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**REAL-WORLD EXPERIENCE CONFIRMS LOW INHIBITOR RATE  
ESTABLISHED IN ADVATE CONTROLLED CLINICAL STUDIES  
FOR HEMOPHILIA PATIENTS**

***Japan PASS interim results presented at Hemophilia 2010 World Congress***

BUENOS AIRES, ARGENTINA, (July 13, 2010) – Baxter International Inc. (NYSE: BAX) today announced final E.U./U.S. post-authorization safety surveillance (PASS) data that support the safety and efficacy profile of ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] previously documented in prospective clinical trials in a new study published in the journal *Haemophilia*.<sup>1</sup> Similar safety, inhibitor profile and efficacy were seen in previously treated patients (PTPs) with severe to moderately severe hemophilia A as well as across a broad range of hemophilia patients in everyday practice. The results are from the large, prospective, open-label, observational study examining 521 patients of any age and with severe to moderately severe hemophilia A who were treated prophylactically (preventatively) or on-demand (as needed) with ADVATE therapy at the discretion of the participating physicians in the United States and 11 countries in the European Union.

In PTPs with severe to moderately severe hemophilia A (n=348), the inhibitor rate was 0.29 percent (95 percent confidence interval [CI] of 0.01 to 1.59 percent). This is comparable with the 0.51 percent (95 percent CI of 0.03 to 2.91

percent) inhibitor rate seen in the ADVATE clinical study in a similar but somewhat smaller group of patients (n=198).

Additionally, interim results from the Japan PASS registry were presented at the Hemophilia 2010 World Congress of the World Federation of Hemophilia. Actual practice patterns in Japan have not been well documented. Japan PASS enrollment data presented at the Congress examined ADVATE treatment regimens among different age groups of people with hemophilia A, demonstrating a higher tendency for prophylactic use among younger patients, with a decrease in prophylactic use in patients older than 20 years of age.

“Importantly, the E.U./U.S. PASS data confirm patients on ADVATE, particularly those with previous exposure to factor VIII products, had a low risk of developing an inhibitor, the management of which remains the greatest challenge for physicians and patients with hemophilia A today,” said investigator Johannes Oldenburg, M.D., Ph.D., head, Institute of Experimental Haematology and Transfusion Medicine, University Clinic Bonn, Germany. “The data from the large registry involving a broad population of patients with hemophilia A are important because they corroborate the safety, immunogenicity profile and efficacy of ADVATE in real-world practice.”

Overall, the PASS registry confirmed the ADVATE therapy safety profile established in controlled clinical studies. No unusual or unexpected adverse events were observed in PASS. Ten serious adverse events were considered related to ADVATE therapy, and included factor VIII (FVIII) inhibitor development, hypersensitivity and decreased drug effect. Ten non-serious adverse events were considered related to ADVATE. These included abdominal pain, abnormal skin odor, abnormal urine odor, psychomotor hyperactivity, asthenia, headache, fatigue, decreased drug effect and anxiety.

“PASS registries allow for an evaluation of broader patient experiences with ADVATE under conditions of routine clinical practice in the general hemophilia A population,” said Bruce Ewenstein, M.D., Ph.D., vice president, Clinical Affairs at Baxter. “These data have confirmed and extend our previous understanding of the safety, inhibitor risk and efficacy parameters of ADVATE and have shed new light on treatment practices in various parts of the world, providing a basis for further research to improve therapeutic options for patients.”

### **About ADVATE PASS**

The E.U./U.S. ADVATE PASS registry included hemophilia A patients with moderate or severe hemophilia who were either naïve to FVIII or had been treated previously with any FVIII product other than ADVATE therapy. Of the 521 treated subjects, 286 were treated on prophylactic regimens, and 193 were treated on-demand throughout the study, with the remaining 42 patients switching regimens one or more times. On-demand and prophylaxis are approved treatment regimens in the European Union; only the on-demand treatment regimen is approved in the United States. Surveillance data were captured for each subject for 12 months during routine and emergent clinic visits as well as during surgical procedures. The dosage regimen, monitoring frequency and frequency of inhibitor testing were determined by each treating physician.

PASS is a prospective, uncontrolled, open label, observational study designed to document the first year of patient experience on ADVATE therapy. PASS offers a sufficiently large sample size, proving to be an accurate, real-world evaluation of the safety and immunogenicity of ADVATE for the treatment of hemophilia A during routine clinical practice. Multiple PASS registries have been initiated globally since 2004, including more than 1,000 hemophilia A patients enrolled in the United States, European Union and Australia, with ongoing studies in Japan, Korea, Taiwan and Italy. The comprehensive clinical research program for ADVATE therapy comprises more than 10 formal studies.

### **About ADVATE**

ADVATE is a full-length (derived from the complete FVIII gene) recombinant FVIII therapy that is free of 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. Since the initial approval of ADVATE seven years ago, more than 7.5 billion international units have been distributed, and ADVATE is the number one chosen hemophilia therapy worldwide.

ADVATE is approved in 50 countries worldwide including the United States, Canada, 27 countries in the European Union, Argentina, Australia, Brazil, Chile, Colombia, Croatia, Hong Kong, Iceland, Japan, Macau, Malaysia, New Zealand, Norway, Puerto Rico, Serbia, Singapore, South Korea, Suriname, Switzerland, Taiwan and Uruguay.

### **Important Risk Information for ADVATE Therapy**

ADVATE is contraindicated in patients with known anaphylaxis to mouse or hamster protein or other constituents of the product.

Allergic-type hypersensitivity reactions, including anaphylaxis, are possible and have been reported with ADVATE. Symptoms have manifested as dizziness, paresthesia, rash, flushing, face swelling, urticaria, dyspnea, and pruritis. Discontinue use if hypersensitivity symptoms occur and administer appropriate emergency treatment.

Patients treated with AHF products should be monitored for the development of FVIII inhibitors. Inhibitors have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs).

If expected plasma FVIII levels are not attained, or if bleeding is not controlled with an expected dose, test for the presence of inhibitors.

The most serious adverse reactions seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to FVIII.

The most common adverse reactions observed in clinical trials (frequency less than 2 percent of subjects) were FVIII inhibitor formation (observed predominantly in PUPs) and headache.

Please see full prescribing information at [www.advate.com](http://www.advate.com).

### **About Baxter**

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, 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.

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### **References**

1. Oldenburg J et al. Postauthorization safety surveillance of ADVATE [antihaemophilic factor (recombinate), plasma/albumin-free method] demonstrates efficacy, safety and low-risk for immunogenicity in routine clinical practice. *Haemophilia*. 2010:1-14.

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2. Manco-Johnson M et al. Prophylaxis versus episodic treatment to prevent joint disease in boys with severe hemophilia. *The New England Journal of Medicine* 2007; 357 (6): 535-544.