T +613 9389 1911 F +613 9389 1434 www.csl.com.au



ASX Announcement

For immediate release

26 May 2016

AFSTYLA® (rFVIII-Single Chain) – FDA approval

CSL Limited (ASX:CSL; USOTC:CSLLY) - CSL today announced that the US Food and Drug Administration (*FDA*) has approved AFSTYLA® [Antihaemophilic Factor (Recombinant), Single Chain], CSL Behring's novel long-lasting recombinant factor VIII single-chain therapy for adults and children with haemophilia A.

AFSTYLA is indicated in adults and children with haemophilia A for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; on-demand treatment and control of bleeding episodes; and the perioperative management of bleeding. AFSTYLA is expected to be available in the US early this US summer.

"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 Director of R&D, CSL Limited. "The approval of AFSTYLA, an innovative and effective haemophilia A therapy, further demonstrates CSL's dedication to developing and delivering novel therapies that have the potential to improve patients' lives. 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 patients with haemophilia A."

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 US Centers for Disease Control and Prevention (CDC), the condition affects approximately 1 in 6,000 male births.

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 longer-lasting factor VIII activity.

AFSTYLA is the first and only single-chain product for haemophilia A that is specifically designed for long-lasting protection from bleeds with twice-weekly dosing available.



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Regulatory agencies in Europe, Switzerland and Australia are currently reviewing CSL Behring's license 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.

For further information, please contact:

Investors:

Mark Dehring Head of Investor Relations CSL Limited

Phone: +613 9389 3407

Email: mark.dehring@csl.com.au

Media:

Sharon McHale Head of Public Affairs CSL Limited Mobile +61 409 978 314

Email: sharon.mchale@csl.com.au