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ASX Announcement

For immediate release

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HAEGARDA® (C1 Esterase Inhibitor Subcutaneous [Human]) FDA Approval

CSL Limited (ASX:CSL; USOTC:CSLLY) today announced that the U.S. Food and Drug Administration (FDA) has approved CSL Behring's HAEGARDA® (C1 Esterase Inhibitor Subcutaneous [Human]), the only subcutaneous therapy indicated for routine prophylaxis to prevent hereditary angioedema (HAE) attacks in adolescent and adult patients. HAE is a rare, genetic, and potentially life-threatening condition that causes painful, debilitating, and unpredictable episodes of swelling on the body, including the abdomen, face, larynx, and extremities.[1]

HAEGARDA is a self-administered, plasma-derived concentrate of C1 esterase inhibitor (C1-INH) injected twice weekly subcutaneously (just under the skin).

"The FDA approval of HAEGARDA is an important milestone for the HAE community because it addresses the primary need of patients: to effectively prevent debilitating HAE attacks," said Dr. Andrew Cuthbertson, Chief Scientific Officer and R&D Director, CSL Limited. "CSL Behring has a long heritage in HAE, and thanks to our clinical trial participants, we're proud to lead the community into the next era of treatment by offering the first and only subcutaneous preventive treatment option."

About Hereditary Angioedema (HAE)

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 deficient or dysfunctional C1-INH, a protein in the blood that helps to control inflammation. Inadequate amounts of properly functioning C1-INH can lead to the accumulation of fluid in body tissues, causing considerable swelling referred to as angioedema.[2] HAE attacks can affect many parts of the body and can spread to multiple sites, including the face, abdomen, larynx, and extremities.[1] Patients who have abdominal attacks of HAE can experience extreme pain, diarrhea, 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 left untreated, death.[1]

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[1] Agostoni A, et al. Hereditary and acquired angioedema: problems and progress: proceedings of the third C1 esterase inhibitor deficiency workshop and beyond. J Allergy Clin Immunol. 2004;114(3 Suppl):S51-131.

[2] Kemp JG, et al. Variability of prodromal signs and symptoms associated with hereditary angioedema attacks: A literature review. Allergy Asthma Proc. 2009;30:492-499.

About HAEGARDA® (C1 Esterase Inhibitor Subcutaneous [Human])

HAEGARDA is a self-administered, plasma-derived concentrate of C1-esterase inhibitor and the only subcutaneous therapy approved in the United States for routine prophylaxis to prevent HAE attacks in adolescent and adult patients.

HAEGARDA targets the root cause of HAE by replacing deficient or dysfunctional natural C1-INH, restoring functional C1-INH levels to above 40 percent of normal levels, a percentage thought to be associated with reduced risk for HAE attacks.[3] HAEGARDA is dosed individually based on body weight so that each patient can achieve functional C1-INH levels.

About CSL

CSL (ASX:CSL; USOTC:CSLLY) is a leading global biotechnology company with a dynamic portfolio of life-saving medicines, 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 - provides life-saving products to more than 60 countries and employs nearly 20,000 people. 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.

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[3] Longhurst H, et al. Prevention of hereditary angioedema attacks with a subcutaneous C1 inhibitor. N Eng J Med. 2017;376:1131-1140.