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Investor News

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Bayer receives EU approval for its hemophilia A treatment Jivi®

- The safety and efficacy profile of Jivi has been demonstrated in more than five years of clinical studies
- Prophylaxis with Jivi enables sustained factor VIII concentrations in the blood over time

Leverkusen, Germany, November 27, 2018 – Bayer announced today that Jivi® (BAY94-9027) has been approved by the European Commission for the treatment and prophylaxis of bleeding in previously treated patients 12 years of age or older with hemophilia A. The recommended prophylactic regimen for Jivi is every five days or, based on patient clinical characteristics, can also be every 7 days or twice weekly. The approval is based on results from the PROTECT VIII trial.

“Infusion frequency is a major challenge for people with hemophilia A and we believe with Jivi we can address those needs without compromising good bleed protection,” said Dr. Elena Santagostino, Director of the Hemophilia Unit for adult and paediatric patients with inherited bleeding disorders at the Angelo Bianchi Bonomi Hemophilia and Thrombosis Centre of the Cà Granda Foundation, Maggiore Hospital Policlinico of Milan, Italy. “With the opportunity to offer a treatment with sustained levels of FVIII for a longer period in the blood and thus provide good bleed protection, patients and family members can feel confident that they or their loved one is well protected from bleeds and can spend more time enjoying a wider range of activities together.”

This is a major approval for Jivi this year following that from the FDA and the more recent approval received in Japan. Jivi is the third hemophilia A treatment in Bayer’s hemophilia portfolio.

About Jivi® (BAY94-9027)

Jivi is a recombinant Factor VIII (rFVIII) replacement therapy, meaning it replaces the reduced or missing FVIII in adults and adolescents 12 years of age or older with hemophilia A. As a site-specifically PEGylated rFVIII, it achieves sustained high-levels of FVIII. FVIII replacement therapy is the standard of care to stop or prevent bleeding and has proven efficacy and safety established over decades of clinical trials and real-world experiences.

About PROTECT VIII study

The EU approval is based on the results of the pivotal PROTECT VIII trial comprised of prophylactic dosing, on-demand treatment, and perioperative management in previously treated adults and adolescents 12 years of age or older with severe hemophilia A.

The study demonstrated that 74 percent of participants who were treated once weekly with BAY94-9027, and all (100 percent) participants who were treated every five days achieved good bleed protection. The patients who stayed on the once weekly regimen in the study had a median annualized bleed rate (ABR) of 0.96; half of them experienced 0 bleeds. Treatment with BAY94-9027 was generally well tolerated both prophylactically and on-demand.

A good safety and efficacy profile has been maintained during more than 5 years of experience during the PROTECT VIII and extension studies. In the PROTECT VIII extension trial, the overall ABR for patients was reduced in comparison to the PROTECT VIII main trial. No patient developed inhibitors and no safety issues were identified.

About Bayer in Hemophilia

Bayer is driven by helping people with hemophilia thrive. We have a deep understanding of the evolving needs and aspirations of people with hemophilia, established over 25 years of partnering with the hemophilia community. FVIII replacement therapy is the standard of care to stop or prevent bleeding. Bayer’s portfolio of FVIII treatments offers people with hemophilia A across all stages of life a treatment to suit their individual needs and lifestyles. We work together with researchers, healthcare professionals and patient groups to build a strong community and help people with hemophilia to live fulfilling lives. Bayer is passionate about spearheading research and investing in developing the next generation of therapies and solutions to help people with hemophilia thrive in the future.

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. Hemophilia A is the most common type of hemophilia, in which blood clotting is impaired because there is a lack or defect of coagulation FVIII. Patients repeatedly experience bleeds in muscles, joints or other tissues, which can result in chronic joint damage over time. Injuries can have severe consequences if not treated appropriately, as the blood clots more slowly in hemophilia patients than in healthy individuals. Hemophilia A has an estimated frequency of 1 in 5,000 male live births, affecting people worldwide. For example, there are approximately 6,000 people with the condition in France, 3,500 in Germany, and 13,000 in the U.S. today.

About Bayer

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 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

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