2014 CSL Behring News Releases

20 February: **CSL Behring and CSL Plasma Employees Open Their Hearts to Those in Need**

20 February: **First patient enrolled in phase III of COMPACT, a study of volume-reduced subcutaneous C1-INH for prevention of Hereditary Angioedema (HAE) attacks**

1 March: **Patient Satisfaction and Convenience Increased with Current Hereditary Angioedema Treatment Options, According to Study Findings**

24 March: **Patient Advocates and Social Workers Will Be Trained on Intricacies of Affordable Care Act with CSL Behring Grant**

24 March: **CSL Behring Launches My Access™ Cost Share Program during Hemophilia Awareness Month**

17 April: **CSL Behring Continues Commitment to Donate Bleeding Disorder Medications to World Federation of Hemophilia**

2 May: **CSL Behring Enrolls First Patient in Global Pediatric Phase III Pivotal Study of Recombinant Factor VIII Single Chain (rVIII-SingleChain) to Treat Severe Hemophilia A**

7 May: **Feature Story: A Mother’s Health -- Having children while living with a rare disease (PI)**

9 May: **CSL Opens World-Class, Advanced Manufacturing Facility for Late-Stage Production of Hemophilia Therapies Now in Development**

12 May: **New Findings Support Less Frequent Dosing in Hemophilia B Patients Treated with Coagulation Factor IX with Recombinant Albumin (rIX-FP)**

14 May: **CSL Behring Proudly Supports HAE Day with Global Partnerships, Donations and Hereditary Angioedema Awareness Events**

20 May: **CSL Behring Launches Hizentra® Co-Pay Relief Program**

24 June: **CSL Behring Announces the 2014 Interlaken Leadership Awards Recipient**
30 July: **Study Suggests C1-INH May Aid in Prevention of Antibody-Mediated Rejection Following Kidney Transplant**

18 August: **Early Diagnosis of Children with Primary Immunodeficiencies Focus of National Awareness Campaign for School Nurses**

16 September: **CSL Behring Announces Last Patient Treated in Phase III Study of Fibrinogen Concentrate to Control Bleeding During Aortic Aneurysm Surgery**

30 September: **CSL Behring Expands Manufacturing Facility in Kankakee, Illinois to Meet Patients’ Growing Needs**

8 October: **CSL Behring Launches $450 Million Capacity Expansion to Meet Growing Need for Lifesaving, Life-Improving Therapies**

13 October: **Plasma Donors Recognized During International Plasma Awareness Week for Helping Save Lives**

28 October: **CSL Behring Signs Strategic Development Agreement with Enable Injections to Market Novel New Drug Delivery Device**

29 October: **CSL Behring Announces Winners of its 13th Annual Gettin’ in the Game℠ Junior National Championship Program**

30 October: **Evidence presented at the 16th Biennial Meeting of the European Society for Immunodeficiencies (ESID) Supports Individualized Dosing with Hizentra®**

10 November: **CSL Limited Launches AEGIS-I, a Phase 2b Clinical Study of CSL112, a Novel Apolipoprotein A-I Infusion Therapy Designed to Rapidly Remove Cholesterol from Arteries and Stabilize Plaque**

18 November: **CSL112 Found to Elevate Cholesterol Efflux in Patients with Coronary Artery Disease and Mechanism for Rapid Cholesterol Efflux Capacity Demonstrated**

1 December: **CMS Extends New Technology Add-On Payment for CSL Behring’s Kcentra®**

4 December: **CSL Issues “Our Corporate Responsibility 2014” Report**

4 December: **EMA Approves Amended Product Label for CSL Behring’s Hizentra®**

8 December: **One Woman's Story: Living and Helping Others with Inherited Lung Disorder**
16 December: CSL Behring Submits Biologics License Application for FDA Approval of Recombinant Fusion Protein Linking Coagulation Factor IX with Recombinant Albumin (rIX-FP) for Hemophilia B Patients
CSL Behring and CSL Plasma Employees Open Their Hearts to Those in Need

Year-round charitable giving includes over $700k to United Way

King of Prussia, PA — 20 February 2014

You can tell a lot about a company and its employees by the way they give back to the community. CSL Behring, its subsidiary, CSL Plasma and their employees do just that, year-round, supporting a wide range of organizations that provide services to people in need.

The annual United Way campaign is the company’s single largest charitable initiative. Together, CSL Behring, CSL Plasma and their employees raised more than $700,000 for United Way in 2013:

- CSL Behring, King of Prussia, PA: $180,396 to United Way of Greater Philadelphia and Southern New Jersey
- CSL Plasma, Boca Raton, Fla.: $370,588 to various United Way chapters
- CSL Behring, Kankakee, Ill.: $162,000 to United Way of Kankakee County

“Our employees give back to their communities by contributing their time and talent as well as their financial support to a number of charitable organizations throughout the year,” said Karen Etchberger, CSL Behring’s Executive Vice President, Quality & Business Services. “They are the heart and soul of our business and our corporate culture of giving. We’re proud of the ways in which they get involved and show they care.”

Denim/Jeans Days an employee favorite

A full slate of charitable programs is well underway this year. Employees in CSL Behring’s King of Prussia, Pa. location are currently in the midst of a Denim Days fundraising event that benefits the Ed Snider Youth Hockey Foundation. The foundation serves youngsters in Philadelphia, Pa. and Camden, N.J. In fact, employees in other CSL Behring locations participate in Denim/Jeans Days throughout the year. By contributing to a designated charity, employees can wear jeans to work on Fridays.

Meanwhile, CSL Behring employees in Kankakee, Ill. wrapped up a fundraiser in January that benefited Gigi’s Playhouse, a Down syndrome family support center. Not to be outdone, employees at CSL Plasma, which has locations in Boca Raton, Fla., Knoxville, Tenn., Indianapolis, Ind., Mesquite, Texas, and plasma collection centers throughout the United States, are busy supporting organizations such as Big Brothers Big Sisters.

Hands-on efforts

Employees also take part in hands-on initiatives. In King of Prussia, they rolled up their sleeves last spring and helped pack 60,000 meals for needy people in the Greater Philadelphia and Southern New Jersey region though the United2Feed program. During the 2013 holiday season, King of Prussia employees achieved a 61% increase over the 2012 holiday season in toy donations to Toys for Tots.

CSL Plasma employees serve food at local community centers, stock city food pantries, hand out warm coats at area coat drives, and collect school supplies and back packs for school children. They also support the work of groups including the Juvenile Diabetes Research, Alzheimer’s, Susan G Komen Breast Cancer and Leukemia and Lymphoma foundations, Wounded Warrior Project, Salvation Army and March of Dimes.

CSL Behring employees in Kankakee do their part by supporting groups and charities such as the YMCA Strong Kids Campaign, Options Center for Independent Living, Hospice of Kankakee Valley, 4-H Club, Intrepid Fallen Heroes Fund, American Cancer Society, and Illinois Tornado Victims Disaster Relief, among other charities.
Patient advocacy
Employees at both CSL Behring and CSL Plasma support advocacy groups that represent the health care interests of patients with rare medical disorders. These include the Immune Deficiency Foundation, Hemophilia Federation of America, Alpha-1 Foundation, Hereditary Angioedema Association, and local patient group chapters.

For information about CSL's global performance in priority areas of its Corporate Responsibility program visit www.csl.com.au.

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 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 www.csibehring.com.

###
First patient enrolled in phase III of COMPACT, a study of volume-reduced subcutaneous C1-INH for prevention of Hereditary Angioedema (HAE) attacks

International study by CSL Behring is world’s first placebo-controlled phase III trial to examine subcutaneous administration of C1-INH for use in treating rare, sometimes life-threatening, condition

King of Prussia — 20 February 2014

CSL Behring today announced it has enrolled the first patient in COMPACT, an international phase III study of a volume-reduced, subcutaneous formulation of C1-esterase inhibitor (C1-INH) concentrate in patients with frequent hereditary angioedema (HAE) attacks (NCT01912456). This phase of the COMPACT program will assess the efficacy and safety of a new formulation of the CSL Behring C1-INH concentrate in preventing hereditary angioedema attacks when the therapy is administered twice weekly under the skin (i.e., subcutaneously) of patients diagnosed with HAE.

COMPACT is an acronym for Clinical Studies for Optimal Management in Preventing Angioedema with Low-Volume Subcutaneous C1-inhibitor Replacement Therapy.

“To date, COMPACT has shown that various doses of this volume-reduced formulation of C1-INH concentrate are well tolerated when administered at a single infusion site twice weekly,” said Bruce Zuraw, MD, Professor of Medicine at the University of California, San Diego, USA, and Chairman of the Steering Committee for the COMPACT program. “We also observed a dose-dependent, physiologically relevant increase in functional C1-INH plasma levels. From a clinical perspective, these results are intriguing and could lead to a more convenient option for people with HAE.”

The COMPACT phase III, double-blind, randomized, placebo-controlled, cross-over study enrolls adolescent and adult patients with HAE types I or II who have frequent attacks. The study will measure the number of hereditary angioedema attacks that subjects experience while receiving each treatment. Subjects will be able to take on-demand medication for acute attacks at any time during the study.

“The COMPACT study is an important demonstration of the commitment CSL Behring has to the HAE community,” said Russell Basser, Senior Vice President of Clinical Research and Development at CSL Behring. “CSL Behring has been a leader in this area for decades, so we are confident that our current efforts to develop a safe, effective and convenient new treatment option for HAE patients will be successful.”

Additional information about the COMPACT trial and participating centers can be found here: http://clinicaltrials.gov/show/NCT01912456

About Hereditary Angioedema
Hereditary angioedema due to decreased C1-esterase inhibitor (C1-INH) is caused by mutations in SERPING1, the gene coding for C1-INH. It is inherited in an autosomal dominant manner. Symptoms of HAE include recurring episodes of edema, or swelling, in the hands, feet, the face, the abdomen, and/or the larynx. Patients who have abdominal attacks of HAE can experience episodes of severe pain, diarrhea, nausea, and vomiting caused by swelling of the intestinal wall. HAE attacks that involve the face and larynx can result in airway closure, asphyxiation, and, if untreated, death. Diagnosis of HAE requires a blood test to confirm low or abnormal levels of C1-INH. For more information about HAE, please visit www.haei.org or www.haea.org.
CSL Behring currently has licensed a C1-inhibitor product in Australia, Canada, Europe, Japan, the United States and several other countries in Asia and South America for treatment of acute attacks of HAE.

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 indicated for the treatment of coagulation disorders including hemophilia and von Willebrand disease, primary immune deficiencies, hereditary angioedema and inherited respiratory disease. 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 subsidiary of CSL Limited (ASX:CSL), a biopharmaceutical company headquartered in Melbourne, Australia. For information: www.cslbehring.com.

###
Patient Satisfaction and Convenience Increased with Current Hereditary Angioedema Treatment Options, According to Study Findings

Analysis also reveals decrease in emergency room visits and hospitalizations

San Diego, CA — 01 March 2014

Findings announced by CSL Behring today show that current hereditary angioedema (HAE) treatment options, such as C1 Esterase Inhibitor (C1-INH) concentrate, are allowing for greater patient satisfaction, higher rates of home treatment and a decrease in the number of hospitalizations and visits to the emergency room. HAE is a rare, potentially fatal swelling disorder caused by a deficiency of C1-INH. Until recently, only limited therapeutic options were available for patients in the U.S. with the condition. Today, HAE patients can choose from multiple options to address their condition. The 48-question online survey of physicians, which was conducted between March and June 2013, closely patterned after an initial survey conducted between October 2009 and February 2010. The data were presented at the 2014 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting.

“The previously conducted survey revealed wide variability in HAE management, leaving questions about the impact of newer treatment options and changes in HAE care,” said Marc A. Riedl, MD, MS, Associate Professor of Medicine and Section Head of Clinical Immunology and Allergy at the UCLA David Geffen School of Medicine, and one of the study’s investigators. “As our results have shown, current treatment practices now align more closely with current HAE treatment guidelines, with patients demonstrating an increase in satisfaction and physicians noticing improved patient outcomes.”

Current HAE guidelines from the World Allergy Organization recommend that all acute attacks be considered for on-demand treatment, and that such treatment be mandatory for attacks affecting upper airways. The guidelines further state that on-demand treatment be given as early in the attack as possible. According to study findings, there was a three-fold increase in the percentage of attacks self-treated at home (8 percent to 27 percent; P<0.00005). Additionally, the study found convenience was reported more frequently as an important treatment decision driver for patients (27 percent versus 10 percent; P<0.00005). Based on these treatment strategies, the percentage of patients perceived by physicians to be very satisfied with HAE treatment increased from 13 percent to 40 percent (P<0.00005).

