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CSL Behring Presents Population Pharmacokinetic Model for Novel Recombinant Factor IX Hemophilia B Treatment That Supports Less Frequent Administration

Recombinant albumin fusion platform forms basis of innovation

Amsterdam, Netherlands — 03 July 2013

CSL Behring today presented a population pharmacokinetic model for recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP) at the International Society on Thrombosis and Haemostasis (ISTH) congress in Amsterdam. The model confirms earlier results from the first-in-human dose escalation trial, which demonstrated improved pharmacokinetics of rIX-FP, with prolonged half-life compared to currently available factor IX.

CSL Behring utilized a population PK approach to predict factor IX activity levels after less frequent administration of rIX-FP to instruct future clinical trials in which extended dosing regimens will be evaluated.

"The information gleaned from this PK model will be useful as we continue our clinical research aimed at developing longer-acting recombinant products for hemophilia," said Russell Basser, M.D., CSL Senior Vice President, Global Clinical Research & Development Senior Vice President. "Developing novel recombinant factor therapies with a longer half-life may result in less frequent dosing for hemophilia patients."

CSL Behring, in collaboration with its parent company, [CSL Limited](#) (ASX: CSL), is developing rIX-FP through its PROLONG-9 clinical trial program.

About the Population Pharmacokinetic Model

The population pharmacokinetic model was built using factor IX activity levels from 37 patients with hemophilia B. The factor IX activity level for each patient was measured using a validated one-stage clotting method after administration of three dose levels (25, 50 and 75 IU/kg) of rIX-FP. Additionally, the effects of age, body weight and baseline factor IX activity on the PK of rIX-FP were evaluated. Model robustness was assessed using nonparametric bootstrap and visual predictive check approaches.

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.

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 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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