Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Out of Session Meeting, 10 November 2022

Section A: Premarket registration applications

At this meeting, the committee provided advice on 2 applications under evaluation by the TGA, as below.

Active ingredient (TRADENAME)	Sponsor	Therapeutic area	Application designations
Applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia (Application Type A)			
tixagevimab and cilgavimab (EVUSHELD)	AstraZeneca Pty Ltd	For treatment / prophylaxis of COVID-19	Provisional

The committee also provided advice on:

- One application for major variations (new dosage form, change/increase in patient group, change in dosage, new strength, new route of administration) (Application Type F)

Further details of the ACM discussion and advice associated with these items may be released within the Australian Public Assessment Reports (AusPARs). To browse all AusPARs see: https://www.tga.gov.au/resources/auspar

Further information

For further information on the Advisory Committee on Medicines, please visit:

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