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UPDATE: Baxalta's BAX 855 Pivotal Data Published in Blood Shows Potential to Provide Strong Bleed Prevention with Twice Weekly Dosing for Patients with Hemophilia A

- **Twice-weekly prophylactic regimen with the investigational, extended half-life recombinant factor VIII resulted in 95 percent reduction in median annualized bleed rate compared to on-demand treatment**
- **BAX 855 is based on ADVATE, a leading standard of care for hemophilia**
- **Baxalta demonstrates continued leadership in advancing science and personalized options to improve the lives of patients with hemophilia A**

DEERFIELD, Ill., July 16, 2015 – Baxalta Incorporated (NYSE: BXLT), a global biopharmaceutical leader dedicated to delivering transformative therapies to patients with orphan diseases and underserved conditions, today announced the publication of the complete data from the Phase II/III pivotal study and Phase I trial of BAX 855 in Blood, the journal of the American Society of Hematology. BAX 855 is Baxalta's investigational, extended half-life recombinant factor VIII (rFVIII) treatment for hemophilia A based on ADVATE [Antihemophilic Factor (Recombinant)], a leading treatment for hemophilia A with more than 11 years of real-world patient experience.

Following on initial presentations of the data in 2014, the publication provides a comprehensive overview of the clinical trial results of BAX 855, which will be marketed in the United States under the brand name ADYNOVATE [Antihemophilic Factor (Recombinant), Pegylated] upon approval. The trial assessed the treatment's safety and efficacy profiles for bleed prevention with a twice-weekly dosing schedule, showing a mean half-life extension of 1.4- to 1.5-fold compared with ADVATE. The positive study results were originally reported in August of 2014 and supported the company's December 2014 submission for approval of BAX 855 to the United States Food and Drug Administration (FDA).

"ADYNOVATE has the potential to offer an important new option for patients, providing the combination of bleed prevention with a simple, twice-weekly dosing schedule," said Leonard Valentino, M.D., global head, Hematology Medical Affairs, Baxalta. "The results of this pivotal trial demonstrate the ability of ADYNOVATE to help further personalize treatment regimens to minimize the impact that hemophilia has on patients' lives."

The prospective, global, multi-center, open-label, two-arm Phase II/III study evaluated BAX 855 among 137 previously treated patients (PTP) with hemophilia A who were aged 12 to 65. Patients were assigned to either twice weekly prophylaxis (40-50 IU/kg, n=120) or on-demand treatment (10-60 IU/kg, n=17). As previously disclosed, BAX 855 met the study's primary endpoint for the prevention of bleeding episodes and the treatment with prophylaxis compared to on-demand treatment. Patients in the twice- weekly prophylaxis arm of the trial experienced a 95 percent reduction in median annualized bleed rate (ABR) as compared with those in the on-demand arm (1.9 vs. 41.5, respectively). BAX 855 was also effective in treating all bleeding episodes, 95.9 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 bleeding episodes (96.1 percent). In the prophylactic group (n=101), 39.6 percent of compliant patients experienced no bleeds. The study also showed that BAX 855 pharmacokinetics offered a 1.4 to 1.5- fold mean extended half-life compared with 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 reactions, were reported. Seven adverse reactions in six patients, including headache, diarrhea, nausea, and flushing were reported.

"Upon approval, ADYNOVATE will be one of the first new treatments that we bring to market as Baxalta, representing a major milestone toward our plan to achieve 20 new product launches by 2020," said Ludwig Hantson, chief executive officer and president, Baxalta. "With a decades-long heritage in hematology and commitment to innovation, we continue to build a patient-centric portfolio that provides new solutions for evolving patient needs."

Baxalta's Continuation Study is ongoing for patients who completed the pivotal trial and the pediatric Phase III study among previously treated patients under the age of 12 with severe hemophilia A. This continuation study is also available for patients who have not participated in previous BAX 855 studies. Upon completion of the pediatric study, Baxalta 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 over 15 years in a number of approved medicines that treat chronic or serious conditions.

Baxalta leads the industry with the broadest portfolio of hemophilia treatments, and meets individual therapy choices with a range of options at each treatment stage.

As an estimated 70 percent of people with hemophilia globally remain undiagnosed and untreated or undertreated, Baxalta is focusing on continuing to innovate to address some of the greatest challenges associated with hematologic disorders including hemophilia.

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 or classic hemophilia) for:

- Control and prevention of bleeding episode
- 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 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 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 ≥10% of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

Please see full prescribing information for ADVATE at: http://www.advate.com//assets/pdf/advate_iri_pi.pdf

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.

This release includes forward-looking statements concerning ADYNOVATE and Baxalta's R&D pipeline, including expectations with regard to regulatory actions and ADYNOVATE's 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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