Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 49, 6 and 7 February 2025

Section A: Premarket registration applications

At this meeting, the committee provided advice on 13 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)			
leniolisib phosphate (JOENJA)	Ballia Holdings Pty Ltd	Activated phosphoinositide 3-kinase delta syndrome	Priority Orphan
futibatinib (LYTGOBI)	Taiho Pharma Oceania Pty Ltd	Advanced or metastatic cholangiocarcinoma	Provisional Orphan
inebilizumab (UPLIZNA)	Amgen Australia Pty Ltd	Neuromyelitis optica spectrum disorders	
lazertinib mesilate monohydrate (LAZCLUZE)	Janssen-Cilag Pty Ltd	Locally advanced or metastatic non-small cell lung cancer	

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elafibranor (IQIRVO)	Ipsen Pty Ltd	Primary biliary cholangitis	
velmanase alfa (LAMZEDE)	Chiesi Australia PTY LTD	Alpha-mannosidosis	Orphan
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
tenecteplase (METALYSE)	Boehringer Ingelheim Pty Ltd	Acute ischaemic stroke	
olaparib (LYNPARZA)	AstraZeneca Pty Ltd	Advanced or recurrent endometrial cancer	
durvalumab (IMFINZI)	AstraZeneca Pty Ltd	Advanced or recurrent endometrial cancer	Priority
bimekizumab (BIMZELX)	UCB Australia Pty Ltd	Moderate to severe hidradenitis suppurativa	
amivantamab (RYBREVANT)	Janssen-Cilag Pty Ltd	Locally advanced or metastatic non-small cell lung cancer	
elexacaftor, ivacaftor, tezacaftor (TRIKAFTA)	Vertex Pharmaceuticals	Cystic fibrosis	Orphan
melphalan hydrochloride (PHELINUN)	Link Medical Products Pty Ltd	Conditioning regimen prior to haematopoietic stem cell transplantation in malignant haematological diseases.	Orphan

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

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