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ASX Announcement

For immediate release 21 February 2023

Portfolio Update

CSL (ASX:CSL; USOTC:CSLLY) advises that the European Commission has overnight granted Conditional Marketing Authorisation of HEMGENIX® (etranacogene dezaparvovec) for the first gene therapy option for the treatment of severe and moderately severe Hemophilia B (congenital Factor IX deficiency) in adults without a history of Factor IX inhibitors by a single infusion.

This follows approval by the US Food and Drug Administration for HEMGENIX® for the same indications on 22 November 2022.

CSL also advises that it has received results from the Phase 3 clinical trial of garadacimab (CSL312). Garadacimab is CSL's investigational monoclonal antibody being developed as a long-term prophylactic treatment for patients with hereditary angioedema (HAE).

Results from the trial, the first to investigate targeting activated Factor XII (FXIIa) to prevent HAE attacks, showed that once-monthly subcutaneous injections of garadacimab significantly reduced the attack rate compared to placebo. Based on these results, CSL will proceed with regulatory submissions to global health authorities later this calendar year for full approval of garadacimab.

Authorised By

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