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

New Label Supports Individualized Therapy Through Greater Dosing Flexibility

From Daily to Once Every Two Weeks (Biweekly); Underscores CSL Behring’s Commitment to Improving Patients’ Lives

KING OF PRUSSIA, Pa. — February 02, 2015—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 the ability to individualize therapy with flexible dosing – treatment at regular intervals from daily to once every two weeks (biweekly) – for people with primary immunodeficiency (PI). Self-administered subcutaneously, Hizentra delivers consistent levels of immunoglobulin G (IgG) regardless of dosing schedule. Hizentra, the first and only 20 percent subcutaneous immunoglobulin, received FDA approval in March 2010 as a once-weekly IgG replacement therapy to help protect people with PI against infections and was approved for biweekly (once every two weeks) dosing in September 2013.

PI is a group of serious diseases that compromise the immune system, leaving patients particularly vulnerable to infection. Approximately 250,000 Americans (or one person per 1,200) have been diagnosed with PI.

“Patient preferences on infusion frequency, time and volume can differ for many reasons, so having a treatment option like Hizentra that can be customized to fit individual lifestyles is important to both patients and the physicians who treat them,” said Ralph S. Shapiro, M.D., Director of the Midwest Immunology Clinic. “Most important, flexible dosing options with Hizentra give PI patients the freedom to manage their condition based on their specific needs, while still providing a consistent level of protection against infections.”
FDA approval of flexible dosing for Hizentra is based on pharmacometrics (modeling and simulation). Clinical trials using these alternative Hizentra dosing regimens were not conducted.

“CSL Behring understands that managing a life-long disorder can be challenging as patients’ lifestyles and treatment requirements may change over time,” said Bill Campbell, Senior Vice President, North America Commercial Operations, CSL Behring. “Offering PI patients the option of dosing Hizentra at regular intervals from daily to once every two weeks further underscores our commitment to providing treatment options that improve patients’ lives.”

For more information about Hizentra individualized therapy, please visit Hizentra.com/Individualize.

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.

Tell your doctor if you have had a serious reaction to other immune globulin medicines or have been told you also have a deficiency of the immunoglobulin called IgA, as you might not be able to take Hizentra. You should not take Hizentra if you know you have hyperprolinemia (too much proline in your blood).

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.

For full prescribing information for Hizentra, including the boxed warning and the patient product information, visit http://www.hizentra.com/consumer/prescribing-information.aspx.

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.

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 disease of the newborn.

CSL Behring operates one of the world’s largest plasma collection networks, CSL Plasma. CSL Behring is a global biopharmaceutical company and a member of the CSL Group of companies. The parent company, CSL Limited (ASX:CSL), is headquartered in Melbourne, Australia. For more information, visit http://www.cslbehring.com/.

###

**Media Contact:**
Greg Healy
CSL Behring
Office: 610-878-4841
Mobile: 610-906-4564
Greg.Healy@cslehring.com