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Bayer gets FDA Approval for Jivi to treat Hemophilia A

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Jivi is the third FDA-approved hemophilia A treatment in Bayer's Hematology portfolio.

Bayer announced 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). Jivi is the third FDA-approved hemophilia A treatment in Bayer's Hematology portfolio.

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.

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.

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