



Talecris Biotherapeutics
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News release

Talecris Biotherapeutics to Add Pathogenic Prion Removal Verification to Thrombate III[®] Labeling

FDA-approved labeling reinforces Talecris' leadership in pathogen safety research and manufacturing applications for protein therapies

RESEARCH TRIANGLE PARK, N.C. (July 6, 2006) — Talecris Biotherapeutics announced today that the Food and Drug Administration (FDA) has approved new product labeling language for Thrombate III[®] (Antithrombin III [Human]), the only FDA-approved therapy for hereditary antithrombin III (AT-III) deficiency. The new labeling, currently under revision to incorporate the FDA-approved language, provides reasonable assurance for patients and healthcare providers that the manufacturing process for Thrombate III[®] removes the risk of low levels of infectivity from pathogenic prions. The new labeling also reaffirms the proven safety profile of Thrombate III[®], derived from 14 years of clinical experience.

“This is another important milestone for Talecris Biotherapeutics, and particularly for our outstanding pathogen safety team, in demonstrating our relentless efforts to produce protein therapies with the highest possible margin of safety,” said Steve Petteway, Ph.D., Senior Vice President, Research and Development at Talecris Biotherapeutics, and a renowned expert on pathogenic prion clearance research.

The labeling approval is the result of continued industry-leading pathogen safety research and manufacturing applications by Talecris. Specifically, Talecris has demonstrated that potential infection risk from pathogenic prions, including those associated with variant Creutzfeldt-Jakob Disease (vCJD, the human form of “Mad Cow”) is significantly reduced during the manufacturing process in the unlikely event such prions are present in the plasma starting material.

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The new labeling was approved based on studies conducted with an experimental agent of transmissible spongiform encephalopathy, considered to be a model for vCJD, demonstrating that 6.0 log₁₀ are removed (99.9999% of any pathogenic prions present).

Available since 1992, Thrombate III[®] has demonstrated a safety and efficacy record that includes infusion of more than 220,000 vials without a single documented case of infectious disease transmission. Talecris pathogen safety scientists continue to set standards for donor screening processes, plasma testing, and manufacturing processes which remove or inactivate known and emerging infectious agents.

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About Thrombate III[®] and Hereditary AT-III Deficiency

Thrombate III[®] is concentrated human antithrombin III (AT-III) from human blood plasma and is the only FDA-approved product for the treatment of hereditary antithrombin III (AT-III) deficiency. It is indicated for the treatment of patients with hereditary AT-III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism. Thrombate III[®] therapy has demonstrated a low occurrence of side effects. In clinical studies with Thrombate III[®], the most common side effects were dizziness, chest tightness, nausea and chills. As with all plasma derived therapeutics, the potential to transmit infectious agents, such as viruses, cannot be totally eliminated. Individuals who receive infusions of blood or blood plasma may develop signs and/or symptoms of some viral infections, particularly hepatitis C. For additional information on Thrombate III[®], please see full prescribing information at www.thrombate.com/balance.

Hereditary AT-III deficiency is a genetic disorder that prevents the body from producing AT-III, an important factor in normal blood anticoagulation and the major plasma inhibitor of thrombin. It is estimated to affect one in 2000 to 5000 people in the general population. Because AT-III is an important anticoagulant present in blood that prevents abnormal clotting, persons with missing or deficient AT-III are at significantly increased risk for thrombosis and embolism, particularly in high-risk situations such as surgery and obstetric procedures. Episodes of thrombosis and pulmonary embolism usually occur after the age of 20 and increases with age and in association with surgery, pregnancy, and delivery. Greater than 85 percent of AT-III deficient individuals will have at least one thrombotic episode and thrombosis will recur in 60 percent of these patients. Thromboembolic events during pregnancy have been reported to be 70 percent.

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About Talecris Biotherapeutics

Talecris Biotherapeutics is a global biotherapeutic and biotechnology company that discovers, develops and produces critical care treatments for people with life-threatening disorders in a variety of therapeutic areas including immunology, pulmonology, and hemostasis. Talecris is proudly building upon a 60-year legacy of innovation and a commitment to improving the lives of people who rely on its therapeutic products. With an emphasis on scientific inquiry and technological excellence, Talecris is expanding its current portfolio of products, programs, and services through its own world-class product development organization as well as through strategic initiatives that leverage its strengths with those of its partners.

Talecris, which earned revenues of approximately \$1 billion in 2005, is headquartered in biotech hub Research Triangle Park, N.C., and employs more than 1,800 talented people. To learn more about Talecris and how our employees are making a difference in the lives of patients and the healthcare community, visit www.talecris.com.

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