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News Release

Not intended for U.S. and UK Media

Bayer receives US approval for modern hemophilia A treatment Jivi® with a step-wise prophylaxis dosing regimen

- Jivi's extended half-life allows for twice-weekly initial dosing
- May be adjusted to every five days and further individually adjusted to less or more frequent dosing

Berlin, August 30, 2018 – Bayer announced today that the United States (U.S.) Food and Drug Administration (FDA) has approved Jivi® (BAY94-9027) for the routine prophylactic treatment of hemophilia A in previously treated adults and adolescents 12 years of age or older in the U.S. The recommended initial prophylactic regimen for Jivi is twice weekly, with the ability to dose every five days and further individually adjust to less or more frequent dosing based on bleeding episodes. The FDA also approved Jivi for on-demand treatment and the perioperative management of bleeding in the same population. This approval is based on results from the Phase 2/3 PROTECT VIII trial. Jivi is the third FDA-approved hemophilia A treatment in Bayer's hemophilia portfolio.

"As a physician who treats hemophilia A patients with a range of individualized needs, Jivi's approved dosing allows me to adjust frequency based on their bleed episodes to maintain protection from bleeds, which is a serious concern among patients," said Mark Reding, M.D., PROTECT VIII Lead Investigator and Associate Professor of Medicine at the University of Minnesota. "Jivi is a welcome option that addresses a growing patient need to integrate treatment with personal lifestyles."

"Jivi is a uniquely designed recombinant Factor VIII product approved in the U.S. for adults and adolescents that offers proven efficacy with the potential for reduced infusion frequency," said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. "Therefore, the FDA approval is an important step forward for patients with hemophilia A in the U.S. Bayer has

also submitted marketing authorization applications for Jivi in the European Union and Japan."

About Jivi® (BAY94-9027)

BAY94-9027 was engineered to have an extended half-life by harnessing proven PEG-technology that delivers higher sustained levels of FVIII, which extends the blood's ability to coagulate for longer. Jivi is approved for the routine prophylactic treatment of hemophilia A in previously treated adults and adolescents 12 years of age or older. Jivi's initial recommended dosing regimen is twice weekly (30-40 IU/kg) with the ability to dose every five days (45-60 IU/kg) and further individually adjust to less or more frequent dosing based on bleeding episodes. The FDA also approved Jivi for on-demand treatment and the perioperative management of bleeding in the same population.

Jivi is a 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 FVIII, Jivi has a half-life of 17.9 hours that delivers sustained levels in the blood. rFVIII 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 FDA approval of Jivi is supported by results of the pivotal Phase 2/3 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 PROTECT VIII study was a 36-week, international, open label trial. Overall 126 patients completed the main study. Part A evaluated pharmacokinetics, efficacy and safety of Jivi for on-demand treatment of bleeds and for prophylactic therapy at different dosing regimens. An optional extension study was available to subjects who completed Part A to assess Jivi over at least 100 accumulated exposure days, which demonstrated bleed protection and a good safety profile of up to a median of 1.9 years (range of 0-2.6 years). Part B evaluated safety and efficacy of Jivi during major surgery. Treatment with BAY94-9027 was generally well tolerated.

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 both now and 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 therefore repeatedly experience bleeds in muscles, joints or other tissues, which can result in chronic joint damage over time. External injuries can have severe consequences if not treated appropriately, as the blood clots more slowly in these 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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Forward-Looking Statements
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