



ASX Announcement

For immediate release

9 January 2017

AFSTYLA® (rFVIII), for Haemophilia A, receives European Commission Approval

CSL Limited (ASX:CSL; USOTC:CSLLY) - CSL today announced that the European Commission has granted marketing authorisation for CSL Behring's AFSTYLA® [Recombinant Human Coagulation Factor VIII, Single Chain] for children and adults with haemophilia A. **AFSTYLA**, CSL Behring's novel, recombinant factor VIII therapy, is the first and only single-chain product for haemophilia A. It is specifically designed for protection from bleeds with two or three times weekly dosing and low unit consumption at both dosing regimens.

AFSTYLA is indicated for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). **AFSTYLA** can be used for all age groups.

"European Commission approval of **AFSTYLA**, an innovative and effective haemophilia A therapy, delivers on CSL Behring's promise to develop and provide novel products that have the potential to improve patients' lives," said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. "We are very excited to add this treatment to our industry-leading portfolio of coagulation therapies and look forward to the positive impact **AFSTYLA** can have on haemophilia A patients in the European Union."

AFSTYLA will be launched in European markets in the coming months, as market access is obtained.

Primarily affecting males, haemophilia A is a congenital bleeding disorder characterised by deficient or defective factor VIII. People with haemophilia A may experience prolonged or spontaneous bleeding, especially into the muscles, joints or internal organs. According to the World Federation of Hemophilia, about 1 in 10,000 people are born with haemophilia, the majority of whom have haemophilia A.

About AFSTYLA®

AFSTYLA (also known as rVIII-Single Chain) for haemophilia A is CSL Behring's recombinant single-chain factor VIII specifically designed for greater molecular stability and longer duration of action through strong affinity to von Willebrand factor (**VWF**). **AFSTYLA** uses a covalent bond that forms one structural entity, a single polypeptide-



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chain, to improve the stability of factor VIII and provide factor VIII activity with the option of twice weekly dosing.

AFSTYLA is approved in the European Union, U.S. and Canada. Additionally, regulatory agencies in markets around the world, including Switzerland and Australia, are currently reviewing CSL Behring's marketing applications for **AFSTYLA**.

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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