Jivi® (antihemophilic factor (recombinant), PEGylated-aucl) – New drug approval

- On August 30, 2018, Bayer announced the FDA approval of Jivi [antihemophilic factor (recombinant), PEGylated-aucl], for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.
    - Jivi is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions.
    - Jivi is not indicated for use in previously untreated patients.
    - Jivi is not indicated for the treatment of von Willebrand disease.
- Hemophilia A is a largely inherited bleeding disorder in which one of the proteins needed to form blood clots in the body is missing or reduced. Patients can repeatedly experience bleeds into their muscles, joints or other tissues. This can result in chronic joint damage over time. External injuries, even if they seem trivial, can have serious consequences if not treated appropriately.
    - 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.
- The safety and efficacy of Jivi for on-demand treatment, perioperative management of bleeding and routine prophylaxis were based on data from the PROTECT VIII study, a 36 week study conducted in 134 previously treated patients (PTPs). The primary efficacy variable of Part A (on demand and prophylaxis treatment) was annualized bleed rate (ABR). In Part B of the study, hemostasis during major surgical procedures was evaluated in 17 patients.
    - In Part A of the study, 46% of patients treated with twice weekly dosing vs. 44% of patients treated with every 5 day dosing vs. 0% of patients treated with on demand dosing had zero bleeds.
    - In Part B of the study, treatment with Jivi provided ‘good’ or ‘excellent’ hemostatic control during all major surgeries.
- Jivi is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.
- Warnings and precautions of Jivi include hypersensitivity reactions, neutralizing antibodies, immune response to PEG, and monitoring laboratory tests.
- The most common adverse reactions (≥ 5%) with Jivi use in PTP ≥ 12 years of age were headache, cough, nausea, and fever.
- The recommended initial dosage of Jivi for routine prophylaxis is 30 – 40 IU/kg intravenously (IV) twice weekly. Based on the bleeding episodes: the regimen may be adjusted to 45 – 60 IU/kg IV every 5 days and a regimen may be further individually adjusted to less or more frequent dosing.
    - Dosage and duration of treatment depend on the severity of the Factor VIII deficiency, the location and extent of bleeding, and the patient’s clinical condition. Careful control of replacement therapy is especially important in cases of major surgery or life-threatening bleeding episodes.

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- Consult the Jivi drug label for dosing recommendations for on demand treatment, control of bleeding episodes and perioperative management of bleeding.

- Bayer's launch plans for Jivi are pending. Jivi will be available as lyophilized powder in single-use vials containing nominally 500 IU, 1000 IU, 2000 IU, or 3000 IU.