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Investor News

Not intended for U.S. and UK Media

Bayer's Jivi® approved in Japan for hemophilia A

Leverkusen, September 21, 2018 – Bayer announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Jivi® (BAY94-9027) for the prophylactic treatment of hemophilia A for adults and adolescents 12 years of age or older in Japan. The recommended usual dose for prophylactic regimens is twice weekly. Jivi can also be dosed once every 5 days or once a week in accordance with the patient' conditions. Jivi is also approved for on-demand treatment and perioperative management of surgeries. Jivi is a site-specifically PEGylated recombinant Factor VIII (rFVIII) that delivers higher sustained levels of FVIII, which extends the blood's ability to coagulate for longer.

"Nowadays, people with hemophilia can lead their daily lives with less worry thanks to factor VIII replacement therapies," said Dr.Teruhisa Fujii, director of the Blood Transfusion Division at the Hiroshima University Hospital. "The approval of Jivi allows certain patients with hemophilia A to preserve coagulation factor levels to prevent bleeding with just one infusion per week. This represents an important improvement, allowing patients more flexibility in their lifestyles."

"The MHLW approval makes Jivi available to patients with hemophilia A in Japan with an option for once weekly dosing dependent on patients' individual needs. Jivi can be dosed flexibly based on their previous bleed episodes, whilst maintaining protection from bleeds across all approved regimens," said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. "Therefore, this approval is an important step forward for people with hemophilia A in Japan. This is the second major approval for Jivi this year following FDA approval in the U.S. in August."

About Jivi®

Jivi® (BAY94-9027) was engineered to have an extended half-life by harnessing proven PEG-technology that delivers higher sustained levels of FVIII, which could extend the blood's ability to coagulate for longer.

Jivi is an rFVIII replacement therapy, meaning it replaces the reduced or missing FVIII in adults and adolescents 12 years of age or older with hemophilia A. 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 approval of Jivi in Japan is supported by the results of the pivotal Phase 2/3 PROTECT VIII trial where Jivi showed protection from bleeds with dosing intervals when used prophylactically twice per week, once every five days, and once a week in previously treated adults and adolescents 12 years of age or older with severe hemophilia A. Jivi is also approved for on-demand treatment and the perioperative management of bleeding in the same population.

The trial demonstrated that 74 per cent of people with hemophilia A participating in the trial and randomized to treatment of BAY94-9027 once weekly and all (100 per cent) participants receiving treatment once every five days achieved good bleed protection. The patients who maintained on the once weekly regimen in the study had a median annualised 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.

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 treatments are 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 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 5,000 people with the condition in Japan, 6,000 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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