Additional findings note that preferences toward danazol, an often-used steroid treatment, have decreased from 56 percent to 23 percent (P<0.00005). Decreases were also observed in HAE attack-related emergency room visits (62 percent to 54 percent; P=NS) and hospitalizations (13 percent to 3 percent; P=0.0001).

About Hereditary Angioedema
HAE is a rare genetic disorder caused by a deficiency of C1 Esterase Inhibitor. It is inherited in an autosomal dominant manner. Symptoms of HAE include episodes of edema – or swelling – in the face, abdomen, larynx and extremities. Patients who have abdominal attacks of HAE can experience episodes of extreme pain, diarrhea, nausea and vomiting caused by swelling of the intestinal wall. HAE attacks that involve the face or throat can result in airway closure, asphyxiation and, if untreated, death. Diagnosis of HAE requires a blood test to confirm low or abnormal levels of C1 Esterase Inhibitor.

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 is a subsidiary of CSL Limited, a biopharmaceutical company with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com. CSL Behring operates one of the world’s largest plasma collection networks, CSL Plasma.
Patient Advocates and Social Workers Will Be Trained on Intricacies of Affordable Care Act with CSL Behring Grant

King of Prussia, PA — 24 March 2014

Navigating the complexities of the Affordable Healthcare Act (ACA) can be challenging, particularly where patients with chronic medical disorders such as hemophilia and von Willebrand disease are concerned. CSL Behring is awarding a Local Empowerment for Advocacy Development (LEAD) grant to help bleeding disorder patients develop a clearer understanding of ACA and potential areas of concern.

The grant will enable Hemophilia of Indiana to help close the information gap by providing training for National Hemophilia Foundation (NHF) chapter staff and hemophilia treatment center (HTC) social workers in five states – Indiana, Michigan, Wisconsin, Illinois and Missouri. The training will address the following areas:

- Issues related to the implementation of the ACA as they pertain to people with bleeding disorders.
- How to assist those with specific chronic health conditions and help to ensure their needs are fully met under the ACA’s 10 “essential health benefits.”
- How to examine whether a person’s insurance coverage, particularly coverage provided through new exchanges, provides a sufficient array of providers (including HTCs) and defined standards that meet those that patients had obtained prior to the passage of ACA.

After completing the training, it is expected that HTC and NHF staff will have greater understanding of specific issues around ACA implementation that impact the quality of healthcare insurance coverage of people with bleeding disorders. Staff will also be better equipped to monitor ACA implementation to identify areas of specific concern for people with bleeding disorders.

In addition, HTC social workers will be more knowledgeable about the ACA and will be able to answer consumers’ questions in an accurate and timely manner. Lastly, the participants will be trained to develop action steps and an advocacy plan for consumers to guide their efforts to secure desired insurance coverage, particularly with regard to plans that provide the best coverage for clotting factor. The training will be held in August in Indianapolis.

Dennis Jackman, CSL Behring’s senior vice president for global healthcare policy and external affairs, said selecting the best coverage for clotting factor can be particularly challenging. “The implementation of ACA could pose a substantial shift in how people are insured. Individuals in the states will have many different plans, some that are part of a state exchange, others that are part of a federal exchange, and still more plans that are a combination of the two, depending on the state. Our goal is to help assure that patients and their caregivers have as much information as possible to assist them in making decisions that are in their best interests.”

Scott Ehnes, executive director of Hemophilia of Indiana, said the grant from CSL Behring is essential to the success of the project. “As the details of this complex healthcare insurance reform initiative become clear, the LEAD grant will enable us to conduct training that addresses areas of concern that are identified as the ACA is implemented, such as issues around the healthcare exchanges.”

CSL Behring also awarded a LEAD grant to facilitate the formation of the Texas Bleeding Disorders Coalition, comprised of three existing patient groups: Texas Central Hemophilia Association, the Lone Star Chapter of NHF, and the El Paso Chapter of NHF. Jackman emphasized the importance of speaking with one voice on behalf of bleeding disorder patients in Texas. “We are happy to support this effort, which will hopefully enable them to expand on their already successful advocacy efforts.”

A third LEAD grant is being awarded to the Louisiana Hemophilia Foundation to establish a dynamic advocacy program that enables the members of Louisiana’s bleeding disorders community to take a more active role in advocating for access to care.
CSL Behring has awarded 51 LEAD grants to patient advocacy organizations totaling more than $630,000 since the program was established in 2008. Proposals are being accepted for the next grant cycle. The deadline for submitting a proposal is April 30, 2014.

**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 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 [www.cslbehring.com](http://www.cslbehring.com).

###
CSL Behring Launches My Access™ Cost Share Program during Hemophilia Awareness Month

My Access Offers Out-of-Pocket Payment Assistance to Eligible People in the United States Who Are Treating Hemophilia A or von Willebrand Disease with a CSL Behring Therapy

King of Prussia, Pa — 25 March 2014

People who are treating hemophilia A or von Willebrand Disease (VWD) with a CSL Behring therapy may now be eligible for financial support through the company’s My Access™ cost share program. My Access helps hemophilia A and VWD patients, who have private insurance, cover the out-of-pocket costs, up to $12,000, associated with treatment.

“CSL Behring has a long history of providing medical innovations and supportive services that make a meaningful difference in the lives of people with a bleeding disorder and those who care for them,” said Lynne Powell, Senior Vice President, North America Commercial Operations, CSL Behring. “My Access serves as another example of CSL Behring’s longstanding commitment to people who are living with a bleeding disorder and we are proud to officially launch this program during Hemophilia Awareness Month.”

My Access is available through CSL Behring’s MySource™ program. For My Access participants, CSL Behring will coordinate with specialty pharmacies, hemophilia treatment centers and outpatient hospital services to cover, up to $12,000 per year, out-of-pocket expenses associated with their CSL Behring hemophilia A or VWD therapy. Participants can reenroll every year. My Access is open to U.S. residents only. Participants must have U.S.-based private insurance that covers their CSL Behring therapy. Individuals covered by state or federally funded programs, such as Medicare, Medicaid and Veterans Health Insurance, are not eligible.

“My Access represents CSL Behring’s thorough understanding of the challenges facing the bleeding disorders community,” said Jesse Schrader, a patient with hemophilia A, who is enrolled in My Access and is a member of CSL Behring’s Gettin' in the Game™ program. “The company’s dedication to addressing the community’s needs is one of the reasons why I choose to partner with CSL Behring.”

For more information, or to enroll in My Access, please visit www.MySourceCSL.com or call the My Source Hotline at 1-800-676-4266 and speak with a My Source Care Coordinator. My Access is administered by a third party patient services organization.

About My Source™
CSL Behring created My Source to provide members of the bleeding disorders community with a single source of information that will enhance their treatment experience. My Source was also designed to meet the specific needs and preferences of each patient by providing customized information each time he or she visits. My Source offers:

- **Education** opportunities that provide members of the bleeding disorders community with information about hemophilia and von Willebrand disease (VWD)
- **Financial support** programs, like My Access, help ensure individuals are able to access their treatment
- **Community** connections that allow members of the bleeding disorders community to share experiences with one another, both online and in person

About Hemophilia A
Hemophilia is an inherited bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles and joints. In nearly all cases, it affects only males. The disorder is caused by deficient or defective blood coagulation proteins known as factor VIII or IX. The most common form
of the disorder is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia A affects approximately 1 in 5,000 to 10,000 people.

**About von Willebrand Disease**

Von Willebrand Disease (VWD), the most common hereditary bleeding disorder in the United States, affects approximately 1 to 2 percent of the U.S. population. It is caused by a deficiency or abnormality of von Willebrand factor, a protein in the blood that is necessary for normal blood clotting. Men and women are equally likely to be affected by the disorder. VWD is classified by type of defect, ranging from Type I (the most common and mildest) to Type III (the least common and most severe).

**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 [www.cslbehring.com](http://www.cslbehring.com).

###
CSL Behring Continues Commitment to Donate Bleeding Disorder Medications to World Federation of Hemophilia

Donated coagulation factor supports WFH Global Alliance for Progress program

King of Prussia, PA — 17 April 2014

CSL Behring announced today that the company will continue its ongoing commitment to the global coagulation disorders community with a donation of product to the World Federation of Hemophilia (WFH). The donation, provided in connection with World Hemophilia Day on April 17, supports WFH’s Global Alliance for Progress (GAP) program aimed at improving the diagnosis and treatment of bleeding disorders in developing countries.

“As we enter our fifth year of supporting GAP, CSL Behring is proud to continue its strong commitment to the global coagulation disorders community,” said Paul Perreault, CEO and Managing Director of CSL Behring. “CSL Behring and WFH are partners who share the goals of improving the lives of patients with bleeding disorders and making a meaningful difference in those regions of the world where management of VWD and hemophilia is a poorly met need.”

In 2009, CSL Behring was the first manufacturer in the world to commit to a three-year contract with WFH to aid the GAP program with coagulation factor donations. The donations were made in installments of 2 million international units three times during the life of the contract, for a total volume of 6 million international units (IUs). CSL Behring has since renewed its product donation contract with WFH, for the period 2013 through 2015.

CSL Behring’s most recent donation includes more than 650,000 international units of product used in treating von Willebrand Disease (VWD) and hemophilia. Product making up the donation has been manufactured at CSL Behring’s Broadmeadows plant in Australia, and the CSL Behring plant in Marburg, Germany, using plasma collected by CSL Plasma in the United States.

“We take great pride in the progress of the GAP program and are grateful for the generous donations made by CSL Behring,” said Alain Weill, President of the WFH. “We look forward to our continued partnership as we strive to help fulfill our commitment to introduce clotting factor concentrates in developing countries where these products might not otherwise be available.”

About Hemophilia and von Willebrand Disease

Hemophilia is a congenital bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. In nearly all cases, it affects only males. The disease is caused by deficient or defective blood coagulation proteins known as factor VIII or IX. The most common form of the disease is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia B is characterized by deficient or defective factor IX. Hemophilia A affects approximately 1 in 5,000 to 10,000 people. Hemophilia B affects approximately 1 in 25,000 to 50,000 people. The recommended treatment for people with hemophilia deficiency is to treat by replacement factor therapy.

Von Willebrand disease, the most common hereditary bleeding disorder in the United States, affects approximately 1 to 2 percent of the U.S. population. It is caused by a deficiency or abnormality of the von Willebrand factor, a protein in the blood that is necessary for normal blood clotting. Men and women are equally likely to be affected by VWD. VWD is classified by type of defect, ranging from Type I (the most common and mildest) to Type III (the least common and most severe).

VWD is caused by a deficiency or abnormality of VWF, a protein in the blood that is necessary for normal blood clotting. Factor VIII replacement therapy, which is also part of the CSL Behring donation, works by replacing the VWF/FVIII complex that is deficient or defective in patients with VWD. The concentrate is purified from pooled human plasma from many carefully screened plasma donors and contains the clotting proteins VWF and FVIII.
About the Global Alliance for Progress
The Global Alliance for Progress (GAP) is a 10-year healthcare development project, launched in 2003. GAP's goal is to greatly increase the diagnosis and treatment of people with hemophilia and other bleeding disorders in developing countries.

The program aims to close the gap between the number of people born with hemophilia and those who reach adulthood, the gap between the estimated and actual number of people diagnosed with bleeding disorders, and the gap between the volume of treatment product needed versus what is available. GAP partners include CSL Behring and other companies, the Jan Willem André de la Porte Family Foundation and the World Health Organization (WHO). Twenty countries have participated in GAP: Algeria, Armenia, Azerbaijan, Belarus, China, Ecuador, Egypt, Georgia, Jordan, Lebanon, Mexico, Moldova, Morocco, Peru, Philippines, Russia, Syria, Thailand, Tunisia and South Africa. Colombia, Brazil, Mexico and Honduras are the first new countries to participate in the GAP Second Decade program.

About the World Federation of Hemophilia
For 50 years, the World Federation of Hemophilia (WFH), an international not-for-profit organization, has worked to improve the lives of people with hemophilia and other inherited bleeding disorders. Established in 1963, it is a global network of patient organizations in 122 countries and has official recognition from the World Health Organization. Visit WFH online at www.wfh.org

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 indicated for the treatment of coagulation disorders including hemophilia and von Willebrand disease, primary immune deficiencies, hereditary angioedema and inherited respiratory disease. The company's products are also used in cardiac surgery, organ transplantation, burn treatment and to prevent hemolytic diseases in newborns. 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 www.cslbehring.com.

###
CSL Behring Enrolls First Patient in Global Pediatric Phase III Pivotal Study of Recombinant Factor VIII Single Chain (rVIII-SingleChain) to Treat Severe Hemophilia A

King of Prussia, PA — 02 May 2014

CSL Behring today announced that the first patient has been enrolled in the pivotal pediatric phase III study to evaluate the efficacy, safety and pharmacokinetics of its novel investigational recombinant factor VIII single chain (rVIII-SingleChain) for the treatment of previously treated children (up to age 11 years) with severe hemophilia A. The study site for this first enrollment is Malaysia.

