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CSL receives approval for ANDEMBRY in Japan to prevent hereditary angioedema

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Approval is based on the results of the international pivotal Phase 3 VANGUARD trial, which included hereditary angioedema patients from Japan

CSL Behring K.K. has received manufacturing and marketing approval from Japan's Ministry of Health, Labour and Welfare (MHLW) for ANDEMBRY (garadacimab) Subcutaneous (SC) Injection 200mg Pens.

The product is approved for the prevention of acute attacks of hereditary angioedema (HAE) and is the first pre-filled pen presentation for once-monthly subcutaneous administration for long-term prophylaxis of HAE. The approval in Japan follows additional recent approvals received in Australia, the United Kingdom, and the European Union.

ANDEMBRY is the first fully human monoclonal antibody in Japan designed to inhibit activated Factor XII (Factor XIIa), which initiates the cascade of events leading to angioedema at various sites of the body.

HAE is a rare, chronic, debilitating, and potentially life-threatening genetic disorder characterised by recurrent and unpredictable attacks of angioedema. Attacks are often painful and can occur in multiple sites of the body, including the abdomen, larynx, face, and extremities. HAE is designated as one of Japan's intractable diseases under the category of "Primary Immunodeficiency Syndrome." Reports indicate that approximately 430 patients in Japan are currently diagnosed and receiving treatment. According to global data, the prevalence of HAE is estimated to be 1 in 50,000 people, suggesting there may be approximately 2,500 patients in Japan.

"ANDEMBRY is a breakthrough therapy as the first and only treatment targeting activated Factor XII, the key initiator of HAE attacks," said Dr Rose Fida, Executive Director and Regional Lead, CSL R&D Japan & China. "With its novel mechanism, once-monthly subcutaneous dosing and easy-to-use pre-filled pen, ANDEMBRY is set to transform the way HAE is managed in Japan."