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Investor News

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Bayer Initiates Phase III Trial of New Recombinant Factor VIII Compound for Treatment of Hemophilia

BAY94-9027 Being Investigated for Prolonged Duration of Effect and Less Frequent Infusions

Leverkusen, Germany, July 8, 2012 – Bayer HealthCare today announced the company has started to enroll patients in an international Phase III trial to evaluate its investigational compound BAY94-9027 for the treatment of hemophilia A. The PROTECT VIII (PROphylaxis in hemophilia A patienTs via directly pEgylated long-aCTing rFVIII) trial is designed to investigate whether BAY94-9027, a recombinant human factor VIII (rFVIII), can prolong the duration of protection from bleeds and with less frequent Infusions when used prophylactically, while also having the ability to treat acute bleeding events.

BAY94-9027 has been engineered to extend the circulating half-life of rFVIII while preserving full biologic activity by inserting a single cysteine (amino acid) site to its surface, which serves as an attachment site for a polyethylene glycol (PEG) polymer.

“Bayer has more than 20 years of research and clinical experience in hemophilia, and continues to invest in innovative ways to advance patient care, such as the development of BAY94-9027,” said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “A longer-acting rFVIII product may result in significant benefit in long-term outcomes and quality of life improvements for people with hemophilia A.”

About the Phase III Study

PROTECT VIII is a multicenter, multinational, partially randomized, open-label trial evaluating the safety and efficacy of BAY94-9027 with different dosing frequencies in both prophylactic and on-demand treatment of bleeding in adults and adolescents with

severe hemophilia A. The study will enroll 120 to 140 previously treated subjects (PTP) worldwide.

About Hemophilia A

Hemophilia A, also known as factor VIII deficiency or classical 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.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), 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 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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