A minimum of 25 previously treated subjects from six to 11 years of age and at least 25 subjects under six years of age who have undergone more than 50 exposure days with a previous factor VIII product are planned to be enrolled in this international, multicenter, open-label study. Subjects will be assigned to either an on-demand or prophylaxis treatment regimen for the treatment of bleeding episodes and will receive rVIII-SingleChain at a dose to be determined by the investigator. Hemostatic efficacy will be assessed by the subject or caregiver and the investigator, who will assess overall efficacy by a 4-point scale.

In an earlier study, rVIII-SingleChain showed improved pharmacokinetics over octocog alfa, the comparator, and demonstrated a safety and efficacy profile that supported advancement to late-stage clinical development. CSL Behring, in collaboration with its parent company CSL Limited, is developing rVIII-SingleChain for the treatment of hemophilia A as part of the AFFINITY clinical trial program.

About rVIII-SingleChain
Recombinant FVIII molecules currently available consist of a heavy and a light chain. Under certain conditions, these chains can dissociate, resulting in the formation of separated, or “dissociated,” rFVIII chains that are not hemostatically active. The CSL Behring rVIII-SingleChain uses a strong, covalent bond that connects the light and heavy chains, thereby creating a stable single chain rFVIII.

In-house CSL Behring studies have shown that the molecular integrity of rVIII-SingleChain is significantly increased using the single-chain design, resulting in a homogenous product that is more stable than currently available FVIII products. In addition, in-vitro studies have shown that rVIII-SingleChain demonstrates a strong affinity for von Willebrand factor (VWF), resulting in a faster and more efficient binding to VWF. The FVIII/VWF complex plays an important role in the physiological activity and clearance of FVIII and has been shown to have an influence on the presentation of FVIII to the immune system.

About Hemophilia
Hemophilia is a congenital bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. In nearly all cases, it affects only males. The disease is caused by deficient or defective blood coagulation proteins known as factor VIII or IX. The most common form of the disease is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia B is characterized by deficient or defective factor IX. Hemophilia A affects approximately 1 in 5,000 to 10,000 people. Hemophilia B affects approximately 1 in 25,000 to 50,000 people. The recommended treatment for people with hemophilia deficiency is to treat by replacement factor therapy.

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, a biopharmaceutical with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com.

###
Feature Story: A Mother’s Health

Having children while living with a rare disease

King of Prussia, PA — 07 May 2014

Learning you have a rare, chronic medical condition can be unsettling, frustrating and downright scary. For primary immunodeficiency (PI) patient Rebecca Johnson, 33, it also made her question whether she could realize her dream of becoming a mother.

It wasn’t until hearing the story of another woman with PI who had a baby that Rebecca’s fears subsided. Now with a baby of her own, Rebecca wants to share her story with other women with PI who may want to start a family.

Lifelong struggles
Throughout her childhood and beyond, Rebecca had repeated illnesses, ranging from pneumonia on her first birthday to staph infections. She also experienced frequent bouts of colds, flu and other maladies.

At age 26, Rebecca was diagnosed with common variable immune deficiency (CVID), one of the most common of the more than 200 types of PI disorders recognized by the World Health Organization. According to the Immune Deficiency Foundation, CVID affects approximately 1 in 25,000 people. CVID is an antibody deficiency that leaves the immune system unable to defend against bacteria and viruses, resulting in recurrent and often severe infections. The condition affects both males and females.

Shortly after diagnosis, Rebecca began treatments with subcutaneous immunoglobulin to boost her immune system. While her overall health improved, Rebecca became concerned about how CVID and its treatment might affect her dream of becoming a mother.

“My immunologist addressed my concerns and connected me with a woman with PI who had recently had a baby,” Rebecca said. “Hearing her story made me feel more comfortable with raising a family despite the challenges of living with PI.”

In March 2012, Rebecca gave birth to her son Grant.

A healthy, happy outlook
Today, Rebecca works full time as an interior design project manager, and enjoys participating in a range of rigorous physical activities, including hiking, biking, traveling with her husband (a personal trainer), and spending quality time with her son.
She continues to treat her condition with Hizentra®, (Immune Globulin Subcutaneous [Human]).

Hizentra, from CSL Behring, is an immunoglobulin replacement therapy indicated for the treatment of primary humoral immunodeficiency. The therapy is administered subcutaneously (under the skin) weekly or biweekly (once every two weeks) to help protect those with PI against infections.

“I learned that living with a rare disease doesn’t mean giving up on your dreams,” Rebecca said. “I encourage people with PI to share their goals and concerns with their doctors.”

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 (destruction of red blood 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, 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.

###
CSL Opens World-Class, Advanced Manufacturing Facility for Late-Stage Production of Hemophilia Therapies Now in Development

King of Prussia, PA — 09 May 2014

- Leading-edge science at the core of $250 million expansion to drive long-term growth in promising bleeding disorders portfolio
- CSL Behring to commercialize therapies produced in part at the facility, pending required approvals
- Opening taking place in advance of World Federation of Hemophilia 2014 Congress in Melbourne, Australia

CSL Limited (ASX:CSL), parent company of CSL Behring which is based in King of Prussia, PA, today opened the CSL Behring Biotechnology Manufacturing Facility in Melbourne, Australia. The new facility, located adjacent to the site’s manufacturing plant for plasma products, is the centerpiece of CSL’s $250 million expansion at its Broadmeadows site and will play an increasingly important role in the company’s global operations, particularly in the late-stage development of new types of hemophilia products. It is one of the largest and most advanced facilities of its kind in the world and will produce novel recombinant therapies on a large scale for international clinical trials.

“This world-class facility is key to the ongoing success of our global R&D strategy and reflects our commitment to providing better treatment options for people who are managing certain bleeding disorders and other life-threatening conditions,” said CSL Chief Executive Officer, Paul Perreault.

The company’s recombinant factor development programs, which comprise the AFFINITY trial and the PROLONG trial for the study of therapies to treat hemophilia A and B, respectively, are central to its long-term growth plans. Several candidates in these trials are showing promise, including rVIII-SingleChain, rIX-FP, and rVIIa-FP.

Recombinant therapies are modified versions of naturally occurring human proteins that have been optimized to provide additional treatment options for patients. CSL has more recently developed specialist capabilities in recombinant-based research, adding to its long-standing expertise in plasma protein therapeutics. CSL’s research and development pipeline currently includes recombinant therapies for a range of rare and serious disease, including bleeding disorders, inflammatory conditions and cancer.

The first therapy to be manufactured in the new Broadmeadows facility will be a novel blood clotting factor (rVIIa-FP) for the treatment of hemophilia. This is one of several longer-acting clotting factors under development by CSL that aims to reduce the number of injections required to maintain normal blood clotting in people with bleeding disorders. Clinical trials of rVIIa-FP in patients are expected to commence later this year in the United States, Europe and Australia. International recruitment is ongoing for the rVIII-SingleChain and rIX-FP studies.
About CSL
The CSL Group, headquartered in Melbourne, Australia, has a combined heritage of outstanding contribution to medicine and human health with more than 90 years of experience in the development and manufacture of vaccines and plasma protein biotherapies. With major facilities in Australia, Germany, Switzerland and the U.S., CSL has about 12,000 employees in nearly 30 countries.

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, a biopharmaceutical with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com.

###
New Findings Support Less Frequent Dosing in Hemophilia B Patients Treated with Coagulation Factor IX with Recombinant Albumin (rIX-FP)

Data showing improved pharmacokinetic profile to be presented at World Federation of Hemophilia World Congress

Melbourne, Australia — 12 May 2014

Interim Phase II/III and III findings presented today by CSL Behring at the World Federation of Hemophilia (WFH) 2014 Congress demonstrate an improved pharmacokinetic (PK) profile of recombinant fusion protein linking coagulation factor IX with recombinant albumin (rIX-FP) among hemophilia B patients of all age groups. These findings suggest an improvement in hemophilia B treatment by allowing a prolonged routine prophylaxis treatment interval of 14 days or potentially longer, compared to the current standard of two to three times per week. Data were presented during an oral session at the WFH Congress in Melbourne, Australia. CSL Behring is a subsidiary of CSL Limited (CSL: ASX), a biopharmaceutical company with headquarters in Melbourne, Australia.

“Patients with hemophilia B and treating physicians are eager for innovative products that are able to decrease the dosing frequency while being effective and reliable in the prevention or treatment of bleeding episodes,” said Elena Santagostino, MD, Ph.D., and lead investigator of this study. “Our interim PK data from two Phase III studies, combined with the Phase I and I/II results, demonstrate that rIX-FP has the potential to satisfy this unmet need by offering a longer dosing interval and fewer injections.”

“This data provides further encouragement to our ongoing efforts to bring forward to hemophilia patients an improved treatment option that will improve their quality of life,” said Charmaine Gittleson, CSL Behring Senior Vice President of Clinical Research and Development. “We look forward to completing this study and moving into the next steps with this promising clinical candidate.”

The interim pharmacokinetic results from the two phase III trials were based on the analysis of pharmacokinetic samples over the course of 14 days in 68 severe hemophilia B patients, ages from 1 to 61 years. A single dose of 50 IU/kg rIX-FP gave a mean FIX activity level above 3% at 14 days in all age ranges. In a paired comparison, the PK profile of rIX-FP demonstrated a 30 to 40 percent greater incremental recovery and greater than five times longer half-life, along with over five-fold larger area under the curve (AUC) and slower clearance compared with patients’ previous plasma-derived and recombinant FIX products.

About the Phase II/III and III Study

The Phase II/III (patients age 12 to 61 years) and Phase III (patients age 1 to 11 years) studies are open-label, multicenter, safety and efficacy studies of rIX-FP in previously treated patients with severe hemophilia B (FIX ≤ 2%). The studies are part of CSL Behring’s PROLONG - 9FP clinical developmental program.

The Phase II/III is a crossover study, designed to compare the change in frequency of spontaneous bleeding events between on-demand and weekly prophylaxis regimen in patients previously receiving only on-demand treatment and the number of patients developing inhibitors against factor IX as primary outcome measures. In addition, the study is also designed to compare multiple prophylaxis regimens of different treatment intervals, including 7-day and 14-day intervals. This study is ongoing since December 2011.

The Phase III primary outcome measures are PK parameters of rIX-FP and the number of subjects developing inhibitors against factor IX. All patients received weekly prophylaxis regimen. This study is ongoing since September 2012.

More information about study design can be found at www.clinicaltrials.gov.
About rIX-FP
CSL Behring engineered rIX-FP to extend the half-life of factor IX through genetic fusion with recombinant albumin. CSL Behring selected albumin as the ideal recombinant genetic fusion partner for its coagulation factor proteins due to its long physiological half-life. In addition, albumin has been shown to have a good tolerability profile, low potential for immunogenic reactions and a well-known mechanism of clearance compared to some other technologies. The cleavable linker connecting recombinant factor IX and recombinant albumin has been specifically designed to preserve the native function of the coagulation factor in the fusion protein, while benefiting from recombinant albumin’s long physiological half-life.

About Hemophilia
Hemophilia is a congenital bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. In nearly all cases, it affects only males. The disease is caused by deficient or defective blood coagulation proteins known as factor VIII or IX. The most common form of the disease is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia B is characterized by deficient or defective factor IX. Hemophilia A affects approximately 1 in 5,000 to 10,000 people. Hemophilia B affects approximately 1 in 25,000 to 50,000 people. The recommended treatment for people with hemophilia deficiency is to treat by replacement factor therapy.

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 (CSL: ASX), a biopharmaceutical company with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com.

###
CSL Behring Proudly Supports HAE Day with Global Partnerships, Donations and Hereditary Angioedema Awareness Events

*Third annual awareness day shines a light on rare, potentially life-threatening condition*

**KING OF PRUSSIA, PA — 14 May 2014**

As a Diamond Sponsor of HAE Day on May 16, 2014, **CSL Behring** is proud to continue its partnership with HAEi, the International Patient Organization for C1 Inhibitor Deficiencies, and patient organizations throughout the world. HAE, or, hereditary angioedema, is a rare, potentially fatal swelling disorder caused by a deficiency of C1-INH, a type of protein.

HAE Day is a global event intended to support better care and an earlier and more accurate diagnosis for HAE patients. The day focuses on engaging and educating the general public and the medical community while raising funds for further national and international HAE initiatives. HAE Day awareness events strengthen the voice of patients and unite HAE patient organizations globally.

