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Baxalta Announces Submission of Supplemental BLAs to Expand Use of ADYNOVATE to Pediatric Patients and Surgical Settings

- ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], currently FDA-approved for adolescent and adult hemophilia A patients 12 years and older, offers proven prophylaxis with a simple, twice-weekly dosing schedule
- Filing supported by positive results of Phase 3 clinical trials of ADYNOVATE in pediatric patients and in peri- and postoperative settings
- ADYNOVATE is built on ADVATE [Antihemophilic Factor (Recombinant)], the world's most prescribed FVIII treatment with more than 12 years of real-world patient experience

BANNOCKBURN, Ill., Feb. 25, 2016 /PRNewswire/ -- 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.

About ADYNOVATE

Indications:

ADYNOVATE is a human antihemophilic factor indicated in adolescent and adult patients (12 years and older) with hemophilia A (congenital factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Routine prophylaxis to reduce the frequency of bleeding episodes

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

Detailed Important Risk Information

CONTRAINDICATIONS

ADYNOVATE is contraindicated in patients who have had prior anaphylactic reaction to ADYNOVATE, to the parent molecule (ADVATE), mouse or hamster protein, or excipients of ADYNOVATE (e.g. Tris, mannitol, trehalose, glutathione, and/or polysorbate 80).

WARNINGS & PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions are possible with ADYNOVATE. Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with other recombinant antihemophilic factor VIII products, including the parent molecule, ADVATE. Early signs of hypersensitivity reactions that can progress to anaphylaxis may include angioedema, chest tightness, dyspnea, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.

Neutralizing Antibodies

Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of ADYNOVATE. Monitor patients regularly for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. Perform an assay that measures factor VIII inhibitor concentration if the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled with expected dose.

ADVERSE REACTIONS

Common adverse reactions (=1% of subjects) reported in the clinical studies were headache and nausea.

For Full Prescribing Information, visit http://baxalta.com/assets/documents/ADYNOVATE_PI.pdf.

About ADVATE

ADVATE has a demonstrated efficacy and safety profile for the treatment of hemophilia A. 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 virtually 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 67 countries worldwide, including the United States, Canada, 28 countries in the European Union, Algeria, Argentina, Australia, Brazil, Brunei, Chile, China, Colombia, Ecuador, Hong Kong, Iceland, India, 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.

Indications:

ADVATE [Antihemophilic Factor (Recombinant)] is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency) 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.

Detailed Important Risk Information

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, pruritus, and vomiting.

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

Serious adverse reactions seen with ADVATE are hypersensitivity reactions, including anaphylaxis, and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions observed in clinical trials (frequency =5% of subjects) were pyrexia, headache, cough, nasopharyngitis, arthralgia, vomiting, upper respiratory tract infection, limb injury, nasal congestion, and diarrhea.

For full prescribing information for ADVATE, visit: http://www.baxalta.com/assets/documents/ADVATE_PI.pdf**.**

About Baxalta

Baxalta Incorporated (NYSE: BXLT) is a global biopharmaceutical leader developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, immunology and oncology. Driven by passion to make a meaningful impact on patients' lives, Baxalta's broad and diverse pipeline includes biologics with novel mechanisms and advanced technology platforms such as gene therapy. Launched in 2015 following separation from Baxter International, Baxalta's heritage in biopharmaceuticals spans decades. Baxalta's therapies are available in more than 100 countries and it has advanced biological manufacturing operations across 12 facilities, including state-of-the-art recombinant production and plasma fractionation. Headquartered in Northern Illinois, with its Global Innovation Center in Cambridge, Mass., Baxalta employs 17,000 employees worldwide.

Forward-Looking Statements

This release includes forward-looking statements concerning ADYNOVATE, including expectations with regard to regulatory filings and potential impact on patients. Such statements are made of the date that they were first issued and are based on current expectations, beliefs and assumptions of management. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Baxalta's control and which could cause actual results to differ materially from those in the forward-looking statements, including the following: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; product quality, manufacturing or supply issues; patient safety issues; and other risks identified in Baxalta's filings with the Securities and Exchange Commission, all of which are available on Baxalta's website. Baxalta expressly disclaims any intent or obligation to update these forward-looking statements except as

required by law.

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