Uploaded to the VFC Website

2016

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Baxalta announces initial results from ADYNOVATE Phase 3 trial for treatment of hemophilia patients

Published on December 22, 2015 at 7:25 AM

Baxalta Incorporated (NYSE: BXLT), a global biopharmaceutical leader dedicated to delivering transformative therapies to patients with orphan diseases and underserved conditions, today announced initial results from a Phase 3 clinical trial of ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], an extended circulating half-life recombinant Factor VIII (rFVIII) treatment for hemophilia A based on ADVATE [Antihemophilic Factor (Recombinant)]. ADYNOVATE was approved by the U.S. Food and Drug Administration (FDA) in November 2015 for use in adolescent and adult hemophilia patients (12 years and older) for on-demand treatment and control of bleeding, and prophylaxis to reduce the frequency of bleeding episodes.

The prospective, uncontrolled, open-label, multi-center Phase 3 study was designed to assess the safety and immunogenicity of ADYNOVATE. The study enrolled 73 previously-treated patients (PTPs) with severe hemophilia A younger than 12 years of age and assessed the treatment's hemostatic efficacy in prophylaxis and treatment of bleeding episodes. All participants received prophylactic ADYNOVATE treatment (median 1.9 infusions per week) and were followed for six months.

ADYNOVATE met its primary endpoint in the study, as 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 and nearly 40 percent (37.9 percent) experienced zero bleeds. The median 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.

"These initial efficacy and safety findings indicate a potentially valuable role for ADYNOVATE to treat pediatric patients with hemophilia A, with data consistent with what was reported in clinical studies among adult patients," said John Orloff, M.D., head of Research & Development and chief scientific officer, Baxalta. "We will continue to build evidence on the value of ADYNOVATE through our robust clinical development program, which will support additional global registrations in the coming years."

With the study results, the company plans to file for marketing authorization in Europe and aims to file for a pediatric indication in the U.S. in early 2016. ADYNOVATE is currently under regulatory review in Japan, Canada and Switzerland. Baxalta plans to present the complete data from this study at a congress in 2016.

In addition to an ongoing study in the surgical setting, Baxalta's continuation study remains ongoing to assess long-term safety and efficacy in PTPs with severe hemophilia A. The company has also recently announced the initiation of a study of previously-untreated patients (PUPs) with severe hemophilia A, as well as a study to evaluate pharmacokinetic (PK)-guided prophylaxis dosing with ADYNOVATE (the PROPEL study).

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 increased 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