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Baxalta seeks FDA approval for ADYNOVATE to treat children with hemophilia A and for use in surgical settings

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Baxalta Incorporated (NYSE: BXLT), a global biopharmaceutical leader dedicated to delivering transformative therapies to patients with orphan diseases and underserved conditions, announced today that it has submitted supplemental Biologics License Applications (sBLAs) to the U.S. Food and Drug Administration (FDA) seeking approval for the use of ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] to treat children under the age of 12 with hemophilia A and for use in surgical settings.

ADYNOVATE is the only extended circulating half-life recombinant Factor VIII (rFVIII) treatment for hemophilia A based on the demonstrated efficacy of ADVATE [Antihemophilic Factor (Recombinant)]. ADYNOVATE was approved by the FDA in November 2015 for use in adolescent and adult hemophilia A patients (12 years and older) for prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding.

"We know there is a great need for innovative new treatments among pediatric patients and during surgery and we look forward to working with the FDA as they review ADYNOVATE for these patients," said Brian Goff, executive vice president and president, Hematology. "We are committed to continually advancing direct factor replacement treatments and specifically to expanding use of ADYNOVATE, providing as many patients as possible access to its proven prophylaxis and simple, twice-weekly dosing schedule."

The submission of ADYNOVATE to treat children under the age of 12 was based on results of a Phase 3 trial designed to assess the efficacy and safety including immunogenicity of ADYNOVATE, which was initially reported in December 2015. Results from the study showed ADYNOVATE met its primary endpoint and no patients developed inhibitory antibodies to ADYNOVATE. In addition, no treatment-related serious adverse events were reported. More than 70 percent (72.7 percent) of patients had no joint bleeds while on treatment with ADYNOVATE (n=66) and nearly 40 percent (37.9 percent) experienced zero bleeds. The median overall annualized bleeding rate (ABR) among patient participants treated with ADYNOVATE was 2.0 (range 0-49.8; mean ABR 3.0), which was comparable to the rates seen in the adult study.

The filing was also supported by the positive results of a Phase 3 study evaluating the efficacy and safety of ADYNOVATE for the perioperative control of hemostasis among 15 patients with severe hemophilia A undergoing surgical procedures, which was reported in December 2015. The study data demonstrated that ADYNOVATE achieved hemostasis control in the perioperative period (from start of the procedure until discharge or day 14) for patients with severe hemophilia A.

Baxalta continues to invest in ADYNOVATE to expand the product's value for more patients worldwide. Baxalta plans to file for marketing authorization in Europe in the first quarter of 2016 and expects regulatory approval of the treatment in Japan in the first half of the year. ADYNOVATE is also under regulatory review in Canada and Switzerland.

ADYNOVATE is built on the full-length ADVATE molecule, a leading treatment for hemophilia A that been used by patients worldwide for more than 12 years. Through a collaboration with Nektar Therapeutics (NASDAQ: NKTR), ADYNOVATE leverages proprietary PEGylation technology designed to extend the amount of FVIII available for use in the body. The technology was selected because it maintains the integrity of the parent molecule (ADVATE) and reduces the time at which the body clears ADYNOVATE, resulting in an extended circulating half-life. This proprietary technology has been used for more than 15 years in a number of approved medicines that treat chronic or serious conditions.

Source:
Nektar Therapeutics
