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News release

Labeling for Gamunex® now Includes Assurances of Removal of Pathogenic Prions During Manufacture

First liquid IGIV therapy to carry FDA-approved labeling for TSE removal demonstrates continued Talecris leadership in pathogen safety

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RESEARCH TRIANGLE PARK, N.C. (July 7, 2005) — Product labeling for Gamunex® (Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified) now contains data demonstrating the capacity of several unique steps in the manufacturing process to remove pathogenic prions, such as those associated with the development of variant Creutzfeldt-Jakob Disease (vCJD). This is the first such approval from the Food and Drug Administration (FDA) for a liquid IGIV (immune globulin [intravenous]) product and demonstrates Talecris Biotherapeutics' continuing leadership in the area of pathogen safety. The new labeling provides quantitative information demonstrating a high margin of safety for Gamunex® against emerging pathogens, such as the abnormal pathogenic prion proteins associated with "Mad Cow" disease and vCJD in humans, creating additional confidence for patients and treaters.

The labeling states that the manufacture of Gamunex®, which incorporates the innovative Caprylate/Chromatography process for improved product purity and prolonged biological activity, provides reasonable assurance that potential infection risk is significantly reduced from pathogenic prions associated with Transmissible Spongiform Encephalopathies (TSEs), such as vCJD, in the unlikely event they are present in donated plasma. The labeling is a result of the industry-leading Talecris research with experimental agents, considered to be models for these pathogenic prions, demonstrating these agents are removed by several individual steps within the production process including cloth filtration and depth filtration.

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Results from extensive Talecris research programs confirm that these steps have a high capacity for removing pathogenic prions (≥ 6.6 logs, or removal of greater than 99.9999% of any pathogenic prions present). Furthermore, Talecris research has proven removal through two separate tests, Western Blot and standard bioassay.

“This is very reassuring, comforting news for the community of patients and their treaters who rely on IGIV therapy,” said Fred Modell, who, with his wife Vicki, co-founded the Jeffrey Modell Foundation. “Now more than ever, product safety is always an important issue, and we are appreciative of the ongoing pathogen safety research and manufacturing applications undertaken by Talecris and any other manufacturers engaging in this initiative to assure optimum safety.”

The continuing commitment to pathogen safety is exemplified by more than 25 years of clinical experience with liquid IGIV without a confirmed case of pathogen transmission. Talecris Biotherapeutics’ industry-leading work to assure removal of pathogenic prions from plasma-based therapeutic proteins began as early as 1995 (then known as Bayer Biological Products). In addition to applying the strictest donor screening and testing procedures, Talecris has carried out extensive research programs to confirm that the manufacturing processes of its plasma-derived protein products have a high capacity for removing pathogenic prions (greater than 99.9999% removal capacity). This research has been consistently published in peer-reviewed journals and has included development of their patented test (a Western Blot Assay) allowing for rapid and accurate determination of pathogenic prion removal during the manufacturing process. Because of their commitment to industry-wide safety of biological products, Talecris scientists made the Western Blot Assay available commercially so other manufacturers also can use it to determine the safety profiles of their products. Work done by Talecris scientists in this area paved the way for manufacturers to submit data to the FDA allowing product labeling claims regarding prion clearance.

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The work done with pathogenic prions reflects Talecris' overall commitment to assure product safety and reliability and provide assurance its products are safe from known as well as emerging pathogens including enveloped viruses such as West Nile and Vaccinia virus and potentially emerging enveloped viruses, such as monkeypox and SARS. Talecris scientists focus on providing robust empiric evidence that pathogen clearance and inactivation processes are effective, as well as understanding the mechanisms of action for those clearance processes.

Talecris' Steve Petteway, Ph.D., Senior Vice President, Research and Development, a world-renowned expert on TSE clearance issues, has served on the FDA's Transmissible Spongiform Encephalopathies Advisory Committee since 2001 because of his recognized expertise in this area. Dr. Petteway commented on Talecris' commitment to pathogen safety research.
"At Talecris, pathogen safety is a fully integrated component of any process we develop. The Caprylate process we developed for Gamunex® (Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified) is an example of that. Our work to demonstrate removal of pathogenic prions, resulting in this new labeling information for Gamunex®, reflects our continuing commitment to invest in research and technologies designed to deliver the highest possible margin of safety for products."

