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Investor News

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Bayer Submits an Application for Market Authorization of Recombinant Factor VIII Product as a Treatment of Hemophilia A in Japan

Leverkusen, Germany, June 30, 2015 – Bayer HealthCare today announced that Bayer Yakuhin, Ltd., Osaka, Japan, has submitted an application for marketing authorization for BAY 81-8973, a recombinant Factor VIII (rFVIII) compound, as a treatment of hemophilia A. BAY 81-8973 is a full-length recombinant factor VIII which has shown clinical benefit of efficacy when used for prophylaxis twice or three times per week, with standard dosages.

“With more than two decades of experience in Japan, Bayer has a strong commitment to the hemophilia community”, said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The submission of BAY 81-8973 in Japan is an important step forward in our continued efforts to improve treatment options for people with hemophilia A.”

The submission was based on positive results from three Phase III trials in children, adolescents and adults including a total of 204 subjects. The LEOPOLD II clinical trial demonstrated the superiority of prophylaxis versus on-demand therapy with BAY 81-8973. Results show a 93.3 percent reduction in median annualized bleeding rate (ABR) in the twice-per-week prophylaxis arm versus on-demand and a 96.7 percent reduction in the three-times-per-week arm versus on-demand. Patients in this study were randomized between the three treatment arms. The actual median ABRs observed were four bleeds when treated two times per week and two bleeds when treated three times versus 60 in the on-demand group. Patients treated in both the twice-per-week arm and the three-times-per-week arm maintained adequate bleeding control while using 20 to 40 IU/KG. When used on-demand, 95 percent of bleeds were controlled with one or two infusions. No clinically relevant treatment-related adverse events occurred and no inhibitor formation was observed. In LEOPOLD Kids (pediatric trial) including 51 pre-treated children <12 years of age, BAY 81-8973 demonstrated good efficacy with twice or

three times per week or every other day prophylaxis regimens, and no inhibitors were observed. A clinical study in previously untreated patients is ongoing. Bayer presented the LEOPOLD II results at the World Federation of Hemophilia (WFH) Congress in May 2014.

About LEOPOLD

The LEOPOLD (Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease) Clinical Development Program consists of 3 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 a randomized, 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. 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 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.

About Hemophilia A

Hemophilia A, also known as factor VIII deficiency or classic hemophilia is a largely inherited bleeding disorder. 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.

About Hematology at Bayer HealthCare

Bayer HealthCare is committed to delivering *Science For A Better Life* by advancing a portfolio of innovative treatments. Hematology at Bayer HealthCare 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 Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. 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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