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Investor News

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Bayer Receives Positive CHMP Opinion for BAY 81-8973 for the Treatment of Hemophilia A in Patients in EU

Leverkusen, Germany, December 18, 2015 – The European Committee for Medicinal Products for Human Use (CHMP) has recommended BAY 81-8973, Bayer's new recombinant factor VIII compound, for approval in the EU for the treatment and prophylaxis of bleeding in patients with hemophilia A for all age groups. BAY 81-8973 is an unmodified full-length recombinant factor VIII compound that, in clinicals trials, has demonstrated control of bleeds and protection from bleeds in hemophilia A patients when used prophylactically two or three times per week.

The final decision of the European Commission on the marketing authorization is expected in the coming weeks. Hemophilia affects approximately 400,000 people around the world and is characterized by prolonged or spontaneous bleeding, especially into the muscles, joints or internal organs.

"Bayer is highly committed to the hemophilia community, exemplified best by our latest development BAY 81-8973, as well as by our long-acting recombinant factor VIII pipeline candidate BAY 94-9027", said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "In addition, we are also pursuing different early stage treatment approaches in hemophilia including an anti-TFPI-antibody."

The positive CHMP recommendation is based on results from the LEOPOLD (Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease) clinical trials, which evaluated BAY 81-8973 in children, adolescents and adults using both, prophylaxis dosing regimens and on-demand treatment.

Bayer has submitted marketing applications for BAY 81-8973 in the US and several other countries and is pursuing regulatory approvals worldwide.

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. Hematology at Bayer includes an approved treatment for hemophilia A and numerous compounds in various stages of development for hemophilia, sickle cell anemia, and other blood and bleeding disorders. Together, these compounds reflect the company's commitment to research and development for these indications, prioritizing specific targets for intervention with the potential to improve the way that rare blood and bleeding disorders are treated.

About LEOPOLD

The LEOPOLD Clinical Development Program consists of three multinational clinical trials designed to evaluate the pharmacokinetics, efficacy, and safety of BAY 81-8973 in subjects with severe hemophilia A (<1% FVIII:C).

LEOPOLD I is an open-label, cross-over Phase III study in males aged 12-65 years. The objectives were to demonstrate the efficacy and safety of BAY 81-8973 when used as prophylaxis, for the treatment of bleeding episodes, and for maintaining hemostasis during surgery. In LEOPOLD I, investigators assigned subjects to either the two- or three-times-weekly dosing regimens based on each patient's phenotype, prior bleeding history and other factors.

LEOPOLD II is a randomized, cross-over, open-label trial also in male subjects aged 12 to 65 years. In this Phase III study, 80 subjects were randomized to receive BAY 81-8973 either as a low-dose prophylaxis regimen (20-30 IU/kg; n=28) twice-per-week, high-dose prophylaxis (30-40 IU/kg; n=31) three-times-per-week, or on-demand (n=21). The primary objective was to demonstrate the superiority of prophylaxis versus on-demand therapy, with the primary endpoint being bleeding frequency at 12 months.

LEOPOLD Kids is an open-label, non-randomized Phase III study. Part A is designed to evaluate the efficacy and safety of BAY 81-8973 for prophylaxis, treatment of bleeds, and surgical management in previously treated children <=12 years of age with twice or three times per week or every other day prophylaxis regimens. Part B of the study, which involves previously untreated patients (PUPs), is ongoing.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care and agriculture. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), 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. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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