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Investor News

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Bayer submits marketing authorization application for BAY94-9027 for the treatment of Hemophilia A in the EU

Pivotal studies with BAY94-9027 showed that bleed protection was achieved with extended dosing intervals

Leverkusen, Germany, September 7, 2017 – Bayer AG has submitted an application for marketing authorization for its long-acting site-specifically PEGylated recombinant human Factor VIII (BAY94-9027) for the treatment of Hemophilia A to the European Medicines Agency (EMA). The regulatory submission is essentially based on the results from the PROTECT VIII trial. In that trial, BAY94-9027 showed protection from bleeds with dosing intervals when used prophylactically once every seven days, once every five days, and twice per week. Bayer has submitted a BLA ('Biologics License Application') for BAY94-9027 in this indication to the US Food and Drug Administration (FDA) in August 2017.

"The number of patients suffering from hemophilia A on a worldwide basis continues to increase, and with it the need for new treatment options with additional benefits for patients who decided to have a more active lifestyle," said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. "With this filing we hope to make a significant contribution towards alleviating the impact of this disease in the future."

In the PROTECT VIII study, BAY94-9027 provided good protection from bleeds when used prophylactically once every seven days, once every five days, and twice per week. BAY94-9027 was also effective for control of bleeding during surgical procedures, and treatment of all bleeds, with the vast majority of events being resolved with one or two infusions.

The standard-of-care for hemophilia A is factor VIII replacement therapy, which needs to be regularly infused into the patient's vein to maintain factor levels high enough to prevent

bleeding into joints, muscles or organs. Due to the short half-life of most currently marketed factor VIII products, prophylaxis may require treatment as often as every other day or three times per week. BAY94-9027 is engineered to prolong activity in the body while preserving full coagulation activity through PEGylation, where a PEG (Polyethylenglycol) molecule is attached to the factor VIII protein at a specific site. PEGylation technology is utilized to prolong the time of drug circulation in the blood.

About Hemophilia A

Hemophilia affects approximately 400,000 people around the world and is a largely inherited disorder in which one of the proteins needed to form blood clots is missing or reduced. In Hemophilia A, the most common type of hemophilia, blood clotting is impaired as a result of a lack or defect of coagulation factor VIII (FVIII). Patients therefore repeatedly experience bleeds in muscles, joints or other tissues, which can result in chronic joint damage. External injuries, even if they are trivial, can have serious consequences if not treated appropriately, as the blood clots more slowly than in healthy individuals. Hemophilia A has an estimated frequency of 1 in 5,000 male live births, affecting approximately 30,000 in Europe, and 14,000 in the U.S. today.

Hemophilia treatment has advanced considerably over the past decades with life expectancy for people with hemophilia significantly increasing from about 11.4 years in 1920 to a potentially normal life span today. Today's research aims to reduce burden of treatment and improve the quality of life of people with hemophilia.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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