FDA Approves Bio Products Laboratory's Gammaplex® 10% for Treatment of Primary immunodeficiency and Chronic Immune Thrombocytopenic Purpura

ELSTREE, UK AND DURHAM, NC – FEBRUARY 7, 2017 - Bio Products Laboratory Limited (BPL), a leading manufacturer of plasma-derived protein therapies, today announced that the U.S. Food and Drug Administration (FDA) has approved Gammaplex® 10% (immune globulin intravenous [human], 10% liquid) for the treatment of primary immunodeficiency (PI) and chronic immune thrombocytopenic purpura (ITP) in adults. Gammaplex 10% is made with the same process as BPL's previously approved intravenous immunoglobulin (IVIG) treatment, Gammaplex® 5% (immune globulin intravenous [human], 5% liquid). Gammaplex 10% is more concentrated than Gammaplex 5%, with an immune globulin G (IgG) concentration of 100g/L, and is stabilized with glycine.

"BPL is pleased to have played a role in the treatment of patients with PI in the U.S. since 2009," said Eric Wolford, PharmD, Vice President of Global Medical Affairs for BPL. "As we developed this new treatment option, it was important that we created a unique study design that would provide new safety and tolerability data for patients and healthcare providers to consider when they choose an IVIG product."

The approval was based on a two-phase, crossover bioequivalence study comparing Gammaplex 10% and Gammaplex 5% in 33 adult patients with PI. The primary endpoint of bioequivalence between the products was achieved and trough levels of IgG were well maintained throughout the study. This study is the first direct comparison of 10% and 5% IVIG products in the treatment of PI.

In the study both Gammaplex 10% and Gammaplex 5% infusion rates were increased incrementally at 15-minute intervals if tolerated by the subject. No notable differences were observed in the safety and tolerability between the products and the Gammaplex 10% infusion rate was increased per the prescribed infusion schedule to maximum infusion rate in 96% of infusions. The mean infusion time for Gammaplex 10% in adult patients was 1 hour and 51 minutes, which was 57 minutes faster than Gammaplex 5%.

The most common adverse reactions in adult subjects receiving Gammaplex 10% in the PI clinical trial were headache (12.5% of subjects), migraine (6.3%), and pyrexia (6.3%). There were no serious product-related adverse reactions in the PI clinical trial.

The safety of Gammaplex 10% has not been established in patients with ITP. The safety profile for Gammaplex 5% has been studied in subjects with ITP, and it is anticipated that the safety profile for both formulations are comparable for ITP patients. The most common adverse reactions in adult subjects receiving Gammaplex 5% in the chronic ITP clinical trial were headache, vomiting, nausea, pyrexia, arthralgia, and dehydration. Serious adverse reactions observed in clinical trial subjects with ITP were headache, vomiting and dehydration.

Primary immunodeficiencies are a constellation of immune disorders that can negatively impact the body's ability to fight infection. In some primary immunodeficiencies the immune system does not manufacture adequate quantities of antibodies such as IgG. Gammaplex 10% acts as replacement therapy in these patients.

"Patients with PI want an IVIG product that is effective in reducing infections and well-tolerated during infusions," said Richard L. Wasserman, M.D., PhD, Medical Director of Pediatric Allergy and Immunology at Medical City Children's Hospital, Dallas, Texas and Gammaplex 10% clinical trial investigator. "Gammaplex 10% may meet these criteria for many patients. Significantly, the product was directly compared to another IVIG formulation in a study protocol that specified infusion rate increases every 15 minutes. This rate escalation schedule may reduce infusion time for patients."

For more information on Gammaplex 10% please visit www.gammaplex.com or call 1-844-4BPLUSA.

About Gammaplex 10%

Gammaplex 10% (immune globulin intravenous [human], 10% liquid) is indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Gammaplex 10% is also indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) in adults.

Gammaplex 10% is contraindicated in patients who have had a history of anaphylactic or severe systemic reactions to human immune globulin and IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

Please see the additional Important Safety Information about Gammaplex 10% below, and the full prescribing information at http://www.gammaplex.com.

Important Safety Information

Thrombosis may occur with immune globulin products, including Gammaplex 10%. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive immune globulin intravenous (IGIV) products, including Gammaplex 10%.

Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Gammaplex 10% does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction or acute renal failure, administer Gammaplex 10% 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.

Gammaplex 10% is contraindicated in patients who have had a history of anaphylactic or severe systemic reactions to human immune globulin and IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor renal function, including blood urea nitrogen (BUN), serum creatinine and urine output. Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV therapy.

Aseptic meningitis syndrome (AMS) may occur infrequently with IGIV treatment. AMS usually begins within several hours to 2 days following IGIV treatment. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

Hemolysis and hemolytic anemia can develop subsequent to IGIV treatments. Patient risk factors that may be associated with development of hemolysis include high dose (>2 g/kg), non-O blood group, and underlying inflammatory state. Noncardiogenic pulmonary edema may occur in patients following IGIV treatment (i.e. transfusion-related acute lung injury [TRALI]). Monitor patients for pulmonary adverse reactions. If TRALI is suspected, test product and patient's serum for anti-neutrophil antibodies.

Gammaplex 10% is made from human plasma and may contain infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent. No cases of transmission of viral diseases or CJD have been associated with the use of Gammaplex 10%.

The most common adverse reactions in adult subjects receiving Gammaplex 10% in the PI clinical trial were headache, migraine, and pyrexia. There were no serious product-related adverse reactions observed in adult clinical trial subjects with PI. The safety of Gammaplex 10% has not been established in patients with ITP. However, the safety profile for Gammaplex 5% has been studied in subjects with ITP, and it is anticipated that the safety profile for both formulations are comparable for ITP patients. The most common adverse reactions in adult subjects receiving Gammaplex 5% in the chronic ITP clinical trial were headache, vomiting, nausea, pyrexia, arthralgia, and dehydration. Serious adverse reactions observed in clinical trial subjects with ITP were headache, vomiting and dehydration.

About Bio Products Laboratory, Ltd.

Bio Products laboratory, Limited (BPL) is a leading manufacturer of plasma-derived protein therapies with global headquarters in Elstree, England, US headquarters in Durham, NC, and a presence in more than 45 countries worldwide. The company has over 60 years of experience developing and manufacturing plasma-derived therapies since being established as part of the Lister Institute in 1950, and currently markets a wide range of products, including coagulation factors, human immunoglobulins, and albumin. BPL is committed to continued investment in research and development to maintain its key position as a reliable supplier of high-quality products to patients and healthcare providers worldwide.

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