FDA Approves New Dosing Option for CSL Behring’s Hizentra®

New Hizentra Label Provides Primary Immunodeficiency Patients
With the Flexibility to Self-Administer Their Treatment Less Frequently

King of Prussia, Pa.—September 27, 2013—CSL Behring announced today that the U.S. Food and Drug Administration (FDA) has expanded the administration options for Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid, to include dosing once every two weeks (biweekly) for people diagnosed with primary immunodeficiency (PI). Hizentra, the first and only 20 percent subcutaneous immunoglobulin, received FDA approval in March 2010 as a once weekly immunoglobulin G (IgG) replacement therapy. Self-administered weekly or biweekly, Hizentra delivers consistent levels of IgG to help protect those with PI against infections.

PI is a group of serious diseases of the immune system. Approximately 250,000 individuals (or one person per 1,200) in the U.S. are diagnosed with PI. Biweekly (every two weeks) dosing with Hizentra offers patients the same level of protection as weekly infusions, while providing users with the option of infusing less frequently. Moreover, because Hizentra can be stored at room temperature, it’s ready to use.

“To provide the best care to PI patients, therapy needs to be individualized to meet particular needs. Fortunately, today we have options on treatment administration, dose and dosing interval,” said Richard L. Wasserman, M.D., Ph.D., Clinical Professor of Pediatrics, University of Texas Southwestern Medical School. “With the approval of biweekly dosing, Hizentra provides PI patients with an additional option to be in greater control of their lives.”

FDA approval of biweekly (every two weeks) dosing for Hizentra is based on the principles of pharmacometrics and pharmacokinetic modeling.

“CSL Behring has long been at the forefront of developing Ig replacement therapy advances that provide healthcare professionals with the ability to individualize treatments to meet their patients’ lifestyle needs and preferences,” said Lynne Powell, Senior Vice President, North America Commercial Operations, CSL Behring. “We are extremely pleased to now offer PI patients the option of dosing Hizentra weekly or biweekly. This new dosing option underscores CSL Behring’s commitment to meeting the individual needs of patients who rely on our lifesaving therapies.”
About Primary Immunodeficiencies
More than 200 types of PIs exist. For individuals with PI, many of them children, infections may not improve as expected with usual treatments and may even keep returning. As a result, patients may face repeated rounds of antibiotics or hospitalization for treatment. Repeated infections can lead to organ damage, which over time can become life-threatening. Some infections, such as meningitis, can even result in death.

For more information on PI, please visit www.Hizentra.com or contact the leading PI patient advocate groups in the U.S., the Immune Deficiency Foundation and the Jeffrey Modell Foundation.

Important Safety Information
Immune Globulin Subcutaneous (Human), Hizentra®, treats various forms of primary immunodeficiency (PI) in patients age 2 and over.

WARNING: Thrombosis (blood clotting) can occur with immune globulin products, including Hizentra. Risk factors can include: advanced age, prolonged immobilization, a history of blood clotting or hyperviscosity (blood thickness), use of estrogens, installed vascular catheters, and cardiovascular risk factors.

If you are at high risk of thrombosis, your doctor will prescribe Hizentra at the minimum dose and infusion rate practicable and will monitor you for signs of thrombosis and hyperviscosity. Always drink sufficient fluids before administration.

Hizentra should not be used if you have had serious negative reactions to immune globulin (Ig) preparations or a deficiency of an Ig known as IgA. Because Hizentra contains the amino acid proline as stabilizer, patients with hyperprolinemia (too much proline in the blood) should not take Hizentra.

Infuse Hizentra under your skin only; do not inject into a blood vessel.

Allergic reactions can occur with Hizentra. If your doctor suspects you are having a bad allergic reaction or are going into shock, treatment will be discontinued. Immediately tell your doctor or go to the emergency room if you have signs of such a reaction, including hives, trouble breathing, wheezing, dizziness, or fainting.
Tell your doctor about any side effects that concern you. Immediately report symptoms that could indicate a blood clot, including pain and/or swelling of an arm or leg, with warmth over affected area; discoloration in arm or leg; unexplained shortness of breath; chest pain or discomfort that worsens with deep breathing; unexplained rapid pulse; and numbness or weakness on one side of the body. Your doctor will also monitor symptoms that could indicate hemolysis (depletion of blood red cells), and other potentially serious reactions that have been seen with Ig treatment, including aseptic meningitis syndrome (brain swelling); kidney problems; and transfusion-related acute lung injury.

The most common drug-related adverse reactions in the clinical trial for Hizentra were swelling, pain, redness, heat or itching at the site of injection; headache; back pain; diarrhea; tiredness; cough; rash; itching; nausea and vomiting.

Hizentra is made from components of human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

Before being treated with Hizentra, inform your doctor if you are pregnant, nursing or plan to become pregnant. Vaccines (such as measles, mumps and rubella) might not work well if you are using Hizentra. Before receiving any vaccine, tell the healthcare professional you are being treated with Hizentra.


You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**About CSL Behring**

CSL Behring is a leader in the plasma protein therapeutics industry. Committed to saving lives and improving the quality of life for people with rare and serious diseases, the company manufactures and markets a range of plasma-derived and recombinant therapies worldwide.

CSL Behring therapies are used around the world to treat coagulation disorders including hemophilia and von Willebrand disease, primary immune deficiencies, hereditary angioedema and inherited respiratory disease, and neurological disorders in certain markets. The company’s products are also used in cardiac...
surgery, organ transplantation, burn treatment and to prevent hemolytic diseases in the newborn. CSL Behring operates one of the world’s largest plasma collection networks, CSL Plasma. CSL Behring is a subsidiary of CSL Limited (ASX:CSL), a biopharmaceutical company headquartered in Melbourne, Australia. For more information, visit [http://www.cslbehring.com/](http://www.cslbehring.com/).

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