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Baxter Presents Additional Data From Pivotal Study Of BAX 855, Extended Half-life Investigational Recombinant FVIII Based On ADVATE For Hemophilia A

DEERFIELD, Ill., Feb. 11, 2015 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) reported that partner Baxter International Inc. today presented additional efficacy and safety data from the Phase III pivotal study of BAX 855, an investigational, extended half-life recombinant factor VIII (rFVIII) treatment for hemophilia A based on ADVATE [Antihemophilic Factor (Recombinant)] at the 8th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) in Helsinki, Finland.

The new data expand on the previously disclosed topline results from the pivotal trial, which found that BAX 855 met the study's primary endpoint in the control and prevention of bleeding episodes and routine prophylaxis. Patients in the twice-weekly prophylaxis arm of the trial experienced a 95 percent reduction in median annualized bleed rate (ABR) as compared to those in the on-demand arm (1.9 vs. 41.5, respectively). The study findings supported Baxter's December 2014 submission for approval of BAX 855 to the United States Food and Drug Administration (FDA).

"These pivotal trial results provide evidence to support the efficacy profile of BAX 855 in controlling, preventing or reducing the frequency of bleeding episodes when administered prophylactically twice weekly. Our goal with BAX 855 is to extend the interval between infusions while maintaining a similar efficacy profile to ADVATE," said John Orloff, M.D., vice president and global head of research and development for Baxter BioScience.

The prospective, global, multi-center, open-label, two-arm Phase III study evaluated BAX 855 among 137 previously treated hemophilia A patients (PTP) who were 12 years or older. Patients were assigned either to twice weekly prophylaxis (40-50 IU/kg, n=120) or on-demand treatment (10-50 IU/kg, n=17). In addition to a reduced ABR, BAX 855 was also effective in treating bleeding episodes, 96 percent of which were controlled with one or two infusions at a median dose of 29.0 IU/kg per infusion. Treatment was rated excellent or good for nearly all episodes (96.2%). In the prophylactic group (n=101), 40 percent of patients experienced no bleeds. The study also showed that BAX 855 pharmacokinetics offered a 1.4-1.5-fold extended half-life compared to ADVATE with a median infusion interval of 3.6 days, supporting the findings from the Phase I trial.

No patients developed inhibitors to BAX 855 and no treatment-related serious adverse events, including hypersensitivity, were reported. Seven adverse reactions in six patients, including headache, diarrhea, nausea, and flushing were reported.

Baxter's continuation study for patients who completed the pivotal trial and the Phase 3 study among previously treated patients under the age of 12 with severe hemophilia A remain ongoing. Upon completion of the pediatric study, Baxter expects to file for marketing authorization with the European Medicines Agency in 2016.

BAX 855 is based on ADVATE, a full-length FVIII molecule with more than 11 years of real-world patient experience. Through a collaboration with Nektar Therapeutics (NASDAQ: NKTR), BAX 855 leverages proprietary PEGylation technology designed to prolong the amount of factor VIII available for use in the body. This proprietary technology has been used for 15 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 the world's most prescribed FVIII treatment. It is currently approved in 66 countries worldwide, including the United States, Canada, 28 countries in the European Union, Algeria, Argentina, Australia, Brazil, Chile, China, Colombia, Ecuador, Hong Kong, Iceland, Iraq, Israel, Japan, Kuwait, Macau, Malaysia, Mexico, Morocco, New Zealand, Norway, Panama, Puerto Rico, Qatar, Russia, Saudi Arabia, Serbia, Singapore, South Korea, Suriname, Switzerland, Taiwan, Tunisia, Turkey, Ukraine, Uruguay, and Venezuela.

Detailed Important Risk Information for ADVATE [Antihemophilic Factor (Recombinant)]
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 ≥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 BioScience
Baxter BioScience is a leading provider of therapeutic treatments that save, sustain and improve the lives of people with rare conditions, chronic diseases or limited treatment options. Supported by advanced technical and manufacturing expertise, Baxter BioScience has a broad pipeline built on a legacy of innovation in bleeding disorders and immunology and is expanding to address emerging opportunities in niche areas of oncology as well as technology platforms such as biosimilars.

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, including expectations with regard to clinical studies and related data, regulatory filings, and its potential impact to patients. 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, manufacturing or supply issues, 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.

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