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ASX Announcement

For immediate release

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IDELVION® (rFIX-FP) - European Commission Approval

CSL Limited (ASX:CSL; USOTC:CSLLY) - CSL today announced that, following the European Medicines Agency (***EMA***) Committee for Medicinal Products for Human Use (***CHMP***) recommendation to grant marketing authorization for IDELVION® (Coagulation Factor IX (Recombinant), Albumin Fusion Protein) for patients with haemophilia B in late February 2016, the European Commission has now approved IDELVION for the treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency).

IDELVION can be used for all age groups (children and adults). The approved treatment regimen includes routine prophylaxis to prevent or reduce the frequency of bleeding episodes; on-demand control; and the perioperative management of bleeding (around the time of surgery).

IDELVION, which was also recently approved in the United States and Canada, delivers high-level protection maintaining factor IX activity levels above 5 percent in most patients over 14-days. As a result, appropriate patients, age 12 and older, can go up to 14 days between infusions and achieve excellent bleeding control. This also reduces the monthly number of units needed for prophylaxis therapy.

“IDELVION provides excellent bleeding control by maintaining factor IX activity levels above 5 percent over a prolonged period of time,” said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. “IDELVION delivers on CSL’s 100 year promise to develop and provide innovative specialty biotherapies that patients need and want. We look forward to bringing IDELVION to the European market and are particularly excited about the positive impact this long-acting therapy can have on the lives of patients with haemophilia B as we enter our next century.”

IDELVION will be launched in European markets in the coming months, as market access and pricing are obtained.

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.. Haemophilia B affects more than 10,000 people throughout Europe according to the European Haemophilia Consortium.

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 also approved in the United States and Canada. Regulatory agencies in Australia, Switzerland and Japan are currently reviewing CSL Behring's license applications for IDELVION.

The European Commission approved IDELVION as an orphan medicinal product -- intended for the safe and effective treatment, prevention or diagnosis of life-threatening or chronically debilitating rare disease that affect not more than 5 in 10,000 people throughout Europe. As an orphan medicinal product IDELVION has been granted market exclusivity for 10 years in the European Union.

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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