



ATryn Available for Patients with Hereditary Antithrombin Deficiency, a Rare Blood Clotting Disorder

Lundbeck Inc. offers recombinant antithrombin treatment option

May 6, 2009 – Lundbeck Inc., a wholly owned subsidiary of H. Lundbeck A/S in Denmark (LUN: Copenhagen Stock Exchange), announced today that ATryn® (Antithrombin [Recombinant]) is now available in the United States. In February 2009, the U.S. Food and Drug Administration (FDA) granted marketing approval of ATryn, developed through recombinant technology, for the prevention of peri-operative and peri-partum thromboembolic events in patients with hereditary antithrombin deficiency (HD AT), a rare and potentially fatal blood clotting disorder. ATryn is not indicated for treatment of thromboembolic events in hereditary antithrombin deficient patients. The product is marketed in the U.S. by Lundbeck Inc. and manufactured by GTC Biotherapeutics, Inc. (NASDAQ: GTCB).

Antithrombin is a naturally occurring protein that helps regulate the blood clotting mechanism in the body. People with hereditary antithrombin deficiency have lower than normal levels of antithrombin, putting them at increased risk for venous thromboembolic events (VTE), including pulmonary embolism and deep vein thrombosis, which can be life threatening, particularly in the high-risk situations of surgery or childbirth. Prior to the availability of ATryn, HD AT patients undergoing surgery or giving birth requiring an antithrombin therapy relied on a human plasma derived product. ATryn is not formulated with human plasma proteins.

“Lundbeck is pleased to bring ATryn to people living with this rare clotting disorder,” said Jeffrey S. Aronin, CEO, Lundbeck Inc. “As a recombinant form of antithrombin therapy, ATryn offers an alternative to human plasma-derived antithrombin. Lundbeck is well positioned to ensure a safe and reliable supply for those who need it, when they need it. In bringing ATryn to market, we remain committed to addressing the medical needs of orphan patient populations.”

Approximately one in 2,000 to one in 5,000 people have hereditary antithrombin deficiency. By the age of 50, approximately 50 percent of people with hereditary antithrombin deficiency will have experienced a VTE.

“ATryn may make a meaningful difference in the lives of patients with hereditary antithrombin deficiency who are at increased risk of blood clots, especially during major surgical procedures or childbirth,” said Dr. Stephan Moll, hematologist, University of North Carolina and Medical Director of the National Alliance for Thrombosis and Thrombophilia. “During these situations, the risk of a patient with hereditary antithrombin deficiency to develop a venous thromboembolism is increased about 20 times compared to the normal population.”

About ATryn

Developed and manufactured by GTC Biotherapeutics, ATryn was created to provide a safe and reliable supply of recombinant antithrombin. ATryn is made by processing the human antithrombin protein from the milk of a select herd of transgenic goats.

The process for producing ATryn involves scientists inserting DNA for the human antithrombin protein into a single-celled goat embryo. This embryo is implanted into a surrogate doe. The resulting transgenic offspring are able to produce high levels of human antithrombin in their milk.

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This protein is collected and purified from the milk to produce ATryn, which is administered to patients by intravenous infusion.

Purified recombinant antithrombin has the same amino acid sequence as antithrombin derived from human plasma. Antithrombin (Recombinant) and plasma-derived antithrombin both contain six cysteine residues forming three disulphide bridges and 3-4 linked carbohydrate moieties. The glycosylation profile of ATryn is different from plasma-derived antithrombin, which results in an increased heparin affinity. When assayed in the presence of excess of heparin the potency of the recombinant product is not different from that of plasma-derived product.

Indications and Usage:

ATryn [Antithrombin (Recombinant)] is indicated for the prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients. It is not indicated for *treatment* of thromboembolic events in hereditary antithrombin deficient patients.

Important Safety Information:

ATryn is contraindicated in patients with known hypersensitivity to goat and goat milk proteins. Allergic-type hypersensitivity reactions are possible. Patients must be closely monitored and carefully observed for any symptoms throughout the infusion period. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis. If these symptoms occur during administration, treatment must be discontinued immediately. Adding ATryn to or withdrawing ATryn from anticoagulants that use antithrombin to exert their anticoagulative effects may alter this effect. To avoid excessive or insufficient anticoagulation, coagulation tests suitable for the anticoagulant used (e.g., aPTT and anti-Factor Xa activity) are to be performed regularly, at close intervals, and in particular in the first hours following the start or withdrawal of ATryn. In such situations, patients should be monitored for the occurrence of bleeding or thrombosis.

The serious adverse reaction that has been reported in clinical studies is hemorrhage (intra-abdominal, hemarthrosis, and post procedural). The most common adverse events reported in clinical trials at a frequency of $\geq 5\%$ are hemorrhage and infusion site reaction.

For more information, please see full Prescribing Information at www.lundbeckinc.com.

About Lundbeck Inc.

Lundbeck Inc. was established in March 2009 following the acquisition of Ovation Pharmaceuticals, Inc. by H. Lundbeck A/S in Copenhagen, Denmark, and has proven success in developing and commercializing high-need treatments. The company is committed to providing innovative therapies that fulfill unmet medical needs of people with severe, and often rare, disorders for which few, if any, effective treatments are available. Lundbeck Inc. has been recognized for excellence in the global pharmaceutical and biotechnology industries with the 2009 North American Frost & Sullivan Award for Entrepreneurial Company of the Year and with the Scrip 2006 and 2007 "Pharma Company of the Year" award for small to mid-sized enterprises. More information about the company, its products and full prescribing information may be found at www.lundbeckinc.com.

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