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FDA approves Novo Nordisk haemophilia A drug

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Singapore: U.S. Food and Drug Administration (FDA) has approved Novo Nordisk's Biologics License Application (BLA) for recombinant coagulation factor VIII, Novoeight.

Novoeight is approved for use in adults and children with haemophilia A for control and prevention of bleeding, perioperative management, routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Novoeight has been studied in the guardian clinical programme, a comprehensive pre-registration clinical trial programmes in the field of haemophilia therapy with more than 210 severe haemophilia A patients. In the completed trials Novoeight demonstrated efficacy in preventing and treating bleeds and had no confirmed inhibitor development, and all patients in the surgery trial were treated effectively. Novoeight will be launched with the newly introduced prefilled device, MixPro.

"The approval of Novoeight marks an important step in offering a new alternative for people with haemophilia A, and demonstrates our commitment to haemophilia," said Mr. Mads Krogsgaard Thomsen, executive vice president and chief science officer at Novo Nordisk.

Awaiting the expiration of existing patents, Novo Nordisk plans to launch in the U.S. Novoeight shortly after April 2015.

Novoeight has already received positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use in September 2013. Applications for regulatory approval have also been submitted in a range of other countries.