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Investor News

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Bayer Submits Application for U.S. FDA Approval for Recombinant Factor VIII Product (BAY 81-8973) for the Treatment of Hemophilia A in Adults and Children

Leverkusen, Germany, December 17, 2014 – Bayer HealthCare today announced that it has filed a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval for BAY 81-8973, a recombinant Factor VIII (rFVIII) compound, for the treatment of hemophilia A in adults and children. BAY 81-8973 is a full-length recombinant factor VIII which has demonstrated clinical evidence of efficacy when used in standard dosage for prophylaxis two times or three times per week. The submission follows Bayer's recent application to the European Medicines Agency (EMA) for approval of the same indication in the European Union. Bayer plans to submit BAY 81-8973 for approval in other countries in the coming weeks and months.

"Data from our comprehensive clinical program LEOPOLD suggest that BAY 81-8973 could become an important new treatment option for people with hemophilia A", said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We are committed to improve the lives of people with hemophilia A, and will continue to invest in research and development for innovative treatments."

The submission was based on positive results from three Phase III trials in adults, adolescents and children 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 two-times-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 across 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 two-times-per-week arm and the three-times-per-week arm maintained adequate bleed control while using 20 to

40 IU/KG. When used on-demand, 95 percent of bleeds were controlled with one or two infusions. Overall no clinically relevant treatment-related adverse events occurred and no inhibitor formation was observed. In the pediatric trial including 51 pre-treated children <12 years of age, BAY 81-8973 demonstrated good efficacy with two or three times per week or every other day prophylaxis regimens, and no inhibitors were observed. A further clinical study in previously untreated patients is ongoing. Bayer presented the LEOPOLD II results at the World Federation of Hemophilia (WFH) 2014 World 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, crossover 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) two-times-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 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.

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 EUR 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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