



Advisory Committee on Medicines

Meeting Statement

Meeting 37 3 February 2023

Section A: Premarket registration applications

At this meeting, the committee provided advice on 6 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)			
lenacapavir (SUNLENCA)	Gilead Sciences Pty Ltd	For treatment of human immunodeficiency virus type 1 (HIV-1)	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
carfilzomib (KYPROLIS)	Amgen Australia Pty Ltd	For the treatment of relapsed or refractory multiple myeloma in combination with daratumumab and dexamethasone	

ibrutinib (IMBRUVICA)	Janssen-Cilag Pty Ltd	For treatment of leukaemia and lymphoma	
zanubrutinib (BRUKINSA)	BeiGene AUS Pty Ltd	For treatment of leukaemia and lymphoma	

The dates of commencement of the evaluation of these applications are available at Prescription medicines: applications under evaluation, see:

<https://www.tga.gov.au/prescription-medicines-applications-under-evaluation>

The committee also provided advice on:

- Two applications 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>

Section B: Post-market items

The ACM was not asked to provide advice on a post-market or safety issue.

Further information

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

<https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-medicines-acm>

or contact the ACM Secretary by email: ACM@health.gov.au