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Australia provisionally approves AstraZeneca's EVUSHELD for pre-exposure prevention of COVID-19

February 28, 2022 | News

Provisional approval of EVUSHELD is subject to certain strict conditions, such as the requirement for the sponsors to continue providing information to the TGA on longer-term efficacy and safety from ongoing clinical trials and post-market assessment



The Therapeutic Goods Administration (TGA) in Australia has granted provisional approval to AstraZeneca for its tixagevimab and cilgavimab (EVUSHELD) for the prevention of COVID-19 in people who are at risk of infection but have not been exposed to the virus, known as pre-exposure prevention of COVID-19.

EVUSHELD has been granted provisional approval for the pre-exposure prophylaxis (prevention) of COVID-19 in people aged 12 years and older weighing at least 40 kg who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments that make it likely that they will not mount an adequate immune response to COVID-19 vaccination.

It is meant for whom vaccination is not recommended due to a history of severe adverse reaction to a COVIDÃ¢â?¬Â•19 vaccine or COVIDÃ¢â?¬Â•19 vaccine component.

According to TGA, pre-exposure prevention with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.

EVUSHELD is administered as two separate, sequential injections of two long-acting monoclonal antibodies, tixagevimab and cilgavimab. These antibodies bind to the spike protein of the SARS-CoV-2 virus at two different sites to stop the virus from entering the body's cells and causing infection.

The Australian Government has secured 36,000 treatment courses of EVUSHELD from AstraZeneca.