FDA Advisory Committee Recommends GTC Biotherapeutics' ATryn* (antithrombin [Recombinant])

If approved, ATryn will be first recombinant human antithrombin available in the U.S.¹

Rockville, Md., January 9, 2009 – GTC Biotherapeutics ("GTC", NASDAQ: GTCB) and OVATION Pharmaceuticals, Inc. announced today that the Blood Products Advisory Committee of the U.S. Food and Drug Administration (FDA) voted that ATryn is safe and efficacious for the prevention and treatment of venous thromboembolism in hereditary antithrombin deficient patients undergoing surgery or childbirth procedures. The FDA considers the recommendations of its Advisory Committees when making its determinations. If approved, ATryn will be the first recombinant human antithrombin available in the U.S.¹

"We are very pleased with the Advisory Committee's recommendation in support of the safety and efficacy of ATryn," said Geoffrey F. Cox, Ph.D., GTC's Chairman and Chief Executive Officer. "ATryn is the first transgenically produced therapeutic to achieve approval in Europe and undergo review by the FDA. ATryn is also a testament to our established strength in recombinant technology, and has the potential to provide an important new treatment option for patients with hereditary antithrombin deficiency."

In September 2008, the FDA assigned Priority Review to GTC's Biologic License Application, or BLA, for ATryn.² Priority Review is granted to applications for products that, if approved, would provide significant advances in treatment or provide a treatment where no sufficient one already exists.³ Under Priority Review, the FDA's target date for action on the BLA is February 7, 2009. GTC has licensed ATryn to OVATION to develop and market it in the U.S.²

"The committee's recommendation takes us a step closer to making ATryn available to people in the U.S. with hereditary antithrombin deficiency, a rare clotting disorder associated with severe complications for which there are few treatment options," said Jeffrey S. Aronin, OVATION President and Chief Executive Officer. "Consistent with our overall focus on addressing unmet medical needs of small patient populations, bringing ATryn to market would give us the opportunity to make a meaningful difference in the lives of people suffering from this rare disorder."

Antithrombin works as a natural anticoagulant in the human body by regulating thrombin, which plays an important role in controlling the formation of blood clots.⁴ ATryn was developed with the key objective to provide the purity, safety and consistency of an unlimited supply of recombinant antithrombin.⁴ Purified recombinant antithrombin has the same amino acid sequence as antithrombin derived from human plasma.⁵

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ATryn is a registered trademark of GTC Biotherapeutics

People with hereditary antithrombin deficiency are at increased risk for venous blood clots, including pulmonary embolism and deep vein thrombosis. ⁴ The prevalence of hereditary antithrombin deficiency in the general population is approximately one in 2,000 to one in 3,000. ⁴ Half these patients may experience a thrombosis before 25 years of age ⁷ and based on one study, up to 85 percent may suffer a thromboembolic event by age 50. ⁸

About ATryn* (antithrombin [Recombinant])

ATryn is the first recombinant antithrombin product approved in the world and the first antithrombin product that has been approved through the centralized European Medicines Agency (EMEA) procedure in the European Union.⁹

ATryn is under review by the FDA for the prevention and treatment of peripartum and perioperative thromboembolic events in patients with hereditary antithrombin deficiency.⁷

The most common adverse events listed in the approved European labeling that may occur during ATryn treatment include dizziness, headache, bleeding, nausea, bleeding at injection site and increased bleeding during treatment.⁷ As with any intravenous protein product, allergic type hypersensitivity reactions are possible.

About GTC Biotherapeutics

GTC Biotherapeutics develops, supplies, and commercializes therapeutic proteins produced through transgenic animal technology. In addition to ATryn, GTC is developing a portfolio of recombinant human plasma proteins with known therapeutic properties. These proteins include recombinant forms of human coagulation factors VIIa, VIII, and IX, which are used for the treatment of hemophilia, and alpha-1 antitrypsin. GTC also has a monoclonal antibody portfolio that includes a monoclonal antibody to CD20 and a monoclonal antibody to CD137. GTC's intellectual property includes a patent in the United States through 2021 for the production of any therapeutic protein in the milk of any transgenic mammal. GTC's transgenic production platform is particularly well suited to enabling cost effective development of proteins that are difficult to express in traditional recombinant production systems as well as proteins that are required in large volumes. Additional information is available on the GTC web site, http://www.gtc-bio.com.

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the timing of the FDA's review of the BLA for ATryn. Such forward-looking statements are subject to a number of risks, uncertainties and other factors that could cause actual results to differ materially from future results expressed or implied by such statements. Factors that may cause such differences include, but are not limited to, the risks and uncertainties discussed in GTC's most recent Annual Report on Form 10-K and its other periodic reports filed with the Securities and Exchange Commission, including the uncertainties associated with dependence upon the actions of regulatory agencies.

GTC cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this document, and GTC undertakes no obligation to update or revise the statements, except as may be required by law.

About OVATION Pharmaceuticals

OVATION is a fast growing biopharmaceutical company that develops and commercializes medically necessary therapies to satisfy unmet medical needs for patients with severe illnesses. Headquartered in Deerfield, Ill., with products available in more than 85 countries, OVATION is committed to having a significant impact on patients' lives through its focus on central nervous system (CNS), hematology/oncology, and hospital-based therapies. The three new launches the company expects over the next three years will be fueled largely by its late-stage CNS pipeline, which is one of the most robust in the industry. OVATION has been recognized for excellence in the global pharmaceutical and biotechnology industries with the 2006 and 2007 "Pharma Company of the Year" award from Scrip magazine for small to mid-sized enterprises. More information about the company, its products and full prescribing information may be found at www.ovationpharma.com.

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CONTACT:

GTC Biotherapeutics, Inc.
Thomas E. Newberry
Vice President, Corporate Communications and Government Relations
(508) 370-5374 or tom.newberry@gtc-bio.com

OVATION Pharmaceuticals, Inc.
Sally Benjamin Young
Vice President of Communications
(847) 727-3265 or syoung@OvationPharma.com

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