Bayer



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Investor News

Development of riociguat is progressing well:

Bayer Schering Pharma Starts Phase III Program of New Drug Against Pulmonary Hypertension

Leverkusen, February 9, 2009 – Based on the positive findings from the clinical development phase II trial, Bayer Schering Pharma has begun a phase III program with its oral agent riociguat. Two phase III trials will investigate the application in patients with both chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH). Riociguat is the first member of a new class of therapeutics stimulating the enzyme soluble guanylate cyclase (sGC). Riociguat showed promising phase II results by significantly improving exercise capacity and hemodynamic parameters, such as pulmonary vascular resistance, cardiac output and pulmonary arterial pressure, compared to baseline values.

“Chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension are life-threatening diseases. The currently available treatments are approved only for pulmonary arterial hypertension, and the median survival time for treated patients is still very limited,” said Prof. Hossein Ardeschir Ghofrani, Head of the Pulmonary Hypertension Division, Department of Internal Medicine, University Hospital Giessen and Marburg, Germany. “We are very encouraged by the positive phase II findings with riociguat which, if replicated in phase III trials, will be an exciting breakthrough for patients with pulmonary hypertension and the physicians who treat them.”

The two studies – CHEST-1 (Chronic Thromboembolic Pulmonary Hypertension sGC Stimulator Trial) and PATENT-1 (Pulmonary Arterial Hypertension sGC Stimulator Trial) – will investigate the efficacy and safety of riociguat in patients with CTEPH or PAH. Over 700 patients will be recruited for the two studies.
The first data from the clinical phase II trial were presented at the Annual Congress of the European Respiratory Society (ERS) in Berlin, Germany, on October 6, 2008.

Further data from the phase II study are to be presented at the American Thoracic Society (ATS) International Conference in May 2009, in San Diego, California, USA.

“Cardiology forms one of the focus areas for Bayer’s drug discovery activities. Riociguat is one of the most promising product candidates we are developing in this field,” said Dr. Frank Misselwitz, Head of Global Clinical Development for cardiovascular diseases at Bayer Schering Pharma. “Riociguat has the potential to overcome the disadvantages of current standard therapies. With the two trials – CHEST-1 and PATENT-1 – we are stepping up our commitment, particularly in indications where a high unmet medical need still exists.”

Pulmonary hypertension affects more than 2.5 million people worldwide – and there are limited treatment options available for the majority of them.

About the CHEST-1 and PATENT-1 phase III trials
CHEST-1 is a phase III multi-center, double-blind, randomized, placebo-controlled trial in patients with inoperable chronic thromboembolic pulmonary hypertension. The trial will involve 270 patients who will be randomized to receive either riociguat or placebo for 16 weeks. The treatment success will be measured as the change from baseline in patients’ exercise capacity, using the six-minute walking distance test. This standard test has been used as a primary endpoint in previous pivotal clinical studies in patients with pulmonary hypertension. After the 16-week treatment in CHEST-1, all patients will have the opportunity to participate in an open-label, long-term study (CHEST-2) during which longer-duration safety and efficacy aspects will be assessed.

PATENT-1 is a phase III multi-center, double-blind, randomized, placebo-controlled trial in patients with pulmonary arterial hypertension who are either treatment-naïve or are being treated with an endothelin receptor antagonist or a prostacyclin analog. The trial will involve 460 patients who will be randomized to receive either riociguat or placebo. The primary endpoint will be the change from baseline in the six-minute walking distance test after 12 weeks of treatment with riociguat compared to the change in the placebo group. After this study, all patients will have the opportunity to participate in an open-label, long-term study (PATENT-2) during which longer-duration safety and efficacy aspects will be assessed.

First results from CHEST-1 and PATENT-1 are currently expected in 2011.

About Pulmonary Hypertension
Pulmonary hypertension (PH) involves an increase in blood pressure in the pulmonary artery, pulmonary vein, or pulmonary capillaries, leading to shortness of breath, dizziness, fainting and other symptoms, all of which are worsened by exertion. PH is a severe disease often marked by significantly restricted exercise tolerance which can lead to heart failure and death.

The World Health Organization (WHO) distinguishes five main categories of PH: pulmonary arterial hypertension (PAH); chronic thromboembolic pulmonary hypertension (CTEPH); PH with left ventricular disease (PH-LVD); PH with lung disease and/or hypoxemia, which include PH with chronic obstructive pulmonary disease (PH-COPD) and PH with interstitial lung disease (PH-ILD); the fifth category contains miscellaneous indications not included in the aforementioned groups. The different categories of PH have different underlying causes and may therefore need to be treated differently. Unfortunately, the only approved therapies currently available are for PAH, which comprises only a small proportion of PH cases. With current therapy, the median survival time for a patient with PAH is five to six years after diagnosis, underscoring the need for new treatments.

About Riociguat
Riociguat is a member of a novel class of therapeutics called soluble guanylate cyclase (sGC) stimulators. It is one of the most advanced development projects in the Bayer cardiology pipeline. Riociguat works through the same signaling pathway as the body's own vasodilating substance, nitric oxide (NO). NO relaxes the musculature in the blood-vessel walls, lowers the pulmonary blood pressure, and relieves the heart by modulating the activity of the soluble guanylate cyclase (sGC) enzyme. Riociguat has a dual mode of action: on the one hand it sensitizes the enzyme to endogenous NO, thus exerting a strong synergism; on the other hand, it is capable of directly stimulating sGC independently of NO. Directly stimulating sGC may avoid shortcomings of other therapeutics targeting the NO pathway, such as phosphodiesterase-5 (PDE-5) inhibitors. Riociguat is currently undergoing trials as a new approach to treating various forms of pulmonary hypertension.

About Bayer Schering Pharma
The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global

activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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