December 7, 2015

Baxalta Presents Additional Data on Newly-Approved ADYNOVATE and Plans for New Indications During 57th American Society of Hematology (ASH) Annual Meeting

- ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] is built on ADVATE [Antihemophilic Factor (Recombinant)], offering proven bleed protection with a simple, twice-weekly dosing schedule
- Additional data from the ADYNOVATE pivotal clinical study and interim efficacy analysis from the surgery study augment clinical profile
- Company initiates several clinical trials on new indications for ADYNOVATE, including studies among previously untreated pediatric patients and dosage studies intended to extend use for more hemophilia A patients worldwide

BANNOCKBURN, Ill., Dec. 7, 2015 /PRNewswire/ -- Baxalta Incorporated (NYSE: BXLT), a global biopharmaceutical leader dedicated to delivering transformative therapies to patients with orphan diseases and underserved conditions, has showcased data on the clinical experience with newly-approved hemophilia A treatment ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] at the 57th American Society of Hematology (ASH) Annual Meeting. ADYNOVATE, an extended circulating half-life recombinant Factor VIII (rFVIII) treatment for hemophilia A, was approved by the U.S. Food and Drug Administration (FDA) in November.

"On the heels of the U.S. approval of ADYNOVATE, we are presenting a series of data and updates that represent our commitment to bringing this new treatment to patients around the world," said Brian Goff, executive vice president and president, Hematology, Baxalta. "ADYNOVATE represents Baxalta's commitment to meeting the needs of hemophilia A patients and our continued pursuit of a bleed-free world. We are constantly innovating to improve care for patients all over the world."

ADYNOVATE Presentations Demonstrate Clinical Profile
Further analyses of the data from the ADYNOVATE pivotal trial investigated characteristics of patients who achieved zero bleeds in the study. In the pivotal trial, 40 of the 101 patients (39.6 percent) achieved zero bleeding during six months of prophylactic treatment with ADYNOVATE. While some characteristics were similar across all participants, patients without bleeding generally had fewer target joints at screening, lower median historical annualized bleeding rates, and lower incidence of blood type O. *(Characteristics of Patients without Bleeding in a Pivotal Trial of Extended Half-Life, Pegylated, Full-Length Recombinant Factor VIII (BAX 855) in the Treatment of Hemophilia A. Pub # 1105)*

Additional post-hoc sub analysis from the pivotal trial addressed joint bleeding patterns among patients receiving twice-weekly prophylaxis treatment with ADYNOVATE. Approximately two-thirds of previously-treated patients (PTPs) in the study (69 of 101 PTPs, 68.3 percent) receiving ADYNOVATE had at least one "target joint" when they entered the study (ankle, knee, hip, or elbow with three or more spontaneous bleeding episodes in any consecutive 6-month period). The analysis found that ADYNOVATE was efficacious in treating breakthrough bleeds and reducing overall annualized joint bleeding rates among patients with "target joints". *(Joint Bleeding Patterns in Patients Treated Prophylactically with an Extended Half-Life, Pegylated, Full-Length Recombinant Factor VIII (BAX 855). Pub # 2300)*

Baxalta has also conducted 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. An interim analysis indicates that ADYNOVATE can support effective hemostatic control in this patient population for the intraoperative (during the procedure), postoperative (24 hours after completion of the procedure), and perioperative (from start of the procedure until discharge or day 14) periods. *(Perioperative Efficacy of an Extended Half-Life, Pegylated, Full-Length Recombinant Factor VIII (BAX 855) in Individual Procedures. Pub # 2299.*

New Research Underway Aims to Extend Use of ADYNOVATE for More Patients
Baxalta continues to invest in additional clinical programs supporting ADYNOVATE with the goal of expanding access to this innovative treatment for more patients around the world.

In November 2015, the company initiated a study of previously-untreated patients (PUPs) and minimally-treated patients (MTPs) with severe hemophilia A. This global, Phase 3 study aims to enroll at least 100 patients between the ages six months and six years to evaluate the safety and hemostatic efficacy of ADYNOVATE in this population.

In parallel, a Phase 3, prospective, randomized, multi-center study has been initiated to evaluate additional dosing regimens with ADYNOVATE, using pharmacokinetic (PK)-guided prophylaxis among approximately 100 adults with severe hemophilia A (the PROPEL study). The study is designed to compare outcomes of PK-guided treatment with ADYNOVATE targeting FVIII trough levels of 1-3 percent vs. approximately 10 percent (8-12 percent). Baxalta is advancing this research in an effort to help more patients achieve zero bleeds through higher trough levels. Please visit clinicaltrials.gov for more information on both studies.

In addition to the 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 recently completed a study assessing ADYNOVATE in pediatric patients with severe hemophilia A with initial results expected early in 2016. These studies are designed to support additional global submissions in the coming years. Baxalta has filed for regulatory approval of the treatment in Japan, Canada and Switzerland. The company expects to file for marketing authorization in Europe in early 2016.

ADYNOVATE is built on the full-length ADVATE molecule, a leading treatment for hemophilia A that been used by hemophilia A patients worldwide for more than 12 years. Through a collaboration with Nektar Therapeutics (NASDAQ: NKTR), ADYNOVATE leverages proprietary pegylation technology designed to prolong 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.

About ADYNOVATE
ADYNOVATE, [Antihemophilic Factor (Recombinant), PEGylated], 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 for ADYNOVATE

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 [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 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, 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.

Please see full prescribing information for ADVATE at: http://www.baxalta.com/assets/documents/ADVATE_PI.pdf.

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.

About Baxalta
Baxalta Incorporated (NYSE: BXLT) is a $6 billion global biopharmaceutical leader developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology. 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. The Baxalta Global Innovation and R&D Center is located in Cambridge, Massachusetts. Launched in 2015 following separation from Baxter International Inc, 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, Baxalta employs 16,000 employees worldwide.

Forward-Looking Statements
This release includes forward-looking statements concerning ADYNOVATE, including expectations with regard to clinical trials, future regulatory actions, expected launch plans 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: clinical trial results; 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 Registration Statement on Form 10 and other Securities and Exchange Commission filings, 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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