CSL Limited
ABN: 99 051 588 348
655 Elizabeth Street
Melbourne
Victoria 3000 Australia
T +613 9389 1911
F +613 9389 1434
CSL.com

ASX Announcement

For immediate release 17 June 2025

U.S. Food and Drug Administration Approves CSL's treatment for Hereditary Angioedema

Melbourne, Australia – CSL (ASX:CSL; USOTC:CSLLY) today announces that the U.S. Food and Drug Administration (FDA) has approved ANDEMBRY® for immediate launch in the United States.

ANDEMBRY® helps prevent attacks of hereditary angioedema (HAE). It is the first and only treatment targeting factor XIIa for prophylactic use to provide sustained protection from attacks of HAE in adult and pediatric patients aged 12 years and older. HAE occurs in about 1 in 50,000 people of any ethnic group.

ANDEMBRY® is also the only treatment to offer once-monthly dosing from the start for all patients and is administered via an autoinjector. It inhibits the top of the HAE cascade by targeting factor XIIa. The pivotal placebo-controlled Phase 3 VANGUARD trial and its open-label extension study showed ANDEMBRY reduced the median number of HAE attacks by more than 99 percent and a least squares mean of 89.2 percent, compared to placebo.[1]

This FDA approval builds on other recent approvals for the treatment in Australia, the United Kingdom, the European Union, Japan, Switzerland and United Arab Emirates.

CSL will launch ANDEMBRY in the United States immediately, with availability through its third-party specialty pharmacy network before the end of June.

Authorised for lodgement by:

Fiona Mead
Company Secretary

[1] The multicenter, randomized, double-blind, parallel-group VANGUARD trial evaluated the efficacy and safety of ANDEMBRY, an investigational first-in-class monoclonal antibody, as a prophylactic treatment for patients with hereditary angioedema. Patients aged 12 years and older with HAE type I or II underwent screening and a run-in study period to verify a baseline attack rate. Patients were randomized 3:2 to receive a loading dose of 400mg followed by 200 mg of ANDEMBRY monthly (n=39) or volume matched placebo monthly (n=25) subcutaneously. After the six-month treatment period, patients were given the opportunity to continue into the open-label extension study, which is currently ongoing.

The ongoing open-label extension of the Phase 3 VANGUARD study is evaluating the long-term safety and efficacy of garadacimab (200 mg monthly) for the prophylactic treatment of hereditary angioedema attacks in ~160 patients for 2 years.

For further information, please contact:

Investors:
Chris Cooper
Head, Investor Relations
CSL Limited
P: +61 455 022 740
E: chris.cooper@csl.com.au

Media:
Brett Foley
Corporate Communications
CSL Limited
P: +61 461 464 708
E: brett.foley@csl.com.au