Baxter Presents Preclinical Data at ISTH on Its Investigational Compound BAX 499 for Potential Subcutaneous Hemophilia Therapy and Final Phase I Data on Recombinant von Willebrand Factor

Three Baxter Scientists Granted Prestigious ISTH Young Investigators Award

KYOTO, Japan--(BUSINESS WIRE)--Jul 26, 2011 - Baxter International Inc. (NYSE: BAX) announced today that new data from a series of studies on BAX 499, an investigational compound for potential subcutaneous hemophilia therapy, were presented this week during the 23rd annual congress of the International Society on Thrombosis and Haemostasis (ISTH) in Kyoto, Japan. BAX 499 is in early stage clinical development to treat blood clotting disorders hemophilia A and B by targeting a novel pathway responsible for regulating the clotting process. The studies presented at ISTH validate the pathway as a potentially viable target for the treatment of hemophilia.

BAX 499 is being studied in a Phase I clinical trial for potential subcutaneous administration that specifically targets to reduce activity of the tissue factor pathway inhibitor (TFPI), which plays a critical role in the blood coagulation cascade. By blocking this inhibitor activity, the treatment may help achieve blood clotting in people with hemophilia.

Targeting TFPI with BAX 499

One oral presentation, “Tissue factor pathway inhibitor aptamer as a potential drug for hemophilia treatment” evaluated whether BAX 499 might block the inhibitory activity of TFPI in an *in vitro* model by measuring the impact of BAX 499 on the generation of thrombin, a key protein necessary for forming a blood clot. In this *in vitro* model, increasing concentrations of BAX 499 improved the rate and amount of thrombin generated, and at the highest levels, thrombin generation was similar to normal coagulation patterns.

“We are encouraged by these data that help deepen our understanding of potential new approaches to address complex blood disorders,” said Hartmut Ehrlich, M.D., vice president, global research and development and medical affairs, Baxter's BioScience business. “The studies presented on BAX 499 validate tissue factor pathway inhibitor as a viable target for subcutaneous hemophilia therapy and we look forward to sharing future data as they become available.”

Related studies presented during ISTH evaluated the interference of BAX 499 inhibition on TFPI, and considered the biological activity of TFPI and the unique mechanisms of the compound that help block TFPI activity. In addition to BAX 499, data were presented on Baxter's preclinical research studying an approach to inhibit TFPI by small peptides.

About BAX 499

BAX 499, formerly known as ARC19499, is a fully synthetic compound that specifically inhibits TFPI activity. Its small size may lead to high bioavailability after subcutaneous administration. The BAX 499 Aptamer Phase I clinical trial was initiated in the United Kingdom in August 2010 and is expected to be completed in the second half of 2011.

Recombinant von Willebrand Factor (rVWF) Study Results

Data were also presented on recombinant von Willebrand Factor (rVWF), the only recombinant replacement protein currently in clinical development, to assess its safety and efficacy for the treatment of von Willebrand disease (VWD). Unlike currently available treatments for von Willebrand disease that are derived from human plasma, Baxter's investigational rVWF does not contain blood-based additives.

The Phase I, 32 patient study evaluated the safety, tolerability, and pharmacokinetic profile of rVWF versus plasma-derived von Willebrand factor (pdVWF), the current standard for treatment for patients with the disease. Four concentrations of rVWF (2, 7.5, 20 and 50 IU VWF:RCo/kg) were administered in a dose-escalating manner in separate cohorts. Results were consistent with previously presented interim results, with no serious and 12 non serious adverse reactions reported in patients with type 3 and severe type 1 VWD. Pharmacokinetics of rVWF/rFVIII compared with pdVWF/pdFVIII were evaluated using a randomized, cross-over design. The data presented at ISTH indicated overall that the pharmacokinetics of rVWF and pdVWF were found to be similar. A larger Phase III trial study is required to further assess the safety and efficacy of rVWF. Baxter anticipates beginning recruitment later this year.

