



ASX Announcement

For immediate release

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CSL Behring to Present Pivotal Data for rVIII-SingleChain and rIX-FP at ISTH Congress

CSL Limited (ASX:CSL; USOTC:CSLLY) today announced that CSL Behring will present more than 20 abstracts, including five oral presentations, from across its hematology portfolio of investigational and branded products at the 2015 International Society on Thrombosis and Haemostasis (ISTH) Congress being held in Toronto June 20 through 25. The presentations will include pivotal trial data for two of its late-stage recombinant products – its novel recombinant factor VIII SingleChain (rVIII-SingleChain) compound for hemophilia A and its long-acting recombinant factor IX albumin fusion protein (rIX-FP) for hemophilia B.

Hemophilia is an inherited bleeding disorder caused by missing or defective proteins that prevent the blood from clotting normally. The condition affects more than 175,000 people worldwide, the majority of whom have hemophilia A.¹

“CSL is proud to be sharing a significant amount of new scientific and clinical research at ISTH’s 2015 conference,” said Dr. Andrew Cuthbertson, Chief Scientific Officer and Director of R&D, CSL Limited. “I am particularly excited that data from our phase III pivotal studies, for both rVIII-SingleChain and rIX-FP, will be presented publically for the first time. These product candidates hold great promise and potential, and could offer patients strong and sustained efficacy and improved convenience with less frequent dosing, two key areas of unmet need. These data, along with abstracts for other R&D candidates and products in our coagulation franchise, reinforce the depth and breadth of CSL Behring’s knowledge and commitment to advancing the care of patients with serious medical conditions and confirms that we remain on track with our development timelines for rVIII-SingleChain and rIX-FP that we announced at our most recent Research and Development Briefing held on 3 December 2014.”

About rVIII-SingleChain

rVIII-SingleChain is a novel recombinant single-chain factor VIII (FVIII) construct specifically designed for greater molecular stability. It uses a strong covalent bond that forms one structural entity, a single chain, to improve the stability and half-life of FVIII.

The Phase III trial, a part of the AFFINITY clinical development program, is an open-label, non-randomized, multi-center study evaluating the efficacy, safety and



ASX Announcement

Page 2

17 June 2015

pharmacokinetics of rVIII-SingleChain. Study design details for rVIII-SingleChain (CSL627) are available at 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 albumin as its 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. 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 February 2015, the U.S. Food and Drug Administration accepted for review CSL Behring's Biologics License Application (BLA) for rIX-FP. In March 2015, the European Medicines Agency (EMA) started the Centralized Procedure for reviewing CSL Behring's Marketing Authorization Application (MAA) for rIX-FP. Upon regulatory approvals, rIX-FP will provide hemophilia B patients with a long-acting treatment option with dosing intervals up to 14 days.

The PROLONG-9FP clinical development program for rIX-FP covers patients from the age of 1 to 61 years. Studies in the program were conducted as open-label, multicenter, safety and efficacy studies of rIX-FP in previously treated patients with hemophilia B (FIX \leq 2%). Study design details for rIX-FP (CSL654) are available at clinicaltrials.gov.

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.



ASX Announcement

Page 3

17 June 2015

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.

For further information, please contact:

Investors:

Mark Dehring
Head of Investor Relations
CSL Limited
Telephone: +613 9389 3407
Email: mark.dehring@csl.com.au

Media:

Sharon McHale
Senior Director Public Affairs
CSL Limited
Telephone: +613 9389 3425
Mobile +614 0997 8314
Email: sharon.mchale@csl.com.au

ⁱ World Federation of Hemophilia. *Report on the Annual Global Survey 2013*