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Australia grants provisional determination to AstraZeneca's Evusheld for adolescents

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Evusheld (tixagevimab co-packaged with cilgavimab) is a long-acting antibody combination for the prevention of COVID-19

On 4 January 2022, the Therapeutic Goods Administration (TGA) in Australia granted a further provisional determination to AstraZeneca in relation to the COVID-19 treatment- tixagevimab and cilgavimab (EVUSHELD), for the prevention and treatment of COVID-19 in adolescents and adults aged 12 years and older.

The original determination of 4 November 2021 was for prevention in adults 18 years and older. This new determination now includes prevention and treatment of COVID-19 in individuals aged 12 years and older.

This treatment consists of two monoclonal antibodies, tixagevimab and cilgavimab. These antibodies bind to the spike protein of the SARS-CoV-2 virus at two different sites. By attaching to the spike protein, the medicine is expected to stop the virus from entering the body's cells and causing infection.

The granting of a provisional determination means that the TGA has made a decision that AstraZeneca is now eligible to apply for provisional registration for EVUSHELD in the Australian Register of Therapeutic Goods (ARTG) in this age group. Provisional determination is the first step in the process. It is anticipated that AstraZeneca will submit an application for provisional registration shortly.

EVUSHELD is not intended to be used as a substitute for vaccination against COVID-19.