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News Release

Bayer Receives FDA Approval for Jivi®, New Hemophilia A Treatment With Step-Wise Prophylaxis Dosing Regimen

Jivi's extended half-life allows for twice-weekly initial dosing and may be adjusted to every five days and further individually adjusted to less or more frequent dosing[1]

Whippany, N.J., August 30, 2018 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has approved Jivi® (BAY94-9027, antihemophilic factor [recombinant] PEGylated-aucl) for the routine prophylactic treatment of hemophilia A in previously treated adults and adolescents 12 years of age or older. The initial recommended 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, which demonstrated bleed protection and safety of up to a median of 1.9 years (range of 0-2.6 years).[1] Jivi is the third FDA-approved hemophilia A treatment in Bayer's Hematology 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 works by replacing the reduced or missing factor VIII (FVIII) in adults and adolescents 12 years of age or older with hemophilia A. Through its site-specific PEGylation, Jivi has a half-life of 17.9 hours that delivers sustained levels in the blood.[1] Jivi is an important new treatment option in recombinant FVIII (rFVIII) replacement therapy. Recombinant factor VIII is the standard of care for hemophilia A and has proven efficacy and safety established over decades of clinical trials and real-world experience.

Treatment with Jivi was well tolerated in the majority of adult and adolescent patients in clinical trials. The most frequently reported adverse reactions in previously treated patients 12 years of age or older were headache, cough, nausea, and fever. A FVIII inhibitor (1.7 BU/mL) was reported in one previously treated adult subject. Repeat testing did not confirm the presence of a FVIII inhibitor.[1]

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 adults and adolescents 12 years of age or older with severe hemophilia A. One hundred and twenty-six patients completed the main study.[1]

“Today’s approval builds on our 25-year partnership with the hemophilia community and underscores our commitment to developing new therapies that help meet the needs of patients living with this life-long disease,” said Carsten Brunn, President of Bayer Pharmaceuticals, Americas Region. “Jivi’s proven efficacy with its unique dosing regimen is an important benefit to patients that we look forward to bringing to the global community, as we pursue additional regulatory approvals for Jivi in other regions around the world.”

Bayer has also submitted marketing authorization applications for BAY94-9027 for the treatment of hemophilia A in the European Union and Japan.

About Jivi (antihemophilic factor [recombinant] PEGylated-aucl)

Jivi is a recombinant factor VIII (rFVIII) replacement therapy, meaning it replaces the reduced or missing FVIII (a protein needed to form blood clots) in hemophilia A patients. Through its site-specific PEGylation, Jivi has a half-life of 17.9 hours that delivers sustained levels in the blood.[1]

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.[1] To learn more about Jivi, visit www.Jivi.com.

About the PROTECT VIII Study

The PROTECT VIII study was a 36-week, Phase 2/3, international, open-label trial conducted in previously treated adults and adolescents 12 years of age or older with severe hemophilia A. 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. Part B evaluated safety and efficacy of Jivi during major surgery.[1]

About Hemophilia A

Hemophilia has an estimated frequency of 1 in 5,000 male live births and affects approximately 400,000 people around the world, including an estimated 20,000 in the U.S. today.[2] It 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. Patients therefore repeatedly experience bleeds in muscles, joints or other tissues, which can result in chronic joint damage. External injuries, even if they seem trivial, can have serious consequences if not treated appropriately.

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.[3]

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 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.us.

Jivi Indications and Important Safety Information

INDICATIONS

- Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.

- Jivi is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. Jivi can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).

- Jivi is not for use in children below 12 years of age or in previously untreated patients.

- Jivi is not used to treat von Willebrand disease.

IMPORTANT SAFETY INFORMATION

- You should not use Jivi if you are allergic to rodents (like mice and hamsters) or to any ingredients in Jivi.

- Tell your healthcare provider about all of your medical conditions that you have or had.

- Tell your healthcare provider if you have been told that you have inhibitors to Factor VIII.

- Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea.

- Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.

- Your body can also make antibodies, called “inhibitors,” against Jivi, which may stop Jivi from working properly. Consult your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.

- If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. You may have developed Factor VIII inhibitors or antibodies to PEG and your doctor may carry out tests to confirm this.

- The common side effects of Jivi are headache, cough, nausea, and fever.

- These are not all the possible side effects with Jivi. Tell your healthcare provider about any side effect that bothers you or that does not go away.

For additional important risk and use information, please see the full Prescribing Information.

You are encouraged to report side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Forward-Looking Statements
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References:

[1] Jivi® [prescribing information]. Whippany, NJ: Bayer; 2018.

[2] Fast Facts (2015, July 15). Retrieved October 19, 2017, from: https://www.hemophilia.org/About-Us/Fast-Facts.

[3] Hemophilia and Aging (2014). Retrieved October 19, 2017, from: https://www.hemophilia.org/sites/default/files/document/files/Nurses-Guide-Chapter-17-Aging.pdf.