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Investor News

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Bayer's Long-Acting Recombinant Factor VIII Demonstrated Effective Prophylaxis with Less Frequent Infusions in Hemophilia A in Phase III Trial

- In the PROTECT VIII study, BAY94-9027 met its primary efficacy and safety objectives for the treatment of patients with hemophilia A
- Extending infusion intervals up to seven days resulted in protection from bleeds comparable to current prophylactic dose regimens
- No patient developed inhibitors to factor VIII during the 36-week treatment period

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Leverkusen, Germany, February 18, 2014 – Bayer HealthCare today announced positive results from the PROTECT VIII trial evaluating the company's investigational site-specific PEGylated recombinant human factor VIII compound BAY94-9027. The study met its primary objective of protection from bleeds with fewer infusions. In the study, the site-specific PEGylated factor VIII provided protection from bleeds when used prophylactically every seven days, every five days, and twice per week. The compound was also effective for treatment of acute and breakthrough bleeds with 91 percent of events resolved with one or two infusions.

"These results are very encouraging," said Jerry Powell, MD and Director of the Hemophilia Treatment Center at the University of California Davis. "We have found that this investigational site-specific PEGylated factor VIII could protect users from bleeds associated with hemophilia A, even when used every seven days. This is a significant advantage over the current standard of care, which requires infusion every two to three days."

"We are pleased that Bayer's site-specific PEGylated factor VIII has been shown to provide longer-lasting protection from bleeds. Reducing the significant burden associated with frequent infusions has long been a key goal of the entire hemophilia community," said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head

of Global Development. “This compound may lead to improvements in long-term outcomes and quality of life for people with hemophilia A.”

The current standard treatment for severe hemophilia A is regularly scheduled prophylactic infusion of factor VIII to keep levels high enough to prevent bleeding. Due to the short half-life of currently marketed factor VIII products, prophylaxis may require treatment as often as every other day. Bayer’s compound is engineered to extend the circulating half-life while preserving full biologic activity through site-specific pegylation. This site-specific pegylation is achieved by inserting a single cysteine (amino acid) on the factor VIII surface, which serves as an attachment site for a polyethylene glycol (PEG) polymer.

Detailed data are scheduled for presentation at the World Federation of Hemophilia Meeting in May 2014 in Melbourne, Australia. Bayer plans to submit marketing authorization applications to regulatory authorities in the U.S., Europe and other countries in the second half of 2015. Evaluation of safety and efficacy during major surgery and PROTECT Kids in pediatric patients are ongoing, and a study in previously untreated patients is planned.

About the PROTECT VIII study and results
PROTECT VIII (PROphylaxis in hemophilia A patienTs via directly pEgylated long-aCTing rFVIII) is a multicenter, multinational, partially randomized, open-label trial with four treatment arms evaluating the safety and efficacy of the site-specific PEGylated factor VIII in previously treated adults and adolescents with severe hemophilia A. 134 subjects were treated in the study. Subjects selected either on-demand or prophylactic treatment upon enrollment. All subjects in the three prophylaxis arms began treatment with the site-specific PEGylated recombinant human factor VIII twice per week. After a ten-week period subjects experiencing more than one bleed during this assessment period stayed on two infusions per week at a higher dose and all other subjects were randomized to either every five- or seven-day treatment for six months. After randomization, subjects who assessed their bleeding control as not adequate could leave the assigned treatment regimen and increase their infusion frequency.

88 percent of subjects met the pre-defined criterion of bleeding control in the ten-week initial assessment period and qualified for randomization. All subjects receiving infusion every five days (n=43) remained in this treatment arm. 44 percent of subjects in the every-five-day treatment arm experienced no bleeds. A median annualized bleeding rate

(ABR) of 1.9 was observed in this treatment arm. 74 percent of the subjects receiving infusion every seven days (n=43) remained in their treatment arm. 37 percent experienced no bleeds. A median ABR of 3.9 (including non-completers) was observed in this treatment arm. The 13 subjects who remained in the two times per week treatment arm, because of their high bleeding rate during the assessment period, reduced their median ABR from 17.4 to 4.1 following dose increase. By comparison, subjects who were treated on-demand (n=20) had a median ABR of 23.

The safety objectives were also met. The site-specific PEGylated factor VIII was well tolerated. Subjects were treated for up to 36 weeks; no inhibitors to factor VIII were confirmed. Two drug-related cases of hypersensitivity reactions were reported. One was assessed as serious, but resolved without medical intervention. No other serious drug-related adverse events were reported.

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 a deficient or defective blood coagulation protein, 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, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.6 billion (2012), 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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