About Recombinant Von Willebrand Factor (rVWF)

Baxter's investigational rVWF concentrate was developed using a plasma- and albumin-free manufacturing method. It is currently the only recombinant replacement protein in clinical development for von Willebrand disease. The European Commission granted orphan designation for Baxter's rVWF in November 2010, and the U.S. Food and Drug Administration granted orphan designation for the compound in November 2010.

Young Investigators Award

Aligned with Baxter's commitment to developing innovative therapies to better manage bleeding disorders, the company continues to foster ongoing excellence in research and innovation among young scientists. This year, three Baxter scientists have received the ISTH's Young Investigators Award, given to young researchers who present highly-rated abstracts during the congress:

- Katharina Steinitz, PhD student, department of immunology, Hemophilia/ Hematology, Baxter Innovations GmbH, Vienna, Austria, presenting “Immune response versus tolerance to FVIII – a new approach to answer burning questions in hemophilia A.”
- Christoph Hofbauer, PhD student, department of immunology, Hemophilia/Hematology, Baxter Innovations GmbH, Vienna, Austria, presenting “FVIII specific CD4+ T cells are important regulators of FVIII inhibitor development in patients with severe hemophilia A.”
- Alexandra Schiviz, manager, department of pharmacology, toxicology and preclinical development, BioTherapeutics, Baxter Innovations GmbH, Vienna, Austria, presenting “Preclinical efficacy testing of Baxter's recombinant ADAMTS 13 in a mouse model of TTP.”

About Hemophilia A & B

Hemophilia is a rare genetic blood clotting disorder that primarily affects males.[1] People living with hemophilia do not have enough of, or are missing, one of the blood clotting proteins naturally found in blood.[1] Two of the most common forms of hemophilia are A and B.[1] In people with hemophilia A, clotting factor VIII is not present in sufficient amounts or is absent.[1] Without enough FVIII, people with hemophilia can experience spontaneous, uncontrolled internal bleeding that is painful, debilitating, damaging to joints and potentially fatal.[1] People with hemophilia B (also called Christmas disease) do not have sufficient amounts of clotting factor IX.[1] In about 30 percent of cases, there is no family history of hemophilia and the condition is the result of a spontaneous gene mutation.[1] According to the World Federation of

Hemophilia, more than 400,000 people in the world have hemophilia.[2] All races and economic groups are affected equally.[2]

About von Willebrand Disease[3]

Von Willebrand disease is the most common type of bleeding disorder and affects both men and women. Patients with von Willebrand disease either produce insufficient von Willebrand factor or carry defective von Willebrand factor and may experience problems with forming clots to stop bleeding. It is estimated that up to one percent of the world's population suffers from von Willebrand disease, but because many people have only mild symptoms, they may not know they have the condition. Research has suggested that as many as 9 out of 10 people with von Willebrand disease have not been diagnosed.

About Baxter International Inc.

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

This release includes forward-looking statements concerning Baxter's clinical efforts with respect to BAX 499, an investigational compound for potential subcutaneous hemophilia therapy, and recombinant von Willebrand Factor (rVWF), a recombinant replacement protein currently in clinical development for the treatment of von Willebrand disease, including in each case expectations with respect to related clinical trials. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: timely submission and approval of anticipated regulatory filings; the successful initiation and completion of additional clinical studies; additional clinical results validating the use of BAX 499 to treat hemophilia; additional clinical results validating the safety and efficacy of rVWF as a treatment of von Willebrand disease; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on the company's website. Baxter does not undertake to update its forward-looking statements.

1. Frequently Asked Questions About Hemophilia. World Federation of Hemophilia. Accessed on: 6 July 2010. Available at: http://www.wfh.org/2/1/1_1_Hemophilia.htm.

2. What is Hemophilia? World Federation of Hemophilia. Accessed on: 6 July 2010. Available at: www.wfh.org/2/1/1_1_Hemophilia.htm.

3. What is Von Willebrand Disease? World Federation of Hemophilia. Accessed on: 6 July 2010. Available at: http://www.wfh.org/2/1/1_2_VWD_What-is-VWD.htm.

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