"HAE is a serious, sometimes life-threatening medical condition that appears in all age groups in all parts of the world," said Paul R. Perreault, Chief Executive Officer of CSL Limited, parent company of CSL Behring. "Often, people who have undiagnosed HAE struggle with symptoms for years before receiving an appropriate diagnosis and effective treatment. Others go their entire lives not realizing their condition even has a name. Building broad public awareness of HAE is an important key to solving these issues for people. Therefore, CSL Behring is proud to continue our support of HAE Day at the international level, and hope our collaborative efforts can increase awareness and effective clinical management of this debilitating disorder."

CSL Behring HAE Day activities will take place throughout the Americas, Europe and Asia. Activities planned for this year include:

- Global participation in the [www.haeday.org](http://www.haeday.org) "Send a Smile" social media event
- Local awareness-raising events at the CSL Behring offices and manufacturing plants, and at CSL Plasma collection centers
- Collaboration with the German HAE patient organization to raise awareness and emphasize the importance of family screening in HAE patients
- Launch of allabouthae.co.uk and facesofhae.co.uk—a dedicated HAE micro-site in collaboration with HAE UK to provide helpful tips and advice direct from people living with HAE in the UK.
- Sponsoring of an HAE symposium at the Second Latin-American Congress on Hereditary Angioedema in Veracruz, Mexico
- Self-infusion training in collaboration with the Argentinean HAE patient organization
- Donations to and support of various HAE patient organizations including those in Brazil, Japan, Mexico, the Scandinavian countries and Spain.

In addition, CSL Behring is a Gold Sponsor of the international HAE conference in Washington, D.C. (May 15-18). As a part of its sponsorship, CSL Behring will provide conference attendees with information regarding the company and its HAE programs.

For more information about HAE Day 2014, please visit [www.haeday.org](http://www.haeday.org).

**About Hereditary Angioedema**

HAE is a rare genetic disorder caused by a deficiency of C1 Esterase Inhibitor. It is inherited in an autosomal dominant manner. Symptoms of HAE include episodes of edema – or swelling – in the face, abdomen, larynx and extremities. Patients who have abdominal attacks of HAE can experience episodes of extreme pain, diarrhea, nausea and vomiting caused by swelling of the intestinal wall.
HAE attacks that involve the face or throat can result in airway closure, asphyxiation and, if untreated, death. Diagnosis of HAE requires a blood test to confirm low or abnormal levels of C1 Esterase Inhibitor.

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 is a subsidiary of CSL Limited, a biopharmaceutical company with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com. CSL Behring operates one of the world’s largest plasma collection networks, CSL Plasma.

###
CSL Behring Launches Hizentra® Co-Pay Relief Program

Eligible Participants to Receive Payment Assistance with Out-of-Pocket Costs Associated with Hizentra® Therapy in the United States

KING OF PRUSSIA, Pa. — 20 May 2014

People managing primary immunodeficiency (PI) with CSL Behring’s Hizentra® (Immune Globulin Subcutaneous [Human]) may now be eligible for financial support through the Hizentra® Co-Pay Relief Program. The new program offers eligible U.S. patients up to $4,000 per year to be applied toward Hizentra co-payments, deductibles and coinsurance. Out-of-pocket therapy costs will be processed seamlessly through the electronic billing systems of specialty pharmacies and physician offices, which means no paperwork is required for the patient, pharmacist or physician.

“CSL Behring is committed to providing medical innovations and supportive services that make a meaningful difference in the lives of people living with a serious health condition,” said Lynne Powell, Senior Vice President, North America Commercial Operations, CSL Behring. “The Hizentra Co-Pay Relief Program is another example of this commitment and was designed to specifically meet the needs of the primary immunodeficiency community by increasing access to Hizentra.”

Enrollment in the Hizentra Co-Pay Relief Program is automated and paperless, and members can access their account online at any time. Patients can contact CSL Behring’s IgIQ resource center at 1-877-355-IGIQ (4447) to confirm eligibility and to discuss the steps for enrolling. The program is open to U.S. residents who are at least 2 years old and diagnosed with PI. Participants must have U.S.-based private insurance that covers Hizentra. Individuals covered by state- or federally funded programs, such as Medicare, Medicare Advantage plans, Medicaid, PCIP, Champus, TriCare, and Veterans Administration (VA), are not eligible.

“For many of the 250,000 people in the U.S. diagnosed with a primary immunodeficiency, immunoglobulin replacement therapy is an essential part of staying healthy,” said Marcia Boyle, President and Founder of the Immune Deficiency Foundation. “We applaud CSL Behring for the company’s long-standing commitment to the PI community and now for the Hizentra Co-Pay Relief Program, which will make a meaningful difference to those taking CSL Behring’s subcutaneous immunoglobulin.”

For more information about the Hizentra Co-Pay Relief Program, please call 1-877-355-IGIQ (4447) or visit www.Hizentra.com/copay.

About Primary Immunodeficiencies

More than 200 types of PIs are recognized by the World Health Organization. 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 about 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 (destruction of red blood 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, 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, a biopharmaceutical with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com.

###
CSL Behring Announces the 2014 Interlaken Leadership Awards Recipient

Interlaken Leadership Awards Program Supports Original Research in the Field of Neuroimmunology

KING OF PRUSSIA, Pa., — 24 June 2014

CSL Behring announced today that Bart C. Jacobs, M.D., Ph.D., Erasmus University Medical Center, Rotterdam, Netherlands, is the recipient of the 2014 Interlaken Leadership Awards for original research in the field of neuroimmunology. Established in 2010, this annual global awards program provides monetary grants and/or product supply for investigational use to researchers whose proposals are likely to advance innovative medical research and knowledge about the potential role of immunoglobulin (Ig) therapy in the treatment of neurological disorders.

A global, cross-functional CSL Behring review committee selected Dr. Jacobs’ proposal to investigate the efficacy of intravenous immunoglobulin (IVIg) treatment in patients with mild Guillain-Barré syndrome (GBS). GBS is an inflammatory disorder of the peripheral nerves characterized by the rapid onset of weakness and, often, paralysis of the legs, arms, breathing muscles and face. While IVIg is recommended in severe GBS, current guidelines recommend providing supportive care only to those with mild forms of GBS.

“Recent studies have demonstrated that a considerable proportion of untreated patients with mild Guillain-Barré syndrome have persistent disability, severe residual fatigue and pain, and poor quality of life, and my hypotheses is that IVIg may improve disease in these patients,” said Dr. Jacobs. “I am honored to have been selected by CSL Behring to receive the Interlaken Leadership Award, and look forward to continuing research into whether IVIg may improve outcomes for those with mild GBS.”

All proposals received for the Interlaken Leadership Awards program were evaluated based on scientific merit, strength of hypothesis, relevance to neuroimmunology and feasibility.

“The Interlaken Leadership Awards underpins CSL Behring’s commitment to saving lives and improving the quality of life for people with rare and serious diseases worldwide by funding innovative research that could lead to the discovery of new treatment options for people who are living with a neurological disorder,” said Bernadine Dixon, Senior Director, Immunology and Pulmonary, CSL Behring. “We look forward to the results of Dr. Jacobs’ research evaluating the potential use of IVIg for treatment of mild Guillain-Barré syndrome, as well as to supporting further original research in the field of neuroimmunology through the Interlaken Leadership Awards.”

To date, the Interlaken Leadership Awards has awarded approximately $3.5 million in grants and/or study drug for research studying Ig therapy in areas such as neuromyelitis optica (NMO), Duchenne muscular dystrophy (DMD), complex regional pain syndrome (CRPS), paraneoplastic syndromes, and autoimmune peripheral neuropathies.

About the International Immunoglobulin Conference in Interlaken

For more than three decades, CSL Behring has sponsored a high-level scientific symposium in Interlaken, Switzerland. First held in 1981, and most recently in April 2014, the International Immunoglobulin Conference focuses exclusively on scientific and clinical research in the field of polyvalent immunoglobulins.

Research presented at the Interlaken Immunoglobulin Conference is consistently at the forefront of immunoglobulin research. Since its inception, the conference has won the respect and support of top international scientists and clinicians from many different fields of research. For more information, please visit: http://www.interlakenleadershipawards.com/symposium.aspx.
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 www.cslbehring.com.

###
Study Suggests C1-INH May Aid in Prevention of Antibody-Mediated Rejection Following Kidney Transplant

Findings presented at the 2014 World Transplant Congress

SAN FRANCISCO — 30 July 2014

A study presented at the 2014 World Transplant Congress evaluated the safety and efficacy of CSL Behring’s C1 Inhibitor (C1-INH) concentrate in preventing antibody-mediated rejection following kidney transplants in highly sensitized patients. C1-INH is a human protein and an important inhibitor of the complement system.

The study shows that post-transplant treatment with C1-INH results in significant increases in the levels of complement components 3 and 4, suggesting that C1-INH inhibits activation of the complement system following transplantation. Antibody-mediated rejection is a major cause of kidney transplant failure and is often associated with activation of complement, a set of proteins that work with antibodies and play a role in the development of inflammation and tissue damage.

“Antibody-mediated rejection is a severe form of rejection that can occur in patients who have undergone a kidney transplant,” said Stanley C. Jordan, M.D., Kidney Transplant, Cedars-Sinai Medical Center in Los Angeles, and one of the study’s investigators. “Our findings provide additional insight into how C1-INH affects complement activation and represent an important advance in the study of complement-targeting therapeutics.”

The placebo-controlled, single-center study evaluated 20 highly sensitized patients, meaning they already had antibodies against donor organs. Subjects were randomized to receive either placebo or 20 IU/kg of C1-INH, administered intra-operatively, then twice a week for seven additional doses. Patients were desensitized with immunoglobulin and rituximab, decreasing the patient’s antibody levels prior to transplant.

According to study findings, fewer patients who were administered C1-INH developed serious adverse events compared to those administered placebo (20 percent versus 30 percent). C1-INH function and antigen levels in blood increased with C1-INH treatment [C1 function (p=0.0007) and C1-INH antigen percent (p=0.013)]. Patients treated with C1-INH experienced increased C3 levels on day 30 (p=0.005), while C4 levels were significantly higher at all time points. During the study period, no patient treated with C1-INH developed antibody-mediated rejection. Twenty percent of patients developed antibody-mediated rejection following the study period. Thirty percent of patients treated with placebo developed antibody-mediated rejection, ten percent during the study period.

This Investigator-Initiated Research study was supported by CSL Behring.

About Antibody-Mediated Rejection

Antibody-mediated rejection is a major cause of kidney transplant failure and a prime barrier to improving long-term outcomes for transplant patients. The types of antibody-mediated rejection vary in acuity and severity. Approximately 10 to 15 percent of kidney recipients experience rejection within one year after transplantation.

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 is a subsidiary of CSL Limited, a biopharmaceutical company with headquarters in Melbourne, Australia. For more information, visit www.cslbehring.com. CSL Behring operates one of the world’s largest plasma collection networks, CSL Plasma.

###
Early Diagnosis of Children with Primary Immunodeficiencies Focus of National Awareness Campaign for School Nurses

The Jeffrey Modell Foundation and National Association of School Nurses are preparing an information blitz to improve early referral and diagnosis

KING OF PRUSSIA, Pa. — 18 August 2014

School nurses reach 98 percent of the 50,000,000 students in U.S. public schools, grades k-12, and are uniquely positioned to facilitate the early diagnosis of serious medical conditions such as primary immunodeficiency (PI).

Even when symptoms are recognized and an appropriate referral is made, diagnosing PI can still be challenging because there are more than 250 PIs and they do not always present in clear patterns. As a result, the underlying cause often goes undetected.

In an effort to reduce the number of undiagnosed cases of PI in school children, CSL Behring has awarded a Local Empowerment Advocacy Development (LEAD) grant to the Jeffrey Modell Foundation (JMF) to develop an education campaign in collaboration with the National Association of School Nurses (NASN). The campaign will help nurses recognize the symptoms of PI in school children and facilitate their referral to a physician.

PIs, according to Vicki Modell, Co-Founder of JMF, are underdiagnosed in children who present with chronic, recurring, and persistent infections. “Quite often, school nurses are the first ‘line of defense,’ in recognizing that these children suffer from repeated infections and missed days at school,” Modell said. “Educating school nurses about the immune system and the 10 Warning Signs of primary immunodeficiency will lead to early and precise diagnosis, appropriate treatment and improved quality of life.”

NASN is customizing content supplied by JMF to meet the needs and appeal to school nurses as part of the PI awareness campaign. This includes producing English and Spanish-version posters that will be mailed to its approximately 16,000 members. NASN will distribute another 1,500 posters in conference bags at its annual meeting.

In addition, NASN will leverage its journal, websites, social media and weekly digest banner placement to promote PI awareness.

A second communication to school nurses reinforcing messaging around PI will also be distributed. In April, NASN will plan promotional activities around World PI Week, including a radio podcast episode, social media, weekly digest blurb and banner.

