



ASX Announcement

For immediate release

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U.S. FDA Accepts for Review CSL Behring's BLA for its Novel rVIII-SingleChain Therapy for Patients with Haemophilia A

CSL Limited (ASX:CSL; USOTC: CSLLY) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review CSL Behring's Biologics License Application (BLA) for its novel investigational recombinant factor VIII single-chain (rVIII-SingleChain) for the treatment of haemophilia A. In the pivotal clinical trial, rVIII-SingleChain met all primary endpoints.

Haemophilia A is a congenital bleeding disorder characterized by deficient or defective factor VIII. People with haemophilia A may experience prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. The condition affects approximately 1 in 6,000 male births.

"CSL Behring has one of the industry's largest portfolios of biotherapies that improve the care and well-being of patients with a bleeding disorder," said Dr. Andrew Cuthbertson, Chief Scientific Officer and Director of R&D, CSL Limited. "Our scientific expertise and relationship with the bleeding disorders community led us to seek further advancements in the care and treatment of haemophilia. Today, we have the only recombinant single-chain factor VIII product in late-stage development for the management of haemophilia A and we are excited to be one step closer to providing this innovative treatment to patients in the U.S."

The BLA submission is based on the AFFINITY clinical development program, which includes a phase I/III open-label, multi-center trial examining safety and efficacy. The pharmacokinetics of rVIII-SingleChain compared with recombinant human antihemophilic factor VIII (octocog alfa) was also studied. Study design details for rVIII-SingleChain are available at clinicaltrials.gov.

About rVIII-SingleChain

Specifically designed for greater molecular stability, rVIII-SingleChain is the first and only single-chain factor VIII (FVIII) product in late-stage development for the treatment of haemophilia A. rVIII-SingleChain (also known as CSL627) has a strong affinity for von Willebrand factor, leading to greater stability and integrity of FVIII in circulation.



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About CSL Behring

The people and science of CSL Behring save lives around the world. We develop and deliver innovative specialty biotherapies, driven by our 100-year promise to help people with life-threatening conditions live full lives. With 14,000 employees and operations in 30 countries, CSL Behring applies world-class R&D, high-quality manufacturing and patient-centered management.

CSL Behring 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 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.

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