BioSpectrum the business of Bio & Health Sciences

Baxter's Hemophilia drug gets US FDA nod

27 October 2014 | News | By BioSpectrum Bureau

Baxter's Hemophilia drug gets US FDA nod

Baxter International has announced that the United States Food and Drug Administration (US FDA) has approved OBIZUR [Antihemophilic Factor (Recombinant), Porcine Sequence] for the treatment of bleeding episodes in adults with acquired hemophilia A (AHA), a very rare and potentially life-threatening acute bleeding disorder.

The drug was granted orphan-drug status by the FDA and its review was prioritized based on AHA's classification as a rare disease and the potential for the treatment to address an important unmet medical need.

"As a new treatment option with the ability to measure FVIII activity in the body, OBIZUR will address important unmet needs for patients with acquired hemophilia A, a potentially life-threatening condition," said Mr Brian Goff, head of Baxter's hemophilia franchise. He added, "This approval reflects Baxter's long-standing commitment to discovering new options for hemophilia patients and adds to our portfolio of treatments that reduce the burden of these diseases."

It is also currently under regulatory review in Europe and Canada.