CSL Behring Presents Phase I Results From Study of Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP) in Healthy Volunteers

Recombinant albumin fusion platform forms basis of innovation

Amsterdam, Netherlands — 03 July 2013

CSL Behring today presented Phase I data of their recombinant fusion protein linking coagulation factor VIIa with albumin (rVIIa-FP) in healthy volunteers at the International Society on Thrombosis and Haemostasis (ISTH) congress in Amsterdam.

CSL Behring, in collaboration with its parent company, CSL Limited (ASX: CSL), is developing rVIIa-FP, a novel therapy to treat hemophilia A and hemophilia B patients who have inhibitors (antibodies that develop in response to treatment with other clotting factors that prevents those treatments from working) as part of the PROLONG 7- FP clinical study program. The objective of the clinical program is to demonstrate that an extended half-life rVIIa-FP will result in a requirement for fewer doses while providing adequate therapeutic response in patients with hemophilia A and B with inhibitors.

"Our goal is to pioneer therapeutic solutions that address real unmet needs in the hemophilia community," said Dr. Debra Bensen-Kennedy, Global Therapeutic Head of Clinical Research and Development at CSL Behring. "With our recombinant albumin fusion technology, we believe we have an innovative and promising approach that may yield long-acting therapies with the potential to truly advance hemophilia treatment."

About the Phase I study
The study enrolled a total of 40 healthy male volunteers between 18 and 35 years of age, who were dosed in five consecutive dose cohorts (140, 300, 500, 750 and 1000 µg /kg). In each cohort, six participants were randomized to a single dose of rVIIa-FP and two to placebo. All participants received anticoagulation with oral vitamin K antagonist to reach an international normalized ratio (INR) between 2 and 3 prior to dosing with rVIIa-FP or placebo.

About rVIIa-FP
rFVIIa is an activated form of factor VII and can bypass the need for factor VIII or IX in people with hemophilia who have developed inhibitors to clotting factor concentrates to restore factor VIII or IX. Preclinical studies have confirmed that CSL Behring's rVIIa-FP has favorable pharmacokinetic properties compared with the existing recombinant FVIIa product. Significant increases in half-life have been observed with CSL Behring's rVIIa-FP across all animal species. The use of a bypassing agent with an extended half-life could offer significant benefit to those affected by hemophilia A or B with inhibitors and may offer patients the opportunity to be treated less frequently than with the currently available product.

About Hemophilia
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 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 A affects approximately 1 in 5,000 to 10,000 people. Hemophilia B is characterized by deficient or defective factor IX. Hemophilia B affects approximately 1 in 25,000 to 50,000 people. The recommended treatment for patients who are factor deficient is to treat by replacement factor therapy. The incidence of inhibitors in individuals with hemophilia A is estimated to be 33 percent and 1 to 6 percent in patients with hemophilia B.

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.

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Media Contacts:
Sheila A. Burke, Director, Communications & Public Relations
Worldwide Commercial Operations
CSL Behring
610-878-4209 (o)
484-919-2618 (c)
Sheila.Burke@cslbehring.com