Kedrion Biopharma Expands Immunoglobulin Therapies Portfolio, Gains Commercial Rights in the U.S. to BIVIGAM®, a Recently Approved IGIV Brand

- Kedrion Biopharma Inc., established in the U.S. market in 2011, is an emerging player in the rare disease arena
- The Company aims to build business rapidly through ongoing organic growth of its brand portfolio and strategic partnerships with other industry leaders
- Gaining rights to commercialize BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid], is the newest partnership that Kedrion Biopharma has finalized in the U.S.; Kedrion Biopharma acquired RhoGAM® Ultra-Filtered PLUS [Rho(D) Immune Globulin (Human)] (300 μg) in 2012 and owns rights globally
- The BIVIGAM license will be retained by Biotest Pharmaceuticals Corporation

In a move to expand on its growing presence within the United States, Kedrion Biopharma today announced it has gained exclusive rights to commercialize another immunoglobulin (IG) brand—BIVIGAM, a 10 percent liquid licensed by Germany-based Biotest Pharmaceuticals Corporation (ETR:BIO). Kedrion Biopharma Inc. is the U.S. subsidiary of Kedrion Biopharma, a world leader in the development and manufacture of therapeutic plasma proteins, headquartered in Lucca, Italy.

BIVIGAM, the most recent entrant into the U.S. immunoglobulin market, was approved by the U.S. Food and Drug Administration in December, 2012 for the treatment of primary humoral immunodeficiency (PI). Kedrion Biopharma will re-launch BIVIGAM in the U.S. in January, 2016.

The addition of BIVIGAM to the Kedrion Biopharma portfolio expands the company’s immunoglobulin portfolio in the United States. Given the well-established and robust network of distributors associated with Kedrion Biopharma, patients who require BIVIGAM will now have improved access to this brand.

“The number of people being treated for primary immunodeficiency, or PI, continues to rise year after year, thanks to recent and important advances in the awareness and diagnosis of this rare and serious disorder,” said Paolo Marcucci, President and Chief Executive Officer of Kedrion Biopharma. “We also know that PI tends to affect different individuals in various ways. For this reason, it is important for patients and their caregivers to have multiple treatment options from which to choose. We are delighted to now have the opportunity to bring BIVIGAM to patients with PI, while also becoming more deeply engaged every day with the rare disease communities in the United States. This is an exciting time for Kedrion Biopharma.”
Analysts forecast the global market for immunoglobulin will grow at an estimated compound annual growth rate of 6.9 percent, to $5.8 billion by 2019. The United States accounts for the largest share, with 71.4 percent. Following a high number of product approvals between 2003 and late 2012, the United States market witnessed a growth rate of 5.7 percent, from $1.8 billion in 2006 to $2.6 billion in 2012, and is estimated to reach $4 billion by 2019.

About Kedrion Biopharma

Kedrion Biopharma is an international company that collects and fractionates blood plasma to produce and distribute plasma-derived therapeutic products for use in treating and preventing serious diseases, disorders and conditions such as hemophilia, immune system deficiencies and Rh sensitization. Kedrion Biopharma Inc, the US subsidiary of Kedrion Biopharma, is headquartered in Fort Lee, New Jersey. Kedrion Biopharma launched US operations in 2011, but the company’s international roots stretch back several decades in the production of blood and plasma-derived products. Kedrion Biopharma places a high value on the welfare of those who benefit from its products, as well as on the people and the communities it serves. Additional information about Kedrion Biopharma can be found at www.kedrion.com and www.kedrion.us.

About Biotest

Biotest is a global company that supplies plasma protein products and biotherapeutic drugs. Our products are primarily used in the therapeutic areas of clinical immunology, haematology and intensive care medicine. Within our areas of specialization, we start from pre-clinical and clinical development to manufacturing and global marketing. Biotest manufactures medicinal preparations derived from human blood plasma using advanced biotechnological processes. Biotest develops and markets these immunoglobulin preparations, coagulation factors and albumins, which are used in the treatment of immune systems disorders and haematopoietic diseases. In addition, Biotest also investigates several monoclonal antibodies for the treatment of autoimmune diseases, including rheumatoid arthritis, and cancers of the blood, including multiple myeloma. Additional information about Biotest can be found at www.biotest.com and www.biotest.de.

