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Idelvion approved for use in children and adults with Hemophilia B

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The U.S. Food and Drug Administration today approved Idelvion, Coagulation Factor IX (Recombinant), Albumin Fusion Protein, for use in children and adults with Hemophilia B. Idelvion is the first coagulation factor-albumin fusion protein product to be approved, and the second Factor IX fusion protein product approved in the U.S. that is modified to last longer in the blood.

"The approval of Idelvion provides another important therapeutic option for children and adults with Hemophilia B to help prevent or control bleeding and reduce the frequency of bleeding episodes," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research.

According to the Centers for Disease Control and Prevention, Hemophilia B is a rare inherited bleeding disorder that prevents blood from clotting normally. The disorder primarily affects males and, rarely, females. People with Hemophilia B can experience repeated episodes of potentially serious bleeding, mainly into the joints, which can be damaged by the bleeding.

Idelvion is used to replace Factor IX, a naturally occurring clotting factor that is missing (functionally deficient) or defective in people with Hemophilia B (also called congenital Factor IX deficiency or Christmas disease). Idelvion is produced by recombinant DNA technology linking Factor IX to albumin, a protein found in blood, which accounts for the product lasting longer when given intravenously. Idelvion is indicated for on-demand (as needed) control and prevention of bleeding episodes, management of bleeding following surgery (perioperative) and as a routine preventative (prophylaxis) measure to reduce the frequency of bleeding episodes. Idelvion potentially requires less frequent injections than unmodified Factor IX when used for prevention.

The safety and efficacy of Idelvion were evaluated in two multicenter studies, which included a total of 90 adult and pediatric patients with Hemophilia B between 1 and 61 years of age. Idelvion was demonstrated to be effective in controlling bleeding episodes and in managing perioperative bleeding. Idelvion used as prophylaxis led to a significant reduction in the rate of spontaneous bleeding episodes per year despite less frequent infusions of Idelvion. No safety concerns were identified in the studies. The most common side effect observed for Idelvion was headache.

Idelvion is manufactured by CSL Behring, headquartered in King of Prussia, Pennsylvania.

Source:
http://www.fda.gov
