



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Advisory Committee on Biologicals

Meeting Statement

Meeting 20, 20 August 2026

Premarket inclusion applications

At this meeting, the committee provided advice on 3 applications under evaluation by the TGA, as below.

Product (TRADENAME)	Product Type	Classification	Sponsor
Applications for a new biological not currently approved in Australia			
Lisocabtagene maraleucel (BREYANZI)	CAR-T cell	Class 4 Biological	Bristol-Myers Squibb Australia
Applications for a variation to an existing biological currently included in the ARTG			
Axicabtagene ciloleucel (YESCARTA)	CAR-T cell	Class 4 Biological	Gilead Sciences
Brexucabtagene autoleucel (TECARTUS)	CAR-T cell	Class 4 Biological	Gilead Sciences

Further information

For further information on the Advisory Committee on Biologicals please visit:

[Advisory Committee on Biologicals](#) or contact the committee support unit by email at MRDCommitteeSupport@health.gov.au