



# ASX Announcement

**For immediate release**

14 November 2016

## **AFSTYLA® (rFVIII-SC) - CHMP recommendation**

**CSL Limited (ASX:CSL; USOTC:CSLLY)** - CSL today announced that the European Medicines Agency (**EMA**) Committee for Medicinal Products for Human Use (**CHMP**) has recommended granting marketing authorisation for CSL Behring's AFSTYLA® [Recombinant Human Coagulation Factor VIII, Single Chain] for patients with haemophilia A.

"For 100 years, CSL has focused on researching and developing innovative therapies that meet the treatment challenges patients face," said Dr Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. "CHMP's positive opinion for AFSTYLA moves us one step closer to bringing this novel treatment option to haemophilia A patients in the European Union. Once approved, AFSTYLA will provide adults and children with a therapy that delivers on our promise to develop and bring to market innovative specialty biotherapies that help patients live full lives."

### **About Haemophilia A**

Primarily affecting males, 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. 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. AFSTYLA uses a covalent bond that forms one structural entity, a single polypeptide-chain, to improve the stability of factor VIII and provide extended factor VIII activity with the option of twice weekly dosing.

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



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## 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](http://www.csl.com.au).

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