FDA Approves Biotest’s BIVIGAM™, an Intravenous Immune Globulin (Human), 10% liquid

Dreieich, Germany and Boca Raton, Florida December 20, 2012: Biotest AG announced today that Biotest Pharmaceuticals Corporation received approval for Bivigam™ for the treatment of patients with Primary Humoral Immunodeficiency (PI) from the U.S. Food and Drug Administration (FDA) yesterday evening. Bivigam™ is the first polyclonal intravenous immune globulin manufactured in the U.S. by Biotest Pharmaceuticals Corporation (BPC) at its Boca Raton, Florida facility. This product is being produced for patients in the United States and the company plans to begin commercial shipments shortly.

Prof. Dr. Gregor Schulz, CEO of Biotest AG said: “Biotest has made a significant commitment in the U.S. to bring a new immune globulin to individuals with primary immunodeficiency. We have invested over $50 million to create a state-of-the-art facility and have expanded our U.S. capabilities from plasma collection to protein purification and product distribution. BPC will eventually produce up to 1.5 million grams (= 1.5 tons) of Bivigam™ in the U.S. facility. We look forward to providing this therapy to patients in the U.S. This will be another milestone in Biotest’s long legacy of providing immune globulin products to patients around the globe”.

The U.S. IVIG market is the largest in the world and Biotest’s entry into this market fulfills the company’s longstanding vision of being a significant global participant. Biotest formed BPC as a U.S. subsidiary in 2007, with the purchase of Nabi Biopharmaceuticals biologics strategic business unit which included a plasma protein plant and plasma collection centers. Today’s approval represents a sales potential of $100 million for BPC.

Marcia Boyle, President & Founder of the Immune Deficiency Foundation, the national patient organization for persons with primary immunodeficiency diseases, commented, “We commend Biotest for its significant commitment and investment in the development of Bivigam™. Its launch provides a new product to our community, helping to assure continued access to this lifesaving therapy for people who live with primary immunodeficiency diseases. We welcome Bivigam™ as a valuable option to help members of our community live healthy and productive lives.”

The Bivigam™ pivotal clinical study successfully achieved its primary endpoints for safety, efficacy and tolerability and the results were recently published in the Journal of Clinical Immunology (Wassermann RL, Church JA, Stein M, et al. Safety, efficacy and pharmacokinetics of a new 10% liquid intravenous
immunoglobulin (IVIG) in patients with primary immunodeficiency. Journal of Clinical Immunology. (See Open access at http://dx.doi.org/10.1007/s10875-012-9656-5).

Bivigam™ is a sugar-free, glycine stabilized intravenous immune globulin that was approved by the FDA on December 19, 2012 and is available in 50 mL (5 gram) and 100 mL (10 gram) tamper-evident vials. The product uses a label with an integrated hanger and the packaging material is latex free. For Full Prescribing Information and more information about the product, the indication and additional services, please visit www.BIVIGAM.com. For ordering information, please contact customer support at 1.800.458.4244 and select Option 1.

Disclaimer

This document contains forward-looking statements on overall economic development as well as on the business, earnings, financial and assets position of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and are thus subject to risks and elements of uncertainty that could result in significant deviation of actual developments from expected developments. The forward-looking statements are only valid at the time of publication. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

About Biotest

Biotest is a provider of pharmaceutical and biotherapeutic drugs. With a value added chain that extends from pre-clinical and clinical development to worldwide sales, Biotest has specialised primarily in the areas of application of clinical immunology, haematology and intensive medicine. In its Plasma Protein portfolio Biotest develops and markets immunoglobulins, coagulation factors and albumins based on human blood plasma. These are used for diseases of the immune and haematopoietic systems. Biotest also researches into the clinical development of monoclonal antibodies, including in the indications of rheumatoid arthritis and cancer of plasma cells. Biotest has more than 1,600 employees worldwide. The preference shares of Biotest AG are listed in the SDAX on the Frankfurt stock exchange.

About Biotest Pharmaceuticals Corporation

Biotest Pharmaceuticals Corporation was created as a wholly-owned US subsidiary of Biotest AG in December 2007. Innovative technologies and a sharp focus on safety are incorporated into every facet of the business. From plasma collection to product manufacturing and distribution – from nature for life – Biotest Pharmaceuticals Corporation is committed to maintaining these same high standards of excellence. For inquiries about the US market, please contact Biotest Pharmaceuticals, 561-989-5800

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