Kedrion Biopharma Immunoglobulin Portfolio: Expanded to Include Four Brands

The partnership announced today brings the total number of immunoglobulin (IG) therapies in the Kedrion Biopharma portfolio to four. The Company already owns the rights to market Gammaked™, [Immune globulin injection (human), 10% caprylate/chromatography purified], a sucrose-free IG therapy indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP), primary immunodeficiency (PI) and idiopathic thrombocytopenic purpura (ITP). The Company also markets RhoGAM® Ultra-Filtered PLUS [Rh(D) Immune Globulin (Human)] (300 µg) and MICRhoGAM® Ultra-Filtered PLUS [Rh(D) Immune Globulin (Human)] (50 µg).
About Primary Immunodeficiency

Primary immunodeficiency diseases (PI) are a group of more than 250 rare, chronic disorders in which part of the body’s immune system is missing or functions improperly. These diseases, which are not contagious, are caused by hereditary or genetic defects, and, although some disorders present at birth or in early childhood, the disorders can affect anyone, regardless of age or gender. Some affect a single part of the immune system; others may affect one or more components of the system.

And while the diseases may differ, they all share one common feature: each disease results from a defect in one of the functions of the body’s normal immune system. Because one of the most important functions of the normal immune system is to protect us against infection, patients with PI commonly have an increased susceptibility to infection.

About BIVIGAM

Warning: Thrombosis may occur with immune globulin intravenous (IGIV) products, including BIVIGAM. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, a history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors. Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. BIVIGAM does not contain sucrose. For patients at risk of thrombosis, renal dysfunction, or renal failure, administer BIVIGAM at the minimum dose recommended and infusion rate practicable. Ensure adequate hydration in patients before administrations. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. See full Prescribing Information for complete boxed warning.

BIVIGAM [Immune Globulin Intravenous (Human), 10% Liquid] is indicated for the treatment of primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. BIVIGAM is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and history of hypersensitivity. Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV therapy. Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments; AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV. As hemolysis can develop subsequent to treatment with IGIV products, monitor patients for hemolysis and hemolytic anemia. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). If TRALI is suspected, test the product and patient for antineutrophil antibodies. Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
Serious adverse reactions observed in clinical trial subjects receiving BIVIGAM were vomiting and dehydration in one subject. The most common adverse reactions to BIVIGAM (reported in ≥ 5% of clinical study subject) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increase, diarrhea, dizziness, and lethargy.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. For more information about BIVIGAM please see full Prescribing Information.

About GAMMAKED

Warning: Thrombosis may occur with immune globulin products, including GAMMAKED. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer GAMMAKED at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. Renal dysfunction, acute renal failure, osmotic nephrosis and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. GAMMAKED does not contain sucrose. For patients at risk of renal dysfunction or failure, administer GAMMAKED at the minimum concentration available and the minimum infusion rate practicable. See full Prescribing Information for complete boxed warning.

GAMMAKED is a 10% liquid immune globulin injection (human) indicated for the treatment of Primary Humoral Immunodeficiency (PI), Idiopathic Thrombocytopenic Purpura (ITP), and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). GAMMAKED is contraindicated in individuals with acute severe hypersensitivity reactions to Immune Globulin (Human). GAMMAKED is also contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity. IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions. Monitor renal function, including blood urea nitrogen, serum creatinine, and urine output in patients at risk of developing acute renal failure. Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV therapy.

Thrombotic events have been reported in association with IGIV. Patients at risk for thrombotic events may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization and/or known or suspected hyperviscosity.

Aseptic Meningitis Syndrome (AMS) has been reported with GAMMAKED and other IGIV treatments, especially with high doses or rapid infusion. There have been reports of
noncardiogenic pulmonary edema [Transfusion-Related Acute Lung Injury (TRALI)], hemolytic anemia, and aseptic meningitis in patients administered IGIV. The high dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern. GAMMAKED is made from human plasma. Because this product is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. GAMMAKED is not approved for subcutaneous use in ITP patients. Due to a potential risk of hematoma formation, do not administer GAMMAKED subcutaneously in patients with ITP. Serious adverse reactions which occurred in the clinical trials were an exacerbation of autoimmune pure red cell aplasia in one subject and pulmonary embolism in one subject with a history of PE. The most common adverse reactions observed in ≥5% patients were:

PI: Intravenous: Headache, cough, injection site reaction, nausea, pharyngitis and urticaria.

Subcutaneous: Infusion site reactions, headache, fatigue, arthralgia and pyrexia.

ITP: Headache, vomiting, fever, nausea, back pain and rash.

CIDP: Headache, fever, chills, hypertension, rash, nausea and asthenia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. For more information about GAMMAKED please see full Prescribing Information.

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Media Contact: Sheila A. Burke Health Biz Write Now, LLC 484 667 6330 (US)