Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Advisory Committee on Medicines

# Meeting Statement

## Meeting 38 – 30 and 31 March 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<br>Orphan |
| glofitamab (COLUMVI) | Roche Products Pty Ltd | Treatment of diffuse large B-cell lymphoma | Provisional<br>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 |

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| | | | |
|---|---|---|---|
| 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 |
| 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