key secondary endpoint, the Clinical Global Impressions – Severity (CGI-S) score.

"We are pleased with the positive results of this study. In addition to previously completed Phase III trials in schizophrenia and bipolar mania, we now have positive Phase IIb studies for cariprazine in both bipolar depression and major depressive disorder. Our goal is to continue developing cariprazine for patients with a broad range of psychiatric conditions," said Marco Taglietti, M.D., Executive Vice President of Drug Development and Research at Forest Laboratories, Inc.

"Cariprazine is a critical element to Richter's discovery platform," explained Dr. Zsolt Szombathelyi, Research Director of Gedeon Richter Plc. "We are pleased with the topline results of the Phase IIb trial and are committed to developing an important new treatment option for patients suffering from bipolar depression."

About this Phase IIb Study
This international, randomized, placebo-controlled, fixed-dose, 8-week Phase IIb trial evaluated the efficacy and safety of cariprazine in the treatment of patients with depressive episodes of bipolar I disorder. Eligible patients included those with bipolar depression who met the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) criteria for bipolar I disorder with a current major depressive episode. Patients also had to have a minimum score of 20 on the 17-item Hamilton Depression Rating Scale (HAM-D), a minimum score of 2 on item 1 of the HAM-D, a minimum score of 4 on the CGI-S, and a maximum score of 10 on the Young Mania Rating Scale (YMRS) at both visit 1 and visit 2.

The study consisted of up to 14 days of screening followed by 8 weeks of double-blind treatment, followed by a 1-week safety follow-up period. During the double-blind treatment period, 584 patients 18 – 65 years of age were randomized to one of four treatment groups: cariprazine 0.75 mg/day, 1.5 mg/day, 3.0 mg/day, or placebo. The primary endpoint was change from baseline in the MADRS total score versus placebo at 6 weeks, using a mixed-effects model for repeated measures (MMRM) analysis. The group who received cariprazine 1.5 mg/day demonstrated statistically significant improvement in the MADRS total score versus placebo at week 6 (cariprazine 0.75 mg/day: -1.9, p=0.1292; cariprazine 1.5 mg/day: -4.0, p=0.0030; cariprazine 3.0 mg/day: -2.5, p=0.1122).

The key secondary endpoint was change from baseline in CGI-S total score versus placebo at 6 weeks, using an MMRM analysis. The group who received cariprazine 1.5 mg/day demonstrated statistically significant improvement in the CGI-S score versus placebo (cariprazine 0.75 mg/day: -0.1, p=0.3025; cariprazine 1.5 mg/day: -0.4, p=0.0132; cariprazine 3.0 mg/day: -0.3, p=0.1122).

Across all cariprazine doses, the most common adverse events (incidence ≥10% and greater than placebo) were akathisia and insomnia.

About Cariprazine

Cariprazine, an investigational drug, is an orally active, potent dopamine D3-preferring D3/D2 receptor partial agonist atypical antipsychotic. It has a low affinity at other receptor sites such as 5-HT2C, muscarinic, and adrenergic receptor sites. Cariprazine is protected by a composition-of-matter patent that expires in 2027 without patent term extension.

Cariprazine is being developed for the treatment of schizophrenia and bipolar mania in adults. On November 21, 2013 the companies announced that the U.S. Food and Drug Administration issued a complete response letter regarding the new drug application for schizophrenia and bipolar mania. In addition, cariprazine is being investigated for the treatment of bipolar depression and as adjunctive treatment for major depressive disorder in adults.

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. Depression that occurs in patients with bipolar disorder is called "bipolar depression."

About Forest Laboratories

Forest Laboratories (NYSE: FRX) is a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. The Company markets a portfolio of branded drug products and develops new medicines to treat patients suffering from diseases principally in the following therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, anti-infective, and cystic fibrosis. Our strategy of acquiring product rights for development and commercialization through licensing, collaborative partnerships, and targeted mergers and acquisitions allows us to take advantage of attractive late-stage development and commercial opportunities, thereby managing the risks inherent in drug development. The Company is headquartered in New York, NY. To learn more, visit www.FRX.com.

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements Involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. Forest assumes no obligation to update forward-looking statements contained in this release to reflect new information or future events or developments.

About Gedeon Richter Plc.

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. Richter's consolidated sales were approximately EUR 1.2 billion (USD 1.6 billion) while its market capitalization amounted to EUR 2.8 billion (USD 3.8 billion) in 2013. The product portfolio of the Company covers almost all important therapeutic areas, including gynecology, central nervous system, and cardiovascular. Having the largest R&D unit in Central Eastern Europe, the Company'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 the scope of biosimilar product development.

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