Dennis Jackman, CSL Behring’s senior vice president for global healthcare policy and external affairs, said educating more school nurses about PIs can have far reaching impact on students and their communities. “Arming school nurses with the knowledge to more quickly recognize symptoms of primary immunodeficiencies, and encouraging them to have candid conversations with students and their families about the disorder, will lead to improved student well-being and success,” Jackman stated.

LEAD grants have also been presented to Greater Florida Hemophilia Foundation (GFHF) and Ohio Bleeding Disorders Council (OBDC). GFHF’s grant will be used to conduct an educational program for social workers at Hemophilia Treatment Centers in Florida. The program consists of a workshop that offers the most updated information about the Affordable Care Act and Medicaid so that social workers can more effectively assist patients and their families with reviewing and changing plans and/or choosing new insurance plans.
OBDC’s grant will be used to support ongoing advocacy initiatives in the state including:

- Providing guidance and input to the Ohio Department of Insurance, and also directly to insurance providers, to ensure that issues critical to the bleeding disorders community are considered in all available market place plans.
- Working with legislators and members of the administration to ensure that any transition of children with hemophilia into Medicaid managed care is continually monitored for accessibility to quality health care.

To date, CSL Behring has awarded 55 LEAD grants to patient advocacy organizations totaling more than $729,000 since the program was established in 2008. Proposals are being accepted for the next grant cycle. The deadline for submitting a proposal is October 31, 2014.

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 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](http://www.cslbehring.com).

About Jeffrey Modell Foundation

Vicki and Fred Modell established the Jeffrey Modell Foundation in 1987, in memory of their son Jeffrey, who died at the age of fifteen from complications of Primary Immunodeficiency – a genetic condition that is chronic, serious, and often fatal.

JMF is a global nonprofit organization dedicated to early diagnosis, meaningful treatments and, ultimately, cures through research, physician education, public awareness, advocacy, patient support, and newborn screening. The Jeffrey Modell Centers Network (JMCN) includes 556 physicians at 234 academic institutions in 196 cities and 78 countries spanning 6 continents. For more information about PI, visit [www.info4pi.org](http://www.info4pi.org) or email the Jeffrey Modell Foundation at info4pi@jmfworld.org.

###
CSL Behring Announces Last Patient Treated in Phase III Study of Fibrinogen Concentrate to Control Bleeding During Aortic Aneurysm Surgery

FLORENCE, ITALY — 16 September 2014

CSL Behring announced today that the last patient has been treated as part of the REPLACE (Randomized Evaluation of fibrinogen versus PLACEbo in complex cardiovascular surgery) Phase III clinical trial. REPLACE is the first randomized, double blinded, placebo-controlled, multicenter study in a large population of patients evaluating fibrinogen concentrate (Human) (FCH) in controlling bleeding during aortic aneurysm surgery.

The REPLACE study was designed to demonstrate the safety, efficacy and tolerability of fibrinogen concentrate in reducing intraoperative bleeding and the amount of donor blood products (e.g., fresh frozen plasma, platelets and red blood cells) needed during complex cardiovascular surgical procedures such as aortic aneurysm surgery. The primary efficacy endpoint measured the total number of units of allogeneic blood products transfused during the first 24 hours after administration of FCH or placebo.

"Given the limitations of current treatment options, new safe and effective therapies are important for protecting cardiovascular surgery patients from severe bleeding and transfusion-associated adverse events," said Dr. Niels Rahe-Meyer, Professor and Head of the Department of Anesthesiology and Intensive Care, Franziskus Hospital, Bielefeld, Germany and coordinating investigator of the study. "We look forward to analyzing our findings from the REPLACE Phase III study to determine if FCH treatment can safely and effectively reduce the number of transfusions needed during cardiovascular surgery."

Timely and effective hemostatic management is important in cardiovascular surgery because the use of allogeneic blood transfusion can worsen clinical outcomes. In particular, studies have shown that blood transfusion during, or after, adult cardiovascular surgery is associated with increased long-term mortality.

"At CSL Behring, we are committed to improving the lives of people with serious health conditions by continuously working to address unmet medical needs with novel therapies," said Charmaine Gittleson, Senior Vice President of Clinical Research and Development, CSL Behring. "This is a significant milestone in the study of fibrinogen concentrate and it brings us one step closer to providing an important treatment option to operating teams and their patients who are experiencing a bleed."

About the REPLACE Study

REPLACE is a Phase III, prospective, multinational, multicenter, randomized, double-blind, placebo-controlled, two-arm study. Patients undergoing elective aortic surgery were randomized in a 1:1 ratio to treatment with FCH or placebo.

Five minutes after surgical haemostasis was completed, patients received a single intra-operative infusion of fibrinogen concentrate or placebo if their blood loss amounted to between 60 and 250 g. If blood loss of 60 g or more continued ten minutes after the administration of study medication was completed, the patient was treated according to a predefined, standardized treatment regimen using allogeneic blood products.

The REPLACE study follows CSL Behring’s Phase II prospective study, performed by the company and collaborators at the Hannover Medical School, Germany. Results from the Phase II study suggest proactive, targeted treatment with fibrinogen concentrate may safely reduce the need for transfusions and restore clotting ability in patients undergoing aortic surgery.
For more information about the REPLACE study, visit http://www.clinicaltrials.gov and search with identifier: NCT01475669.

About Fibrinogen and Fibrinogen Concentrate

Fibrinogen, also called Factor I, is a protein needed for blood clotting and for stopping bleeding. Diminished concentrations of fibrinogen limit the body's ability to support clotting at the wound area and increase the risk of bleeding. In patients who undergo major surgery, such as aortic surgery, fibrinogen concentration and subsequently clot strength, decrease during the operation. Correcting the levels of fibrinogen in these patients is critical in controlling bleeding.

CSL Behring’s fibrinogen concentrate has more than 25 years of global clinical use. The company’s Integrated Safety System helps ensure its fibrinogen concentrate meets high quality and safety standards for virus inactivation and reduction. The processes involved in the manufacture of CSL plasma-derived products meet the highest regulatory standards for purity, safety and quality.

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 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.csibehring.com.

###
CSL Behring Expands Manufacturing Facility in Kankakee, Illinois to Meet Patients' Growing Needs

The 140,000-square foot expansion has received regulatory approval from the U.S. Food & Drug Administration.

KING OF PRUSSIA, Pa — 30 September 2014

CSL Behring announced that it is set to commence operations in its newly expanded facility now that the U.S. Food & Drug Administration (FDA) has granted approval. The expansion significantly increases plasma processing and albumin production capacity in the Kankakee, Ill. facility.

The new facility will use the same state-of-the-art technology as CSL Behring’s long-standing manufacturing center of excellence in Bern, Switzerland. This is an important step towards a common fractionation process throughout CSL Behring’s global manufacturing network. The expansion is necessary due to the growing worldwide demand for CSL Behring’s immunoglobulins and albumin.

CSL Behring’s Executive Vice President Global Operations and Planning, Mary Sontrop, said the expansion in Kankakee is part of CSL Behring’s multi-site expansion plan, which includes the expansion of its manufacturing facilities in Broadmeadows, Australia; Bern, Switzerland; and Marburg, Germany.

“CSL Behring is committed to serving patients with rare diseases in all corners of the world,” Sontrop said. “In today’s competitive market, we continually explore the latest technology that’s available, and evaluate how it can make our operations and physical plant more efficient to meet patients’ growing needs. Increasing Kankakee’s ability to fractionate plasma and produce albumin and intermediate paste is an important step for our global operations.”

Sontrop explained that the intermediate paste produced in Kankakee is sent to CSL Behring’s other manufacturing facilities where it is used to make therapies for the treatment of immune deficiencies, bleeding and other medical disorders. Albumin is a plasma expander that quickly makes up for blood loss in accident victims, and that is also used to treat burn patients.

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 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/.

###
CSL Behring Launches $450 Million Capacity Expansion to Meet Growing Need for Lifesaving, Life-Improving Therapies

Company further increases global manufacturing capabilities with production expansions of albumin in Australia and plasma intermediates in U.S. to meet escalating patient demand for innovative treatments

KING OF PRUSSIA, Pa — 08 October 2014

CSL Behring today announced a multi-year, $450 million two-site global capacity expansion – the latest in a series of recent production expansions to meet the growing need for its lifesaving and life-improving therapies that are used to treat patients with rare and serious medical disorders around the world.

This expansion further strengthens CSL Behring’s global manufacturing capabilities with production capacity increases of albumin at its Broadmeadows facility (Melbourne, Australia) and plasma intermediates at its Kankakee site (Illinois, U.S.) The cross-functionality that is enabled by the capacity expansions will allow CSL Behring to leverage its global manufacturing network, helping to optimize the manufacturing efficiencies of immunoglobulin and albumin. Of the $450 million investment, $240 million will be for Kankakee and $210 million for Broadmeadows.

"As a global science-based company with decades of experience and insight, we are uniquely positioned to serve patients with rare and serious diseases. Providing innovative treatments to save and extend lives is an important part of our patient care, including ensuring we have the capabilities and capacity to meet patients’ growing needs. Our latest production expansion means the critical base material for our leading therapies will continue to be available -- enabling us to deliver on our promise to patients around the world," said Chief Executive Officer Paul Perreault.

CSL Behring applies its expertise in protein science to produce lifesaving and live-improving therapies for patients with rare and serious diseases around the world. This is accomplished through a sophisticated interchange of plasma and plasma intermediates produced at four integrated global sites in Kankakee, Broadmeadows, Bern (Switzerland), and Marburg (Germany.)

At Broadmeadows, the new facility will become an integral part of CSL Behring’s global supply chain and significantly expand its albumin manufacturing capacity. Albumin is a plasma expander that quickly makes up for blood loss in accident victims, and that is also used to treat burn patients. About 200 jobs will be created during construction in Broadmeadows, and 190 highly skilled manufacturing jobs will be in place when the new facility is fully operational. The new facility will comprise two manufacturing modules. Construction of the first module will begin in the next several weeks and will take about four years to complete. Broadmeadows currently has 650 employees.

At Kankakee, the expansion will substantially increase the production of plasma intermediates. CSL Behring uses plasma intermediates to make albumin and also immunoglobulins. The expansion is expected to be completed in 2017, at which time 300,000 square feet will have been added to the site.

Earlier this year, CSL Behring said it intended to build a leading-edge recombinant production site in Lengnau, Switzerland where the company plans to produce proteins to treat immune deficiency diseases. The company also opened in May its state-of-the-art Biotechnology Manufacturing Facility on the grounds of Broadmeadows. Today’s announcement follows the U.S. Food & Drug Administration’s recent regulatory approval to commence operations from a previous expansion of Kankakee’s manufacturing operation, which added 140,000 square feet.

Note: View manufacturing footage

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. The company operates in nearly 30 countries with approximately 13,000 employees.

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 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/.

###
PLASMA DONORS RECOGNIZED DURING INTERNATIONAL PLASMA AWARENESS WEEK FOR HELPING SAVE LIVES

CSL Plasma center openings are on the rise, as is the demand for plasma protein therapies for the treatment of rare and serious diseases.

King of Prussia, Pa. — 13 October 2014

2014-10-13 Plasma Donors Recognized, Collection Centers On the Rise

PLASMA DONORS RECOGNIZED DURING INTERNATIONAL PLASMA AWARENESS WEEK FOR HELPING SAVE LIVES CSL Plasma center openings are on the rise, as is the demand for plasma protein therapies for the treatment of rare and serious diseases. King of Prussia, Pa. CSL Behring and its subsidiary, CSL Plasma, join the Plasma Protein Therapeutics Association (PPTA) in saluting the contributions of plasma donors during International Plasma Awareness Week (IPAW), celebrated October 12-18.

CSL Behring and its subsidiary, CSL Plasma, join the Plasma Protein Therapeutics Association (PPTA) in saluting the contributions of plasma donors during International Plasma Awareness Week (IPAW), celebrated October 12-18.

The week-long observance, which is sponsored by PPTA and its member-companies, recognizes the critical role donors play in ensuring a reliable and secure source of human plasma as worldwide demand continues to rise. Plasma donations are used to make plasma protein therapies for the treatment of rare and serious diseases such as bleeding disorders and immune deficiencies.

CSL Plasma operates one of the largest plasma collection networks in the world and has been expanding its network of centers to keep up with the growing demand for plasma-derived therapies. In just the past year, CSL Plasma has opened 18 centers in the United States in Alabama, Missouri, Georgia, Arizona, Florida, Washington, Illinois, North Carolina, Michigan, Mississippi, South Carolina, Minnesota, Texas and Oregon.

CSL Plasma Senior Vice President and General Manager, Randy Furby, said IPAW provides an opportunity to raise global awareness of plasma protein therapies and rare diseases, as well as thank donors for their contributions, which are so essential to the health and well-being of patients with rare diseases worldwide.

