Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 36, 1 and 2 December 2022

Section A: Premarket registration applications

At this meeting, the committee provided advice on 14 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)			
avacopan (TAVNEOS)	Vifor Pharma Pty Ltd	For treatment of vasculitis	Orphan
edaravone (RADICAVA)	Teva Pharma Australia Pty Ltd	For treatment of amyotrophic lateral sclerosis (ALS)	Orphan
prabotulinumtoxinA (NUCEIVA)	PPD Australia Pty Ltd	For treatment of glabellar lines	
pralsetinib (GAVRETO)	Roche Products Pty Ltd	For treatment of lung cancer	Provisional
pralsetinib (GAVRETO)	Roche Products Pty Ltd	For treatment of thyroid cancer	Provisional

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tirzepatide (MOUNJARO)	Eli Lilly Australia Pty Ltd	For treatment of type 2 diabetes mellitus	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
baricitinib (OLUMIANT)	Eli Lilly Australia Pty Ltd	For treatment of alopecia areata	
ivacaftor (KALYDECO)	Vertex Pharmaceuticals	For treatment of cystic fibrosis	Orphan
polatuzumab vedotin (POLIVY)	Roche Products Pty Ltd	For treatment of lymphoma	
tofacitinib (XELJANZ)	Pfizer Australia Pty Ltd	For treatment of anklyosing spondylitis	
upadacitinib (RINVOQ)	AbbVie Pty Ltd	For treatment of axial spondyloarthritis	

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:

- One application for the registration of a new biosimilar medicine
- 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