Press Release

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CSL progresses new bleeding disorder therapies

MELBOURNE, **Australia** – CSL Limited has this week presented promising results from a number of clinical studies involving a new group of therapies for the treatment of haemophilia.

Haemophilia is an inherited disorder caused by the failure to produce certain proteins required for blood clotting. These proteins are known as clotting factors.

Children and adults with haemophilia suffer prolonged or spontaneous internal bleeding, especially in the muscles and joints, which can lead to severe arthritis, chronic pain and disability. Factor replacement therapy is required up to three times a week to reduce these bleeding episodes.

CSL has a long history of developing factor replacement therapies, derived from human plasma, for patients who are factor deficient.

Over the past several years, CSL has been developing recombinant versions of several clotting factors including some fused with another plasma protein, albumin. The company is trialling these albumin fusion clotting factors and has shown the technology is able to extend the effect of the treatment.

“We are very encouraged by the results of our clinical studies, which aim to develop longer-acting and more effective products for people with haemophilia,” said Dr Russell Basser, CSL Senior Vice President, Global Clinical Research and Development.

“The investigation of novel ways to extend the life of recombinant clotting factors in patients may result in a significant reduction in the number of weekly infusions for people with haemophilia.”

The study results were presented at the International Society of Thrombosis and Haemostasis congress in Amsterdam this week.

These promising data provides CSL the evidence needed to advance the studies to completion. Further clinical studies are being planned for other recombinant clotting factors in development, and are expected to be the first therapies produced in CSL Behring’s new Biotechnology Facility in Broadmeadows, Melbourne.

“This world-class facility is the largest of its kind in Australia and was constructed to support the late stage development of novel recombinant therapies in our R&D pipeline” said General Manager of CSL Behring Australia, Dr Simon Green.

The recently completed facility is currently producing test batches of recombinant proteins and is on track to start manufacture of clinical trial material early next year.

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About the studies

For more information about the studies presented at the International Society of Thrombosis and Haemostasis congress, visit:

1. Phase I Results From Study of Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP) in Healthy Volunteers
2. Results from Study of Recombinant Single-Chain Factor VIII (rVIII-SingleChain) for Treatment of Hemophilia A
3. Population Pharmacokinetic Model for Novel Recombinant Factor IX Hemophilia B Treatment That Supports Less Frequent Administration
4. Clinical Efficacy of Recombinant Fusion Protein Linking Coagulation Factor IX with Albumin (rIX-FP) for Once Weekly Prophylaxis in Patients with Severe Hemophilia B

For more information about the International Society on Thrombosis and Haemostasis congress, visit: http://www.isth.org/?page=ISTHCongresses

About Haemophilia

Haemophilia 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 haemophilia A, or classic haemophilia, in which the clotting factor VIII is either deficient or defective. Haemophilia A affects approximately 1 in 5,000 to 10,000 people. Haemophilia B is characterized by deficient or defective factor IX. Haemophilia B affects approximately 1 in 25,000 to 50,000 people. The recommended treatment for patients who are factor deficient is replacement factor therapy which is a concentrate from either human plasma (a component of blood) or genetically engineered cell line made by DNA technology, called *recombinants.* Recombinant factor VIIa is currently used in people with haemophilia who have developed antibodies, or inhibitors, to Factor VIII or IX.

About CSL

Headquartered in Parkville, Melbourne, 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 US, and employs over 11,000 people in more than 27 countries.

CSL Behring, a subsidiary of CSL, is a leader in the manufacture of plasma protein therapeutics. CSL Behring's therapies are used around the world to treat coagulation disorders including haemophilia 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 haemolytic diseases in the newborn. CSL Behring operates one of the world's largest plasma collection networks, CSL Plasma.

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