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ZLB Behring

VIRTUE clinical trial opens to primary immunodeficiency patients across the U.S.

Examines quality of life of patients on newly-approved vivaglobin

KING OF PRUSSIA, PA-September 12, 2006. ZLB Behring has announced the launch of the VIRTUE Trial, a Phase IV clinical trial of the study medication Vivaglobin„µ (Immune Globulin Subcutaneous, Human), the first and only U.S. Food and Drug Administration-approved subcutaneous immunoglobulin (Ig) treatment for patients with primary immunodeficiency (PI). VIRTUE [Vivaglobin Investigator Research Trial on Use and Experience], will evaluate patient satisfaction and annual rate of serious bacterial infection using Vivaglobin subcutaneous administration for one year after conversion from intravenous immunoglobulin therapy.

VIRTUE will enroll 100 PI patients at 50 sites across the country, making it the largest-ever trial of subcutaneous (i.e., under the skin) immunoglobulin therapy in the United States. Patients enrolled in the study will self-administer the study medication for one year. During the trial period, patients will be asked to assess overall health-related quality of life, comparing experience receiving the study medication and their previous intravenous treatment experience. Additionally, VIRTUE will identify which patients are more inclined to use SC treatment because of the improvement in their quality of life.

"Being able to self-administer Vivaglobin at home will add a great deal of flexibility and convenience to the lives of many patients who woni¦t have to go to the doctori¦s office any longer to receive their therapy," said Dr. Melvin Berger, Professor of Pediatrics and Pathology at Case Western Reserve University and one of the lead researchers for the trial. "Some patients suffering from PI may not be able to use IVIg because of poor venous access, intolerability or severe adverse effects. Other patients may be too busy or cannot afford to take the time off from work or school to get to an infusion center every three or four weeks. SC, or subcutaneous treatment, may benefit these patients."

The study medication, Vivaglobin, which was approved by the U.S. Food and Drug Administration in January of this year, is delivered directly under the skin via a small portable pump. In Phase III trials, the study medication was shown to be a safe and effective immunoglobulin replacement therapy for treating patients with PI. In those studies, 65 patients self-administered Vivaglobin at home every week for 12 months, for a total of 3,658 infusions. The annual rate of serious bacterial infections, the primary endpoint, was 0.04 infections per subject per year.

Patients in that trial who were assessed for health-related quality of life reported increases in general health and showed a preference for SC administration over IV administration. VIRTUE will increase the experience of physicians and patients with Vivaglobin. They will gain more data on SC treatment and how that impacts the quality of life for patients. In addition to comparing the historical IV experience of patients, researchers will be looking at adverse events and if SC treatment improves that area as well.

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VIRTUE is now accepting applications from individuals who wish to enroll. Interested patients should call 1-800-504-5434.

About the Study Medication

The study drug, Vivaglobin, is derived from human plasma. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be eliminated completely.

In clinical trials, the most frequent adverse event was injection-site reaction, consisting of mild or moderate swelling, redness and itching. No serious local site reactions were observed and reactions tended to decrease substantially after repeated use. Other adverse events included headache, gastrointestinal disorder, fever, nausea, sore throat and rash.

As with all immune globulin products, the study medication is not recommended for individuals with a history of anaphylactic or severe systemic response to immune globulin preparations and in persons with selective immunoglobulin A deficiency who have known antibody against IgA. If anaphylactic or anaphylactoid reactions are suspected, administration should be discontinued immediately. Patients receiving Ig therapy for the first time, receiving a new product or not having received Ig therapy within the preceding eight weeks may be at risk for developing reactions including fever, chills, nausea and vomiting. On rare occasions, these reactions may lead to shock. Such patients should be monitored in a clinical setting during the initial administration.

Ig administration can transiently impair the efficacy of live attenuated virus vaccines, such as measles, mumps and rubella. In clinical stuties, administration of Vivaglobin has been shown to safe and well tolerated in both adult and pediatric subjects. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels. Safety and efficacy were not studied in subjects under two years of age. For more information about Vivaglobin, please visit www.vivaglobin.com.

About Primary Immunodeficiencies

PIs are a group of usually genetic disorders that cause a malfunction in part or all of the immune system that prevents the patient from fighting off infections common everyday germs can cause. For individuals with PI, many of them children, infections may not improve with treatment as expected and may keep returning. As a result, patients may face repeated rounds of antibiotics or may be hospitalized for treatment. Repeated infections can lead to organ damage that over time can become life-threatening. In some severe cases of PI, infections may result in a patient being hospitalized repeatedly. Some infections such as meningitis could result in death.

About ZLB Behring

ZLB Behring is a global leader in the plasma protein biotherapeutics industry. Dedicated to improving the quality of life for patients throughout the world, ZLB Behring provides safe and effective plasma-derived and recombinant products and offers patients a wide range of related services. The company's broad portfolio of life-saving therapeutics is used in the treatment of individuals with hemophilia and other bleeding disorders, immune deficiency disorders and inherited emphysema; for the prevention of hemolytic diseases for the newborn; in cardiac surgery patients; and in shock and burn victims. Additionally, ZLB Behring operates one of the world's largest, fully owned plasma collection networks. ZLB Behring is a subsidiary of CSL Limited, a biopharmaceutical company that operates worldwide from its headquarters in Melbourne, Australia. For more information, please visit www.ZLBBehring.com.