Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 39 – 1 and 2 June 2023

Section A: Premarket registration applications

At this meeting, the committee provided advice on 15 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)			
andexanet alfa (ANDEXXA)	AstraZeneca Pty Ltd	For treatment of reversal of anticoagulation.	Provisional
atogepant (AQUIPTA)	AbbVie Pty Ltd	For the treatment of migraines.	
capmatinib (TABRECTA)	Novartis Pharmaceuticals Australia Pty Ltd	For treatment of non-small cell lung cancer.	Orphan
imlifidase (IDEFIRIX)	Hansa Biopharma Pty Ltd	For desensitisation treatment.	Provisional Orphan

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selpercatinib (RETEVMO)	Eli Lilly Australia Pty Ltd	For the treatment of non-small cell lung cancer.	Provisional
tafasitamab (MINJUVI)	Specialised Therapeutics Alim Pty Ltd	For the treatment of Diffuse Large B-cell Lymphoma (DLBCL)	Provisional Orphan
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
cefuroxime sodium (CEFINTRA)	Aspen Pharmacare Australia Pty Ltd	For treatment of postoperative endophthalmitis.	
clobetasol propionate (XOBET)	Douglas Pharmaceuticals Australia	For treatment of steroid responsive dermatoses.	
dapagliflozin (FORXIGA)	AstraZeneca Pty Ltd	For the treatment of heart failure.	
dupilumab (DUPIXENT)	Sanofi-Aventis Australia Pty Ltd	For the treatment of prurigo nodularis (PN).	
dupilumab (DUPIXENT)	Sanofi-Aventis Australia Pty Ltd	For the treatment of severe atopic dermatitis in patients aged 6 months to 11 years.	
sacituzumab govitecan (TRODELVY)	Gilead Sciences Pty Ltd	For the treatment of breast cancer.	Priority
upadacitinib (RINVOQ)	AbbVie Pty Ltd	For the treatment of Crohn's disease.	
zoledronic acid (Multiple tradenames)	Arrotex Pty Ltd	For the treatment of breast cancer in postmenopausal women.	

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:

- 1 application for variation to the registered entry resulting in a change to the PI (Application Type J)

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