"The rapid expansion of our network of collection centers reflects CSL Behring and CSL Plasma’s commitment to ensuring the continuous supply of plasma that is necessary to providing high-quality, lifesaving therapies to the rare disease community," Furby added.

Because plasma-derived therapies are crucial for patients’ well-being and health, an appropriate supply of products is absolutely essential and depends on a sufficient supply of collected plasma. The current collection system, which includes voluntary compensated donations, allows for an appropriate product supply that would otherwise be difficult if not impossible to achieve.

Carl Schlacht exemplifies the importance of maintaining an appropriate supply of plasma-derived therapies. Diagnosed with primary immune deficiency before his first birthday, he didn’t let a weakened immune system stop him from pursuing his dream of becoming a professional Supercross racer. Now Carl travels throughout the United States, speaking to groups of young people with immune system disorders, and encouraging them to follow their dreams.

"You can be anything you want to be," Carl tells young audiences, "whether it’s a professional athlete, a chemist or a teacher. You are not defined by your immune deficiency." Carl is quick to recognize the lifesaving contributions of plasma donors, which are used to make therapies to treat immune system disorders. "Without the plasma they’re willing to donate, my life, our lives, would be very different. I can’t thank plasma donors enough."

Page:42
CSL Plasma is celebrating IPAW 2014 by holding a variety of activities in its centers nationwide to promote greater understanding and appreciation among patients, employees and donors. CSL Plasma staff is personally thanking donors in the centers for their time, and emphasizing the impact their donations have on patients’ lives. Other activities focus on educating community and civic leaders about donors and the economic impact of a plasma center on the community. CSL Plasma centers on average infuse between $5 and $6 million directly into the local economy in wages and donor compensation.

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 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 www.cslbehring.com.

###
CSL BEHRING SIGNS STRATEGIC DEVELOPMENT AGREEMENT WITH ENABLE INJECTIONS TO MARKET NOVEL NEW DRUG DELIVERY DEVICE

King of Prussia, Pa. — 28 October 2014

CSL Behring announced today that its affiliate company, CSL Behring AG, of Bern, Switzerland and Enable Injections, LLC, of Franklin, Ohio have signed a long-term development agreement for a new and innovative drug delivery system intended to improve the comfort, convenience and treatment compliance for patients with rare and serious diseases.

As part of the strategic global collaboration, Enable will develop, manufacture and sell its innovative treatment administration device, which was specifically designed for subcutaneous dosing, to CSL Behring for use with one of its products on an exclusive worldwide basis. CSL Behring has the option to add subsequent additional products and extend the term of the agreement for additional periods. CSL Behring and Enable have also agreed to discuss other potential subcutaneous product partnerships. Under the terms of the agreement, Enable will receive an upfront payment, as well as specific milestone payments over the next several years. Additional royalty payments are also called for throughout the course of the agreement. Further terms of the agreement were not disclosed.

"At CSL Behring, we are committed to serving patients with rare and serious diseases by providing treatments that save and extend lives," said Bob Repella, Executive Vice President, Global Commercial Operations, CSL Behring. "One of the ways we do this is by focusing on medical advancements and new technologies that address patients' needs and improve their quality of life. Through our collaboration with Enable Injections, we hope to bring patients a delivery option that makes administration of their therapy easier, helps improve treatment compliance and offers them greater freedom and flexibility to treat their condition in a way that fits their individual needs."

"People living with chronic diseases have to routinely manage their condition," said Mike Hooven, CEO of Enable Injections. "Our innovative drug delivery system makes administering a life-long treatment easier and much more convenient. We are thrilled to partner with a scientific leader like CSL Behring to, upon regulatory approvals, bring this device to patients in the rare disease community who may benefit from our innovative drug delivery system."


About Enable Injections LLC

Enable Injections is a company that has developed a platform technology to deliver high viscosity/volume payloads up to 20cc to the subcutaneous tissue. The system uses standard vial, syringe or cartridge container closure, and can automatically mix lyophilized solutions. Founded February 2010, the company has R&D and manufacturing facilities in Franklin, Ohio.

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 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/.

###
CSL Behring Announces Winners of its 13th Annual Gettin’ in the GameSM Junior National Championship Program

JNC is the Bleeding Disorders Community’s Original Golf and Baseball Competition for Kids with Hemophilia and/or von Willebrand disease (VWD) and Their Families

PHOENIX — 29 October 2014

CSL Behring announced that William McCarthy from the Western Pennsylvania Chapter of the National Hemophilia Foundation and Nicholas Cleghorn from the Bleeding Disorders Advocacy Network are the national winners of the 2014 Gettin’ in the GameSM Junior National Championship (JNC) program in golf and baseball, respectively. The JNC, launched in 2002, is CSL Behring’s annual baseball and golf competition that encourages kids to remain active despite the challenges a bleeding disorder can pose, while allowing them to develop life-long connections with other members of the community.

“CSL Behring has a long history of providing medical innovations and supportive services, like the JNC and My Source, that make a meaningful difference in the lives of those with a bleeding disorder and those who care for them,” said Bill Campbell, Senior Vice President, North America Commercial Operations, CSL Behring. “We congratulate William and Nicholas and all of the competitors on their tremendous accomplishments during the event and throughout the year. CSL Behring’s commitment to the community is long-standing and the JNC demonstrates our team’s passion for what they do.”

CSL Behring’s JNC program is the first and only national golf and baseball competition designed specifically for the bleeding disorders community. In addition to the competitive activities, this event provides children and their caregivers with educational information and opportunities to interact with others in the community.

“CSL Behring understands that it can be helpful for members of the bleeding disorders community to interact with others who face similar challenges,” said Kim Phelan, Vice President, The Coalition for Hemophilia B. “CSL Behring’s programs, like the JNC, allow our members to make connections with those who share similar experiences, and we greatly appreciate these opportunities.”

In addition to naming national golf and baseball champions, CSL Behring recognized Chase Tulledge from Hemophilia of Indiana as the event’s national raffle winner. For more information about the JNC program or the wide variety of resources for the bleeding disorders community offered by CSL Behring, please visit www.mysourcecsl.com or call 1-800-676-4266. CSL Behring’s My Source program provides one-stop access to educational information, financial support and community connections to individuals living with hemophilia and/or VWD.

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 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/.

###
Evidence presented at the 16th Biennial Meeting of the European Society for Immunodeficiencies (ESID) Supports Individualized Dosing with Hizentra®

Presentations focus on Hizentra flexible dosing regimens and push administration

PRAGUE — 30 October 2014

The goal of individualized therapy in the treatment of primary immunodeficiency (PI), a serious, life-threatening and lifelong condition, is to provide patients with the best clinical outcome. Individualized therapy is now possible thanks to recent advances in the field of IgG replacement therapy, which offer increased flexibility for physicians and patients.

Data evaluating flexible and individualized dosing and administration of Hizentra® (Immune Globulin Subcutaneous [Human]) for the treatment of primary and secondary immunodeficiencies (PI and SID) were presented by CSL Behring at the 16th Biennial Meeting of the European Society for Immunodeficiencies (ESID). The presentations include clinical observations and research that aim to investigate and advance the individualization of Hizentra therapeutic approaches.

Data from a clinical study and from clinical practice evaluating the investigational, manual push administration of Hizentra therapy were presented at an official satellite symposium of ESID sponsored by CSL Behring:

- Interim analysis of a phase IV observational, non-interventional, prospective study (CHHINSTRAP) to assess patient satisfaction with an investigational “rapid” (manual push) administration of Hizentra, was presented by Professor Anna Šedivá, Deputy Director for Science, Research and Innovation and Vice-Head of the Department of Immunology at Motol University Hospital, Prague, Czech Republic and President of the 16th ESID Biennial meeting. The interim results as measured by the Treatment Satisfaction Questionnaire for Medication (TSQM) showed overall improvement over baseline with the manual push administration technique in all four dimensions for evaluation (effectiveness, side effects, convenience, and overall satisfaction).

  *Note: The highest approved infusion rate for Hizentra is 25/ml/hour/site.

  “Having different IgG treatment and administration options that fit the individual needs and lifestyles of people living with immunodeficiencies is extremely important, as PI is a condition requiring lifelong, continual therapy to prevent frequent and recurring infections,” said Professor Šedivá. “This new research evaluating the potential of different Hizentra dosing and administration approaches represents exciting progress towards delivering a truly individualized IgG therapy regimen to each immunodeficiency patient.”

- In addition, Dr. Alex Richter, Clinical Immunology Consultant at University Hospitals Birmingham NHS Foundation Trust and Clinical Senior lecturer at the University of Birmingham, Birmingham, UK presented learnings from a case series in a clinical practice setting that highlighted the simplicity and flexibility of manual push administration.

  Frequent manual push is one alternative to the “classical” weekly subcutaneous immunoglobulin infusion; however, everyone’s lifestyle and medical needs are different. Therefore, offering alternative dosing options provides an opportunity to enhance clinical outcomes.

Additional Hizentra Posters Presented at ESID

In the poster, Subcutaneous Immunoglobulin Replacement Therapy – Flexible Dosing (abstract 250), a retrospective analysis of 92 PI patients, Dr. Sai S. Duraisingham and colleagues from Barts Health NHS Trust, London, UK, observed no difference in clinical outcomes between “classical” weekly dosing or 10-14 day subcutaneous administration of IgG replacement therapy (SCIg); adding to the
current data supporting the protective effects of Hizentra for up to 14 days, an important finding for patients who choose to extend their time between infusions.

In an additional poster: Patient-Reported Overall Well-Being as a Measure Of Wear-Off Effect In IVIG-Treated Patients with Primary Immune Deficiency (abstract 198) – data were presented from two prospective, phase III, open-label studies of 86 patients, which showed that overall well-being based on patient’s self-perception decreased during the last week of three- or four-week dosing cycles of intravenous administration of IgG replacement therapy (IVIg) in approximately half of patients.

“Clinicians have long been concerned that the protective effects of IVIG may ‘wear off’ by the end of three- or four-week dosing interval, as IgG levels decline and patients become more susceptible to infections,” said Dr. Mikhail Rojavin, CSL Behring, Global Clinical Program Director and one of the authors of the open-label Phase III study. “One potential solution to minimize wear-off could be to increase the frequency of administration as well as to switch to subcutaneous replacement therapy based upon the individual needs of the patient.”

The data presented by CSL Behring at ESID today supports the use of Hizentra in dosing regimens that are flexible and allow physicians and patients to individualize therapy for optimal treatment outcomes.

About Primary and Secondary Immunodeficiencies

Immunodeficiencies constitute a group of more than 150 diseases that affect the cells, tissues and proteins of the immune system. In people with primary or secondary immunodeficiency, certain components of the immune system are either absent or functioning inadequately, leaving them more susceptible to infection. In children, especially, infections may not improve with treatment as expected and may keep returning. As a result, patients may face repeated rounds of antibiotics and hospitalization for treatment. Repeated infections can lead to organ damage, which, over time, can become life threatening.

About Hizentra

Hizentra (Immune Globulin Subcutaneous [Human]), the first and only 20 percent SCIg developed for subcutaneous use, is approved in North America, Europe and Japan. In the United States, Hizentra is indicated for the treatment of patients with primary immunodeficiency, and contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations or components of Hizentra, and in persons with selective immunoglobulin A deficiency who have known antibody against IgA and a history of hypersensitivity. For more information, including full U.S. prescribing information, visit http://www.hizentra.com/. In all 29 European/European Economic Area member states and Japan, Hizentra is authorized for treating patients diagnosed with PI as well as secondary immunodeficiencies.


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 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/.

###
CSL Limited Launches AEGIS-I, a Phase 2b Clinical Study of CSL112, a Novel Apolipoprotein A-I Infusion Therapy Designed to Rapidly Remove Cholesterol from Arteries and Stabilize Plaque

**CSL112 Represents a Promising Investigational Therapy That May Fill a Void in Reducing Early Recurrent Cardiovascular Events in Patients Who Have Suffered a Heart Attack**

KING OF PRUSSIA, Pa — 10 November 2014

CSL Limited today announced the launch of AEGIS-I, a Phase 2b clinical study of CSL112, a novel formulation of apolipoprotein A-I (apoA-I). Administered as a short series of weekly infusions, CSL112 is designed to rapidly remove cholesterol from the arteries and stabilize lesions at risk of rupture. This represents a new approach to reduce the high incidence of early recurrent cardiovascular events in the days and weeks following a heart attack.

“Patients are at highest risk of experiencing a recurrent cardiovascular event in the first 30 days following the index event and physicians have few treatment options to address this risk,” said C. Michael Gibson, M.S., M.D., Professor of Medicine at Harvard Medical School and AEGIS-I Study Chairman. “CSL112 holds the potential to work quickly to reduce early recurrent events, thereby addressing a substantial unmet medical need.”

