



ASX Announcement

For immediate release

30 August 2016

FDA Accepts CSL Behring's BLA for First Subcutaneous Prophylactic Therapy to Prevent Hereditary Angioedema Attacks

CSL Limited (ASX:CSL; USOTC:CSLLY) - CSL today announced that the US Food and Drug Administration (**FDA**) has accepted for review CSL Behring's Biologics License Application (**BLA**) for its low-volume subcutaneous (SC) C1-Esterase Inhibitor (**C1-INH**) Human replacement therapy, CSL830, as prophylaxis to prevent Hereditary Angioedema (**HAE**) attacks. HAE is a rare genetic disorder caused by a deficiency of C1-INH, one of the proteins that work with the body's immune system to control inflammation. Symptoms of HAE include episodes of swelling in the face, abdomen, larynx and extremities and can be fatal if untreated.

"The review of this application is another step towards providing advanced prophylactic treatment options to people living with HAE," said Dr Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. "Since CSL Behring first reported the possibility of C1-INH replacement therapy for HAE over 40 years ago, we have remained committed to innovative research and providing advanced treatment options to people living with HAE. Subcutaneous prophylaxis is the next important step in helping HAE patients to prevent HAE attacks."

About Hereditary Angioedema

HAE is a rare and potentially life-threatening genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people. HAE is caused by lack of or malfunctioning C1-INH. As a result, there are inadequate amounts of properly functioning C1-INH, leading fluid to build up in body tissues, causing considerable swelling episodes referred to as angioedema. HAE attacks can affect many parts of the body and can spread to multiple sites, including the face, abdomen, larynx and extremities. Patients who have abdominal attacks of HAE can experience episodes of extreme pain, diarrhoea, nausea and vomiting caused by swelling of the intestinal wall. HAE attacks that involve the face or throat can result in airway closure, asphyxiation and, if untreated, death.

About Subcutaneous C1 Esterase Inhibitor (C1-INH)

C1 Esterase Inhibitor (Human) is an investigational, low-volume, subcutaneous prophylactic therapy. C1-INH replaces the missing or malfunctioning C1-INH protein in patients with a C1-INH deficiency, thereby preventing HAE attacks.



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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.

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