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ASX Announcement

For immediate release

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IDELVION® (rFIX-FP) – FDA approval

CSL Limited (ASX:CSL; USOTC:CSLLY) - CSL today announced that the U.S. Food and Drug Administration (***FDA***) has approved IDELVION [Coagulation Factor IX (Recombinant), Albumin Fusion Protein], CSL Behring's novel, long-acting albumin fusion protein linking recombinant coagulation factor IX with recombinant albumin for the treatment of haemophilia B.

IDELVION is the first and only factor IX therapy that delivers high-level protection with up to 14-day dosing in appropriate patients. This dosing interval has been achieved while maintaining high levels of factor activity, above 5 percent over 14 days at 75 IU/kg. This reduces the monthly number of units needed for prophylaxis therapy.

"IDELVION has the potential to significantly impact the treatment of haemophilia B as it maintains factor IX activity levels above 5 percent over a prolonged period of time. This provides excellent bleeding control," said Dr Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. "IDELVION is the first product from our innovative recombinant factor development program to receive FDA approval. We are proud to add this new therapy to our growing portfolio of bleeding disorder products, and are particularly excited about the positive impact treatment with IDELVION can have on the well-being of patients with haemophilia B."

IDELVION is indicated in the U.S. in children and adults with haemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; on-demand control and prevention of bleeding episodes; and the perioperative management of bleeding (around the time of surgery). IDELVION is expected to be available in the U.S. later this month.

About Haemophilia B

Haemophilia B is a congenital bleeding disorder characterized by deficient or defective factor IX; nearly all affected patients are male. People with haemophilia B may experience prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. According to U.S. Centers for Disease Control and Prevention, the condition affects approximately one in 25,000 male births.

About IDELVION

CSL Behring engineered IDELVION to extend the half-life of recombinant factor IX through fusion with recombinant albumin. CSL Behring selected recombinant albumin as its fusion partner for its coagulation factor proteins due to its long physiological half-life.

IDELVION is approved in Canada. The European Medicines Agency's Committee for Medicinal Products for Human Use (***CHMP***) recently recommended granting marketing authorization for IDELVION in the European Union. Regulatory agencies in Australia, Switzerland and Japan are also currently reviewing CSL Behring's license applications for IDELVION.

About CSL

CSL is a leading global biotherapeutics company with a dynamic portfolio of life-saving innovations, including those that treat haemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL — including our two businesses CSL Behring and Seqirus — operates in over 30 countries with more than 16,000 employees. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For more information, please visit www.csl.com.au.

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