AEGIS-I is a Phase 2b, global, randomized, placebo-controlled, dose-ranging study investigating the safety and tolerability of multiple dose administration of CSL112 in 1,200 patients who experienced an acute myocardial infarction or heart attack. Secondary outcome measures include time-to-first occurrence of a major adverse cardiovascular event (MACE) defined as cardiovascular death, myocardial infarction (MI), ischemic stroke and hospitalization for unstable angina. Results of the study are expected in 2016.

“We are excited to advance the clinical development program for CSL112 with the launch of the AEGIS-I study which will investigate the safety and efficacy of CSL112 administered in the post MI setting,” said Denise D'Andrea, Senior Global Clinical Program Director Cardiovascular Therapies Clinical Development.

“AEGIS-I will also allow us to select the dose to take into the phase 3 outcomes trial where we will test the hypothesis that rapid removal of cholesterol with CSL112 will stabilize plaque and thereby reduce the incidence of early recurrent cardiovascular events.”

**About Coronary Heart Disease**

Coronary heart disease stems from problems related to plaque buildup in the walls of the arteries, a condition known as atherosclerosis. As plaque builds up, the arteries narrow, making it more difficult for blood to flow and creating a risk for heart attack or stroke.

Despite advances in therapy, coronary heart disease remains a leading cause of death globally. In the US alone:

- There are 515,000 new heart attacks and 205,000 recurrent heart attacks annually
- One heart attack occurs every 44 seconds
- 1 in 6 deaths is due to coronary heart disease

**About CSL112**

CSL112 is a novel formulation of apolipoprotein A-I (apoA-I), the primary functional component of high-density lipoprotein (HDL). It is purified from human plasma and reconstituted to form HDL particles suitable for intravenous infusion. Studies have shown that the infusion of CSL112 rapidly
elevates markers of reverse cholesterol transport, a process by which cholesterol is removed from arteries and transported to the liver for clearance. CSL112 may offer a novel option for rapidly stabilizing atherosclerotic lesions and is being studied for reduction in the risk of early atherothrombotic events in acute myocardial infarction patients.

About CSL
Headquartered in Melbourne, Australia, CSL Limited is a global biopharmaceutical company that develops, manufactures and markets biotherapies to prevent and treat rare and serious human diseases. CSL owns major facilities in Australia, Germany, Switzerland and the United States, and employs over 13,000 people in more than 27 countries. Visit www.csl.com.au for more information.

###
CSL112 Found to Elevate Cholesterol Efflux in Patients with Coronary Artery Disease and Mechanism for Rapid Cholesterol Efflux Capacity Demonstrated

Two New Research Studies Provide Further Support for the Potential Role of CSL112 in the Reduction of Early Recurrent Cardiovascular Events following Myocardial Infarction

KING OF PRUSSIA, Pa — 18 November 2014

Two research studies presented today at the American Heart Association Scientific Sessions in Chicago provide further understanding of the mechanisms by which CSL112, a novel formulation of apolipoprotein A-I (apoA-I), may reduce the high incidence of early recurrent cardiovascular events seen in post MI patients. Early recurrent cardiovascular events are associated with high morbidity and mortality, and reducing early events is an important target for new therapies.

Andreas Gille, M.D., Ph.D., CSL Head of Clinical and Translational Science Strategy, presented a poster session titled, CSL112 enhances cholesterol efflux equally in patients with high and low HDL functionality. Data pooled from studies in 93 healthy subjects and 44 patients with stable atherosclerotic disease showed that CSL112 caused strong and quantitatively similar elevation in cholesterol efflux, independent of baseline efflux activity. Patients with cardiovascular disease are known to have lower cholesterol efflux capacity, and these data suggest that CSL112 may effectively elevate efflux in patients with impaired HDL function.

The mechanism by which CSL112 rapidly increases cholesterol efflux capacity was the topic of a poster presentation by Svetlana Didichenko, M.D., CSL Senior Scientist, titled, Mechanism of HDL remodeling induced by CSL112. In vitro studies showed that infused CSL112 is rapidly remodeled to form pre-β1 HDL, a type of HDL with superior cholesterol efflux capacity, and that this remodeling accounts for the immediate and robust increase in cholesterol efflux capacity observed upon infusion of CSL112.

“Both studies advance our understanding of the role of CSL112 in rapidly inducing cholesterol efflux, the first step in reverse cholesterol transport, and its potential to rapidly reduce early recurrent cardiovascular events in the post MI setting,” said Samuel Wright, Global Strategic Director of Cardiovascular Therapeutics, CSL Behring.

About CSL112
CSL112 is a novel formulation of apolipoprotein A-I (apoA-I), the primary functional component of high-density lipoprotein (HDL). It is purified from human plasma and reconstituted to form HDL particles suitable for intravenous infusion. Studies have shown that the infusion of CSL112 rapidly elevates markers of reverse cholesterol transport, a process by which cholesterol is removed from arteries and transported to the liver for clearance. CSL112 may offer a novel option for rapidly stabilizing atherosclerotic lesions and is being studied for reduction in the risk of early atherothrombotic events in acute myocardial infarction patients.

About CSL
Headquartered in Melbourne, Australia, CSL Limited is a global biopharmaceutical company that develops, manufactures and markets biotherapies to prevent and treat rare and serious human diseases. CSL owns major facilities in Australia, Germany, Switzerland and the United States, and employs over 13,000 people in more than 27 countries. Visit www.csl.com.au for more information.

###
CMS Extends New Technology Add-On Payment for CSL Behring's Kcentra®

Designation Helps Improve Patient Access to Kcentra in the Inpatient Hospital Setting

KING OF PRUSSIA, Pa. — 01 December 2014

CSL Behring today announced that the Centers for Medicare and Medicaid Services (CMS) has extended the new technology add-on payment (NTAP) for Kcentra® (Prothrombin Complex Concentrate [Human]) through September 2015 for eligible Medicare beneficiaries treated in the inpatient hospital setting. Kcentra, the first and only non-activated 4-factor prothrombin complex concentrate (4F-PCC) approved by the U.S. Food and Drug Administration (FDA), is indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with acute major bleeding or in need of an urgent surgery or invasive procedure. Kcentra, first approved for use in the U.S. in April 2013, received its NTAP designation effective October 1, 2013.

"CMS's decision to extend Kcentra's NTAP designation further recognizes this novel treatment as an important clinical advancement for patients in need of urgent warfarin reversal," said Bill Campbell, Senior Vice President, North America Commercial Operations, CSL Behring. "The NTAP designation will continue to help provide broader access to Kcentra in hospitals and further underscores CSL Behring's commitment to developing and making innovative treatments for serious medical conditions widely accessible."

Unlike fresh frozen plasma (FFP), the most widely used agent for warfarin reversal, Kcentra does not require thawing or blood type matching and can be administered more quickly and with less volume than FFP.

About the New Technology Add-On Payment (NTAP) Policy

The CMS NTAP policy was implemented in 2001 to support timely access to innovative therapies for Medicare beneficiaries in the inpatient hospital setting that are not adequately paid for under the Medicare Severity Diagnosis-Related Groups (MS-DRGs). To be eligible for an NTAP, the product must be new and inadequately paid for under existing MS-DRGs, and must provide a significant clinical improvement over existing therapies. CMS will continue to reimburse hospitals an additional amount, up to $1,587.50, for cases involving Kcentra that exceed the MS-DRG payment amount.


Prevalence of Warfarin Therapy

Each year, approximately three to four million people in the U.S. are treated with the oral anticoagulant warfarin to prevent blood clots from forming following a stroke, heart attack, heart valve surgery, deep vein thrombosis/pulmonary embolism, or certain types of irregular heartbeat, such as atrial fibrillation. However, because of the deficiency in blood clotting factors induced by warfarin treatment, patients may experience severe bleeding. It is estimated that emergency departments across the U.S. see approximately 29,000 cases annually for warfarin-associated bleeding.

About Kcentra®

In more than 25 countries, CSL Behring markets Kcentra as Beriplex® or Confidex®. In December 2012, the FDA granted Orphan Drug Designation to Kcentra for the treatment of patients needing urgent reversal of Vitamin K antagonist therapy due to major bleeding and/or surgical procedures. The FDA's Orphan Drug Designation program provides orphan status to unique drugs and biologics defined as those intended for the safe and effective treatment or prevention of rare diseases that affect fewer than 200,000 people in the U.S. Orphan designation qualifies the sponsor of the product for important tax credits, elimination of FDA license application fees and certain marketing incentives.
Important Safety Information

Kcentra®, Prothrombin Complex Concentrate (Human), is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA—e.g., warfarin) therapy in adult patients with acute major bleeding or the need for urgent surgery or other invasive procedure. Kcentra is for intravenous use only.

WARNING: ARTERIAL AND VENOUS THROMBOEMBOLIC COMPLICATIONS

Patients being treated with Vitamin K antagonist therapy have underlying disease states that predispose them to thromboembolic events. Potential benefits of reversing VKA should be weighed against the risk of thromboembolic events, especially in patients with history of such events. Resumption of anticoagulation therapy should be carefully considered once the risk of thromboembolic events outweighs the risk of acute bleeding. Both fatal and nonfatal arterial and venous thromboembolic complications have been reported in clinical trials and postmarketing surveillance. Monitor patients receiving Kcentra, and inform them of signs and symptoms of thromboembolic events. Kcentra was not studied in subjects who had a thromboembolic event, myocardial infarction, disseminated intravascular coagulation, cerebral vascular accident, transient ischemic attack, unstable angina pectoris, or severe peripheral vascular disease within the prior three months. Kcentra might not be suitable for patients with thromboembolic events in the prior three months.

Kcentra is contraindicated in patients with known anaphylactic or severe systemic reactions to Kcentra or any of its components (including heparin, Factors II, VII, IX, X, Proteins C and S, Antithrombin III and human albumin). Kcentra is also contraindicated in patients with disseminated intravascular coagulation. Because Kcentra contains heparin, it is contraindicated in patients with heparin-induced thrombocytopenia (HIT).

Hypersensitivity reactions to Kcentra may occur. If patient experiences severe allergic or anaphylactic type reactions, discontinue administration and institute appropriate treatment.

In clinical trials, the most frequent (≥2.8%) adverse reactions observed in subjects receiving Kcentra were headache, nausea/vomiting, hypotension, and anemia. The most serious adverse reactions were thromboembolic events, including stroke, pulmonary embolism and deep vein thrombosis.

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

The safety and efficacy of Kcentra in pediatric use have not been studied, and Kcentra should be used in women who are pregnant or nursing only if clearly needed.

For more information about Kcentra, please visit www.kcentra.com/ or call toll-free 1-855-4KCENTRA. For full prescribing information, please visit www.kcentra.com/prescribing-information.aspx.

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 www.cslbehring.com.

###
CSL Issues “Our Corporate Responsibility 2014” Report

Led by CSL Behring performance, the company focuses on sustainable business practices, strong results to provide patients with lifesaving, life-enhancing therapies around the world.

KING OF PRUSSIA, Pa. — 04 December 2014

CSL Behring’s parent company CSL Limited (ASX:CSL) has issued its annual corporate responsibility report – “Our Corporate Responsibility 2014.” The report details the global biopharmaceutical company’s performance across key priority areas from July 1, 2013 through June 30, 2014 – recording another strong performance led by CSL Behring.

The company has consistently achieved growth through the disciplined execution of its business strategy – investing in research and development to advance therapies for unmet medical needs, growing its core portfolio of products by expanding indications and markets, and a relentless commitment to productivity and efficiency.

CSL Limited CEO and Managing Director Paul Perreault emphasizes that people are the driving force behind the company’s strong performance. “People are our greatest asset, and the ability to create a safe and rewarding environment filled with opportunities for our people is critical. So, too, is our unwavering focus on placing the needs of patients at the core of all that we do.

“Ensuring we can continue to provide lifesaving and life-enhancing therapies requires us to believe, think and act in a responsible and sustainable way. I am pleased to introduce Our Corporate Responsibility 2014 report, which illustrates our ongoing commitment with tangible examples.”

Highlights of CSL’s economic, social and environmental performance include:

- Economic contribution direct to local economies of US$4.9 billion, a 5% increase on the previous year, including global community investment of US$32.8 million to patient, biomedical and local communities;
- Research and Development investment of US$466 million with more than 40 clinical studies in operation across the pipeline – 22 product registrations/indications for serious diseases in various markets, an increase on the previous year;
- 179 GMP regulatory audits of our manufacturing facilities with no impact on product marketing licenses;
- Second consecutive year of 7% growth in the total workforce, reaching 13,468 employees as of June 30, 2014;
- Health and safety performance saw lost time due to injury (LTIFR), lost days (DLFR) and incidences of medical treatment (MTIFR) reduced by 20%, 30% and 12%, respectively;
- Maintained compliance with environmental laws and regulations across global operations;
- Despite an expanding facility footprint, CSL experienced moderate increases in absolute numbers across environmental indicators;
- Commenced an enterprise-wide climate change risk assessment, taking into consideration updated observations and forecasts from the United Nations Intergovernmental Panel on Climate Change (IPCC).

