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Baxter Announces Positive Top-Line Results from Its Phase 3 Study of BAX 855, Extended Half-Life Recombinant FVIII for Hemophilia A Patients

Twice-Weekly Prophylactic Regimen Resulted in 95% Reduction in Median Annualized Bleed Rate Compared to On-Demand
Company Initiating Phase 3 Study of BAX 855 in Pediatric Hemophilia A Patients

DEERFIELD, Ill., Aug. 21, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) reports Baxter International Inc. today announced positive results from its Phase 3 pivotal clinical trial of BAX 855, an investigational, extended half-life recombinant factor VIII (rFVIII) treatment for hemophilia A based on ADVATE [Antihemophilic Factor (Recombinant)], which met its primary endpoint in reducing annualized bleed rates (ABR) in the prophylaxis arm compared to the on-demand arm.

Top-line results from the prospective, global, multi-center Phase 3 study demonstrated that BAX 855 met its primary endpoint in the control and prevention of bleeding, routine prophylaxis and perioperative management for patients who were 12 years or older. Patients in a twice-weekly prophylaxis arm experienced a 95 percent reduction in median ABR as compared to those in the on-demand arm (1.9 vs. 41.5, respectively). BAX 855 was also effective in treating bleeding episodes, 96 percent of which were controlled with one or two infusions. The half-life of BAX 855 was 1.4 - 1.5 times that of ADVATE, consistent with the findings from the Phase 1 study. No patients developed inhibitors to BAX 855 and no treatment-related serious adverse events, including hypersensitivity, were reported. The most common (three patients) product-related adverse event was headache.

"The positive results of the BAX 855 study reflect our ongoing, long-term commitment to drive innovation and expand treatment options for patients with hemophilia," said John Orloff, M.D., vice president and global head of research and development for Baxter BioScience. "We look forward to advancing the BAX 855 program to U.S. regulatory submission by the end of this year."

The multi-center, open-label study evaluated BAX 855 among 138 adolescent and adult patients with previously-treated hemophilia A. Patients received treatment twice weekly (45 IU/kg) or on-demand, and were followed for six months. The primary objective of the study was the reduction in ABR during the treatment period compared to on-demand treatment. The study also evaluated the safety and immunogenicity of the compound when administered on either prophylaxis or on-demand treatment regimens.

Baxter expects to submit a Biologics License Application (BLA) for BAX 855 to the U.S. Food and Drug Administration (FDA) before the end of 2014 and will present additional data in the coming months. In addition to an ongoing continuation study for patients who have completed the pivotal trial, the company is initiating a Phase 3, prospective, open-label, multi-center study to evaluate the safety and efficacy of BAX 855 among 60 previously treated patients under the age of 12 with severe hemophilia A. Consistent with guidelines published by the European Medicines Agency (EMA) that require a study in children less than 12 years of age prior to filing, Baxter expects to file a Marketing Authorization Application with the EMA upon the completion of the pediatric study.

BAX 855 is based on ADVATE, a full-length FVIII molecule with more than 10 years of real-world experience. Through a collaboration with Nektar Therapeutics (NASDAQ: NKTR), BAX 855 leverages proprietary PEGylation technology designed to extend the duration of activity of proteins in the body. This proprietary technology has been used for over 10 years in a number of approved medicines that treat chronic or serious conditions.

About ADVATE
ADVATE is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency or classic hemophilia) for:

- Control and prevention of bleeding episodes.
- Perioperative management.
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

ADVATE is not indicated for the treatment of von Willebrand disease.

ADVATE has a demonstrated efficacy and safety profile. ADVATE is a full-length (derived from the complete FVIII gene)

recombinant FVIII product that is processed without any blood-based additives. Because no blood-derived components are added at any stage of the manufacturing process, the potential risk of transmitting pathogens that may be carried in blood-based additives is eliminated. There have been no confirmed reports of transmission of HIV, HBV or HCV with rFVIII treatments.

ADVATE is approved in 64 countries worldwide, including the United States, Canada, 27 countries in the European Union, Algeria, Argentina, Australia, Brazil, Chile, China, Colombia, Croatia, Ecuador, Hong Kong, Iceland, Iraq, Japan, Kuwait, Macau, Malaysia, Mexico, Morocco, New Zealand, Norway, Panama, Puerto Rico, Russia, Serbia, Singapore, South Korea, Suriname, Switzerland, Taiwan, Tunisia, Turkey, Ukraine, Uruguay, and Venezuela.

Detailed Important Risk Information for ADVATE

CONTRAINDICATIONS
ADVATE is contraindicated in patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product.

WARNINGS & PRECAUTIONS

Hypersensitivity Reactions
Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. Symptoms include dizziness, paresthesia, rash, flushing, facial swelling, urticaria, dyspnea, and pruritus.

Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

Neutralizing Antibodies
Neutralizing antibodies (inhibitors) have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration.

ADVERSE REACTIONS
The serious adverse reactions seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions observed in clinical trials (frequency $\geq$ 10% of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

Please see full prescribing information for ADVATE at: http://www.baxter.com/downloads/healthcare_professionals/products/ADVATE_PI.pdf

About Baxter in Hemophilia
Baxter has more than 60 years experience in hemophilia and has introduced a number of therapeutic firsts for hemophilia patients. Baxter has the broadest portfolio of hemophilia treatments in the industry and is able to meet individual therapy choices, providing a range of options at each treatment stage. The company's work focuses on optimizing hemophilia care and improving the lives of people worldwide living with bleeding disorders.

About Baxter International Inc.
Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

This release includes forward-looking statements concerning BAX 855 and related clinical studies, including expectations with regard to regulatory filings. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; additional clinical results; changes in laws and regulations; product quality or supply or patient safety issues; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.

SOURCE Nektar Therapeutics; Baxter International Inc.