November 30, 2015

Baxalta Announces U.S. Availability of ADYNOVATE, A New Treatment for Adult Patients with Hemophilia A With a Simple, Twice-Weekly Dosing Schedule

- ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], approved by the FDA in November, is built on ADVATE [Antihemophilic Factor (Recombinant)], which been used by Hemophilia A patients worldwide for more than 12 years
- Baxalta's hemophilia A portfolio continues to grow, building on a legacy of commitment to advancing healthcare for the hemophilia community

BANNOCKBURN, Ill., Nov. 30, 2015 /PRNewswire/ -- Baxalta Incorporated (NYSE: BXLT), a global biopharmaceutical leader dedicated to delivering transformative therapies to patients with orphan diseases and underserved medical conditions, today announced the launch and first shipments of ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], an extended circulating half-life recombinant factor VIII (rFVIII) treatment for hemophilia A based on full-length ADVATE [Antihemophilic Factor (Recombinant)]. The treatment was approved by the U.S. Food and Drug Administration (FDA) in November.

"Patients living with hemophilia are increasingly looking for and need treatment options that can address their individual needs," said Dr. Michael Tarantino, medical director of the Bleeding & Clotting Disorders Institute. "The simplicity of ADYNOVATE's twice weekly dosing schedule offers an important new option for the hemophilia community, delivering first and foremost on what matters most - bleed protection, while also easing the schedule of their prophylactic treatment."

With ADYNOVATE, Baxalta expands its industry-leading hemophilia portfolio and further widens the variety of treatment options to meet individual patient needs at each treatment stage. The company continues to invest in ADYNOVATE to expand the product's value for more hemophilia patients worldwide. As the company prepares for additional global introductions of ADYNOVATE, the treatment has been submitted for regulatory approval in Japan. Following completion of the pediatric study in early 2016, Baxalta expects to file for marketing authorization in Europe.

"We are excited to be able to introduce ADYNOVATE to patients in the United States just weeks after receiving FDA approval, marking the first of many planned product launches in our broad pipeline," said Brian Goff, executive vice president and president, Hematology. "Looking ahead, we're continuing to build the value of ADYNOVATE with additional studies for new indications, and plan to deliver this innovative treatment to more patients around the world as we continue to pursue our vision of a Bleed-Free World."

ADYNOVATE was developed through a collaboration with Nektar Therapeutics (NASDAQ: NKTR). For more information on ADYNOVATE, please visit www.adynovate.com or www.adynovatepro.com. Additional resources are available at www.hematologysupport.com.

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: www.advate.com /assets/pdf/advate_iri_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 bloodbased 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, 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, regulatory actions, commercial launch plans and the 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 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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