To view the complete “Our Corporate Responsibility 2014” report, click here. CSL invites stakeholders to provide feedback on its report via an anonymous survey (https://www.surveymonkey.com/s/F839KMG). For the first 150 responses, CSL will donate US $50 per survey to the World Federation of Hemophilia.

About CSL Limited
Headquartered in Melbourne, Australia, CSL Limited (ASX:CSL) is a global biopharmaceutical company that develops, manufactures and markets biotherapies to prevent and treat rare and serious human diseases. CSL owns major facilities in Australia, Germany, Switzerland and the US, and employs over 13,000 people in more than 27 countries.

**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 global biopharmaceutical company and a member of the CSL Group of companies. The parent company, CSL Limited (ASX:CSL), is headquartered in Melbourne, Australia.

###
EMA Approves Amended Product Label for CSL Behring’s Hizentra®

New Label Supports Greater Flexibility and Ability to Individualize Dosing

BERN, Switzerland — 04 December 2014

CSL Behring announced today that the European Medicines Agency (EMA) has approved the amended product labeling for Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid. The new label provides the ability to individualize treatment with flexible dosing – to administer Hizentra at intervals from daily to once every two weeks (biweekly).

Hizentra, the first and only 20 percent subcutaneous immunoglobulin, is an important treatment option for people diagnosed with primary and secondary immunodeficiencies (PI and SID). Hizentra was first granted marketing authorization in April 2011, for all 29 European/European Economic Area member states.

Immunodeficiencies are a group of serious diseases that compromise the immune system, leaving patients particularly vulnerable to infection. Patients with immunodeficiencies require life-long treatment, and for many, immunoglobulin replacement therapy (IgG) is an essential part of staying healthy. Hizentra delivers consistent levels of IgG, with the convenience of daily to biweekly dosing to protect these patients against infection.

“The ability to customize the dosing regimen of Hizentra provides physicians with more options to meet the individual needs of patients on Ig therapy, including the potential to reduce infusion time and volume,” said Bob Repella, Executive Vice President, Global Commercial Operations, CSL Behring. “CSL Behring understands that managing this life-long disorder can be challenging as patients’ lifestyles and treatment requirements may change over time. The option to dose Hizentra at flexible intervals provides even more freedom to patients, by allowing them to manage their condition based on their specific needs, which could enhance treatment compliance and clinical outcomes.”

EMA approval of the updated prescribing information for Hizentra is based on simulations by empirical population pharmacokinetic modeling. Patients should not change their dosing interval without first discussing it with their physician.

About Primary and Secondary Immunodeficiencies
Immunodeficiencies affect as many as 10 million people worldwide, and constitute a group of more than 150 diseases that affect the cells, tissues and proteins of the immune system. In people with primary or secondary immunodeficiency, certain components of the immune system are either absent or functioning inadequately, leaving them more susceptible to infection. In children, especially, infections may not improve with treatment as expected and may keep returning. As a result, patients may face repeated rounds of antibiotics and hospitalization for treatment. Repeated infections can lead to organ damage, which, over time, can become life-threatening.

About Hizentra
Hizentra (Immune Globulin Subcutaneous [Human]), the first and only 20 percent SCIg developed for subcutaneous use, is approved in North America, Europe and Japan. In the United States, Hizentra is indicated for the treatment of patients with primary immunodeficiency, and contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations or components of Hizentra, and in persons with selective immunoglobulin A deficiency who have known antibody against IgA and a history of hypersensitivity. For more information, including full U.S. prescribing information, visit http://www.hizentra.com/. In all 29 European/European Economic Area member states and Japan, Hizentra is authorized for treating patients diagnosed with PI as well as secondary immunodeficiencies. For more information, including full Summary of Product Characteristics, visit http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002127/human_med_001440.jsp&mid=WC0b01ac058001d124.
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 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.csbehring.com/.

Page:60
(Family Features) Wheezing, shortness of breath and chronic bronchitis are often associated with asthma or chronic obstructive pulmonary disease (COPD). However, they are also symptoms of a serious genetic form of emphysema called Alpha-1 Antitrypsin Deficiency, also known as Alpha-1.

For Peggy Iverson and her family, the symptoms and risk of this life-threatening condition are all too familiar.

Alpha-1 is a hereditary condition in which the body does not produce a protein known as alpha-1 antitrypsin, which protects lungs from damage. Alpha-1 has been identified in nearly all populations and ethnic groups, and it is the most common known genetic risk factor for emphysema. The National Institutes of Health estimate that more than 100,000 Americans may have Alpha-1; only 10 percent of these cases have been properly diagnosed. Up to 3 percent of people diagnosed with COPD may have undetected Alpha-1.

The importance of early diagnosis and intervention

Alpha-1 is commonly first misdiagnosed as asthma or COPD. In fact one study shows that 43 percent of Alpha-1 patients see at least three doctors before receiving a correct diagnosis—and that it takes an average of nearly eight years from first symptoms to diagnosis. During that time, lung damage progresses.

Peggy Iverson shares her story with others managing Alpha-1

Peggy's mother, Helen Kline, was 45 years old when she began experiencing shortness of breath. She learned she had lung damage, even though she had never smoked. Further testing soon revealed Helen had Alpha-1. Unfortunately, Helen's lung function continued to decline, and she passed away from Alpha-1 in 1984, at the age of 54, just nine years after her diagnosis. Because of her mother's diagnosis, Peggy was tested for Alpha-1 in her mid-20s and learned that she too had the condition.

For Peggy, this early diagnosis made all the difference. It allowed her to make lifestyle changes to protect her lungs, which included seeing a pulmonologist yearly.
Peggy was able to begin treatment immediately when her lung function began to decline in 2000. Nowadays, Peggy treats her condition with Zemaira® (Alpha-1 Proteinase Inhibitor [Human]), from CSL Behring, which works to restore the alpha-1 antitrypsin protein her body lacks.

Peggy, who is now 61 years old, is striving to help others with Alpha-1 find the education and support they need to manage their condition and lead happy lives.

**Inspired to help**

In 2006, Peggy attended her first Alpha-1 national conference and was inspired to begin an Alpha-1 support group in her hometown in Iowa. After running the local support group for five years, Peggy became a coordinator with AlphaNet, a not-for-profit organization serving the specific needs of those with Alpha-1.

As an AlphaNet Coordinator, Peggy provides support, education and resources to others with Alpha-1, on an ongoing basis, to help them manage their condition. Most important, though, she gives others hope.

"It is possible to live a great life with Alpha-1 due to the many resources and treatments available," said Peggy.

This initiative is part of the Alpha-1 Disease Management and Prevention Program developed by AlphaNet to support those with Alpha-1, their families and healthcare providers. The goal of the program is to help those with Alpha-1 improve their quality of life and efficiently manage health resources.

"I feel blessed to serve those with Alpha-1 every day," said Peggy. Peggy also heads fundraisers for Alpha-1 research and enjoys spending time with her husband, Pete, and two sons, both carriers of the Alpha-1 gene.

CSL Behring is a global biotherapeutics company committed to the Alpha-1 community. For more information about CSL Behring or Alpha-1, visit [www.zemairacarez.com](http://www.zemairacarez.com).

**Who Should Be Tested for Alpha-1?**

The American Thoracic Society (ATS) recommend Alpha-1 screening for people who have:

- COPD, emphysema, or irreversible asthma
- Recurrent pneumonia or bronchitis
- Unexplained liver disease
- A brother or sister diagnosed with Alpha-1

Alpha-1 can be diagnosed through a simple blood test conducted by a healthcare professional.

**Important Safety Information**

Alpha1-Proteinase Inhibitor (Human), Zemaira® is indicated to raise the plasma level of alpha1-proteinase inhibitor (A1-PI) in patients with A1-PI deficiency and related emphysema. The effect of this raised level on the frequency of pulmonary exacerbations and the progression of emphysema have not been established in clinical trials.

Zemaira may not be suitable for everyone; for example, people with known hypersensitivity to components used to make Zemaira, those with a history of anaphylaxis or severe systemic response
to A1-PI products, and those with certain IgA deficiencies. If you think any of these may apply to you, ask your doctor.

Early signs of hypersensitivity reactions to Zemaira include hives, rash, tightness of the chest, unusual breathing difficulty, wheezing, and feeling faint. Immediately discontinue use and consult with physician if such symptoms occur.

In clinical studies, the following adverse reactions were reported in at least 5% of subjects receiving Zemaira: headache, sinusitis, upper respiratory infection, bronchitis, fatigue, increased cough, fever, injection-site bleeding, nasal symptoms, sore throat, and swollen blood vessels.

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

Please see full prescribing information for Zemaira.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch, or call 1-800-FDA-1088.
CSL Behring Submits Biologics License Application for FDA Approval of Recombinant Fusion Protein Linking Coagulation Factor IX with Recombinant Albumin (rIX-FP) for Hemophilia B Patients

**CSL Behring Continues Improving Patient Well-Being; Key Milestone Achieved in PROLONG-9FP, Company’s Recombinant Factor IX Fusion Protein Development Program**

KING OF PRUSSIA, Pa. — 16 December 2014

CSL Behring announced today it has submitted a biologics license application (BLA) to the United States Food and Drug Administration (FDA) for the marketing authorization of its long-acting fusion protein linking recombinant coagulation factor IX with recombinant albumin (rIX-FP). Once approved by the FDA, rIX-FP (Coagulation Factor IX {Recombinant}, Albumin Fusion Protein) will provide people with hemophilia B and their physicians a long-acting treatment option with dosing intervals up to 14 days.

“As we mentioned at our recent R&D investor briefing, submission of our BLA to the FDA for rIX-FP is a significant milestone for CSL Behring’s recombinant factor IX development program and moves us one step closer to bringing this innovative therapy to hemophilia B patients in the U.S.,” said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. “Our strong partnership with and commitment from the hemophilia community led us to develop rIX-FP based on novel recombinant albumin fusion technology. This technology has led to a long-acting treatment candidate that continues our legacy of improving the well-being of patients with bleeding disorders and other rare diseases.”

**About PROLONG-9FP Clinical Development Program**

CSL Behring’s BLA is based on the results from the PROLONG-9FP Phase II/III (patients ages 12 to 61 years) study. The Phase II/III pivotal study was an open-label, multicenter, safety, pharmacokinetic (PK) and efficacy study of rIX-FP in previously treated patients with severe hemophilia B (FIX ≤ 2%).

This study was designed to compare the change in frequency of spontaneous bleeding events between on-demand treatment and a weekly prophylaxis regimen in patients previously receiving only on-demand treatment; and the number of patients developing inhibitors against factor IX as primary outcome measures. The study evaluated multiple prophylaxis regimens, including 7-day and 14-day intervals. A sub-study evaluated the prevention and control of bleeding in patients with hemophilia B undergoing a surgical procedure.

Study design details for rIX-FP (CSL654) are available at www.clinicaltrials.gov.

**About rIX-FP**

CSL Behring engineered rIX-FP to extend the half-life of recombinant factor IX through genetic fusion with recombinant albumin. CSL Behring selected recombinant albumin as its recombinant genetic fusion partner for its coagulation factor proteins due to its long physiological half-life. In addition, recombinant albumin has been shown to have a good tolerability profile, low potential for immunogenic reactions and a well-known mechanism of clearance. The cleavable linker connecting recombinant factor IX and recombinant albumin has been specifically designed to preserve the native function of the coagulation factor in the fusion protein, while benefiting from recombinant albumin’s long physiological half-life.

In 2012, the FDA granted Orphan Drug Designation for rIX-FP for the treatment and prophylaxis of bleeding episodes in patients with hemophilia B. The designation includes routine prophylaxis treatment, control and prevention of bleeding episodes, and prevention and control of bleeding in
perioperative settings. The FDA's [Orphan Drug Designation program](https://www.fda.gov) provides orphan status to unique drugs and biologics defined as those intended for the safe and effective treatment or prevention of rare diseases that affect fewer than 200,000 people in the U.S. Orphan designation qualifies the sponsor of the product for important tax credits, elimination of FDA license application fees and certain marketing incentives.

**About Hemophilia B**

Hemophilia B (congenital factor IX deficiency) is characterized by deficient or defective factor IX and affects approximately 1 in 25,000 to 50,000 people. Hemophilia B is a congenital bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. Nearly all hemophilia B patients are male.

**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](http://www.csl.com.au) (ASX:CSL), is headquartered in Melbourne, Australia. For more information, visit [http://www.cslbehring.com](http://www.cslbehring.com).

###

---

Page:65