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

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

BUENOS AIRES, ARGENTINA, (July 13, 2010) – Baxter UK today announced final E.U./U.S. post-authorization safety surveillance (PASS) data that support the safety and efficacy profile of ADVATE [Antihaemophilic Factor (Recombinant), Plasma/Albumin-Free Method] previously documented in prospective clinical trials in a new study published in the journal *Haemophilia*.¹ Similar safety, inhibitor profile and efficacy were seen in previously treated patients (PTPs) with severe to moderately severe haemophilia A as well as across a broad range of haemophilia 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 haemophilia 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 haemophilia 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 Haemophilia 2010 World Congress of the World Federation of Haemophilia. 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 haemophilia 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 haemophilia 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 haemophilia 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.

Deborah Brady, Business Unit Director for BioScience at Baxter UK said, “This publication provides further confidence to clinicians and patients that Advate offers an effective, well tolerated treatment. The formal clinical study data is now reinforced through the everyday experience of a great many physicians and patients.”

About ADVATE PASS

The E.U./U.S. ADVATE PASS registry included haemophilia A patients with moderate or severe haemophilia 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 haemophilia A during routine clinical practice. Multiple PASS registries have been initiated globally since 2004, including more than 1,000 haemophilia 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 comprises therapy 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 haemophilia 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.

About Baxter

Baxter UK is a subsidiary of Baxter International Inc. that develops, manufactures and markets products that save and sustain the lives of people with haemophilia, 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 [antihemophilic factor (recombinate), plasma/albumin-free method] demonstrates efficacy, safety and low-risk for immunogenicity in routine clinical practice. *Haemophilia*. 2010:1-14.