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Baxter Submits Application To Japan's MHLW For Approval Of BAX 855, Extended Half-Life Recombinant FVIII Based On ADVATE For Hemophilia A

DEERFIELD, Ill., April 16, 2015 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) reported today that partner Baxter International Inc. announced that the company has submitted a new drug application (NDA) to Japan's Ministry of Health, Labour and Welfare for the approval of BAX 855, an investigational, extended half-life recombinant factor VIII (rFVIII) treatment based on ADVATE [Antihemophilic Factor (Recombinant)] for patients over 12 years of age with hemophilia A.

"We continue to advance BAX 855 as a potential new treatment for hemophilia A patients around the world who are seeking options that support their individual needs," said John Orloff, M.D., vice president and global head of research and development for Baxter BioScience. "With more than a decade of experience with ADVATE and an extensive global presence, our BAX 855 program represents our continued commitment to supporting the hemophilia community, particularly this week as we celebrate World Hemophilia Day with our colleagues around the globe."

The submission follows the filing to the United States Food and Drug Administration (FDA) in late 2014 and is based on positive results from a prospective, global, Phase 3 study of 137 previously treated patients (PTP). The results, presented during the European Association for Haemophilia and Allied Disorders (EAHAD) meeting in February 2015, demonstrated that BAX 855 met its primary endpoint in the control and prevention of bleeding episodes and routine prophylaxis for patients who were 12 years or older.

Patients in a twice-weekly prophylaxis arm experienced a 95 percent reduction in median annual bleed rate (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. No patients developed inhibitors to BAX 855 and no treatment-related serious adverse events, including hypersensitivity, were reported. The most common product-related adverse reaction was headache (3 patients).

Baxter continues to advance a continuation study for patients who completed the pivotal trial and a Phase 3 study among previously treated patients under the age of 12 with severe hemophilia A. Once the pediatric study has been completed, the company expects to file for marketing authorization with the European Medicines Agency in 2016 and intends to seek post-approval label expansion in the U.S. for previously-untreated pediatric patients.

BAX 855 is based on ADVATE, a full-length FVIII molecule with more than 12 years of real-world experience. Through a collaboration with Nektar Therapeutics, BAX 855 leverages proprietary pegylation technology designed to extend the duration of activity of the protein 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 the world's most prescribed FVIII treatment. It is currently approved in 64 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, 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 $\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, 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.

Media Contact

Kellie Hotz
(224) 948-5353, media@baxter.com

Investor Contacts
Mary Kay Ladone, (224) 948-3371
Clare Trachtman, (224) 948-3085

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