



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

# ACM meeting statement, Meeting 38, 30-31 March 2023

Advisory Committee on Medicines

**Published:**

18 May 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)			
concizumab (ALHEMO)	Novo Nordisk Pharmaceuticals Pty Ltd	To prevent or reduce the frequency of bleeding	Priority  Orphan
glofitamab (COLUMVI)	Roche Products Pty Ltd	Treatment of diffuse large B-cell lymphoma	Provisional  Orphan
olipudase alfa (XENPOZYME)	Sanofi-Aventis Australia Pty Ltd	For the treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD)	Orphan
rimegepant (NURTEC)	Pfizer Australia Pty Ltd	For the treatment of migraines	COR-B
tagraxofusp (ELZONRIS)	A. Menarini Australia Pty Ltd	For the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Orphan

Active ingredient (TRADENAME)	Sponsor	Therapeutic area	Application designations
teclistamab (TECVYALI)	Janssen-Cilag Pty Ltd	For treatment of relapsed or refractory multiple myeloma	Provisional
tremelimumab (IMJUDO)	AstraZeneca Pty Ltd	For treatment of unresectable hepatocellular carcinoma	
Applications for a 'new indication', or additional therapeutic use, for an already approved medicine (Application Type C)			
durvalumab (IMFINZI)	AstraZeneca Pty Ltd	For treatment of unresectable hepatocellular carcinoma	
cemiplimab (LIBTAYO)	Sanofi-Aventis Australia Pty Ltd	For treatment of non-small cell lung cancer	
obinutuzumab (GAZYVA)	Roche Products Pty Ltd	To reduce the risk of cytokine release syndrome	
olaparib (LYNPARZA)	AstraZeneca Pty Ltd	For treatment of breast cancer and prostate cancer	
risdiplam (EVRYSDI)	Roche Products Pty Ltd	For treatment of spinal muscular atrophy)	
finerenone (KERENDIA)	Bayer Australia Pty Ltd	For treatment of chronic kidney disease	

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:

- 2 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](mailto:ACM@health.gov.au)

### Print version

 **Download PDF** (<https://www.tga.gov.au/sites/default/files/2023-05/acm-meeting-statement-meeting-38-30-and-31-march-2023.pdf>) [91.26 KB]

### Topics:

[Advisory bodies and committees](https://www.tga.gov.au/about-tga/advisory-bodies-and-committees) (<https://www.tga.gov.au/about-tga/advisory-bodies-and-committees>).

[Medicines](https://www.tga.gov.au/products/medicines) (<https://www.tga.gov.au/products/medicines>).

### Outcome of:

[Advisory Committee on Medicines \(ACM\)](https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-medicines-acm) (<https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-medicines-acm>).

[ACM meeting #38, 30-31 March 2023](https://www.tga.gov.au/resources/event/committee-meetings/acm-meeting-38-30-31-march-2023) (<https://www.tga.gov.au/resources/event/committee-meetings/acm-meeting-38-30-31-march-2023>).