Another example of the Talecris commitment to pathogen safety is the recent FDA approval for in-house nucleic acid testing (NAT) for hepatitis B virus (HBV) in source plasma. NAT testing is the state-of-the-art for pathogen detection, and Talecris is the only fractionator conducting in-house NAT testing on source plasma for human immunodeficiency virus (HIV), hepatitis C (HCV), and HBV using FDA-approved tests. Further, Talecris is the only laboratory licensed by FDA to test for HBV in plasma using NAT. This provides Talecris with even greater control in establishing the safety of its plasma donations, above and beyond the strict standards and protocols already in place for the screening and donation process.

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About Gamunex®

Gamunex® (Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified) is a lifesaving IGIV therapy that contains antibodies purified from the donated blood plasma of thousands of people and is used to treat a variety of health problems, both as a means of immune replacement and for modulating the immune system. In patients with primary immune deficiency disease (PIDD), Gamunex® provides antibodies, which are not produced by the patient's body. Gamunex® is also indicated as a treatment for patients with idiopathic [immune] thrombocytopenic purpura (ITP), in which it acts as an immune modulator, regulating the platelet count.

Gamunex® is indicated for the treatment of primary humoral immunodeficiency and idiopathic thrombocytopenic purpura. The most common side effects noted during clinical trials included headache, vomiting, fever, nausea, rash, and back pain. For additional information on Gamunex®, see Full Prescribing Information at *www.gamunex.com.*

The Talecris Commitment to Innovation and Reliable Supply

Because the production method determines the efficacy, tolerability, and safety of an IGIV product, Gamunex® was developed using a "clean sheet" approach to create a completely new and optimal production process for the IGIV therapy. This innovative process includes breakthrough purification steps using Caprylate/Chromatography that improve product purity and also help preserve the biological activity of the product by replacing the solvent-detergent method used in previous generations of IGIV products.

To support the regulatory approvals of Gamunex® in the United States, Canada, and Germany, the largest and most rigorous clinical trials program in IGIV history were conducted, demonstrating excellent efficacy, safety, and tolerability of Gamunex® compared to Gamimune® N, 10% (Immune Globulin Intravenous [Human], 10%) in patients with ITP and PIDD.

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More than $250 million have been invested in a new state-of-the-art production facility designed and built around the new manufacturing process for Gamunex® (Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified). The facility is the first of its kind dedicated solely to the production of IGIV, allowing Talecris Biotherapeutics to produce a safe and reliable supply of Gamunex®. Since 2001, IGIV releases to the United States have increased by 46%, and to continue meeting increasing demand for product, Talecris increased supply to the U.S. market by 14% from 2003 to 2004. In 2005, we have taken action to further increase production of Gamunex® including processing additional liters of plasma.

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About Talecris Biotherapeutics
Talecris is a newly formed company with the assets and history of Bayer HealthCare Biological Products Division's plasma business. With global headquarters in Research Triangle Park, N.C., primary manufacturing facilities for Talecris products in Clayton, N.C., and additional fractionation and manufacturing facilities of Precision Pharma Services in Melville, N.Y, Talecris employs nearly 1,700 people.

Inheriting a legacy of more than 60 years of providing lifesaving and life-enhancing plasma-derived therapeutic proteins, Talecris is well positioned to become recognized as the global leader in developing and delivering premium protein products. Through its people, technology, and state-of-the-art facilities, Talecris will build on this long history of innovation through a focused, entrepreneurial approach to new product development, application of cutting-edge manufacturing technologies, and marketing and customer service. Talecris is talented industry professionals providing critical care treatments and services for patients, while maintaining a vision for the future of care.

Information about Talecris can be found at *www.talecris.com*. To receive e-mail updates when new information is added to the Talecris Web site, please register at *www.talecris.com/media_contact.cfm.*

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