

FDA OKs drug to treat bleeding disorder

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The U.S. Food and Drug Administration has approved Humate-P for the treatment of a specific bleeding disorder called von Willebrand disease.

Humate-P (Antihemophilic Factor/von Willebrand Factor Complex) was approved for prevention of excessive bleeding during and after surgery in certain patients with mild to severe von Willebrand disease, or vWD. The disease is the most common inherited bleeding disorder, affecting about 1 percent of the U.S. population.

Humate-P is the second biological product to be approved for the management of surgery and invasive procedures in patients with vWD in whom the medication desmopressin might not work. The first biological product, Aphanate, was approved by FDA in February. However, FDA officials said Humate-P is the first product specifically for patients with severe vWD who are undergoing major surgery.

Humate-P is manufactured by CSL Behring GmbH, located in Marburg, Germany.

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