Bayer

Investor News

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Bayer to Discontinue Phase II Clinical Trial for Long-Acting Recombinant Factor VIII Following Interim Analysis

- Study will not be able to meet primary endpoint
- Bayer remains committed to developing its long-acting recombinant factor VIII compounds; alternative candidates in development

Leverkusen, January 25, 2010 – Bayer Schering Pharma AG, Germany has announced that an independent Data Safety and Monitoring Board (DSMB) has completed an interim analysis of a phase II trial (the LIPLONG study) of the company's long-acting recombinant factor VIII, BAY79-4980. The DSMB concluded that the study will not be able to achieve the predetermined efficacy endpoint (non-inferiority). No safety concerns were raised. As a result of the DSMB findings and recommendation, Bayer has decided to discontinue the study.

LIPLONG is a randomized, double-blind active comparator controlled study designed to demonstrate the non-inferiority of BAY79-4980 infused in hemophilia A patients once a week as compared with Kogenate® FS, antihemophilic factor (recombinant), which is infused three times per week.

"While we are disappointed with the outcome of the analysis, we remain committed to developing our long-acting recombinant factor VIII compounds," said Kemal Malik, M.D., member of the Board of Management of Bayer Schering Pharma AG and Head of Global Development. "It is our goal to enable once weekly prophylaxis dosing as well as other factor therapies, such as BAY VII, a modified recombinant factor VII therapy for hemophilia A and B in patients with inhibitors." Further analyses of the LIPLONG data will be carried out over the next months.

Furthermore, Bayer has sought scientific advice from regulatory agencies for the clinical development of a directly PEGylated recombinant factor VIII molecule, which in preclinical models has a doubled half-life. Proof of concept trials in humans are scheduled to start in

late 2010. The company's current projects in hemophilia also include the development of an improved full-length FVIII molecule.

About Hemophilia A

Hemophilia A, also known as factor VIII deficiency or classic hemophilia, is largely an inherited bleeding disorder in which one of the proteins needed to form blood clots in the body is missing or reduced. Hemophilia A, the most common type of hemophilia, is caused by deficient or defective blood coagulation proteins, known as factor VIII. Hemophilia A is characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. Approximately 400,000 people around the world have hemophilia.

About Bayer

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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. 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.

About Bayer Schering Pharma

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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