



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Meeting 33, Thursday 2 and Friday 3 June 2022

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 11 applications under evaluation by the TGA. The applications included:

Active ingredient (TRADENAME)	Sponsor	Therapeutic area
Type A (new biological entity)		
faricimab (VABYSMO)	Roche Products Pty Ltd	For treatment of neovascular age-related macular degeneration and diabetic macular oedema.
Type A (new chemical entity)		
asciminib (as hydrochloride) (SCEMBLIX)	Novartis Pharmaceuticals Australia Pty Ltd	For treatment of Philadelphia chromosome positive chronic myeloid leukaemia in chronic phase.
Type C (extension of indications)		
cabotegravir (APRETUDE)	ViiV Healthcare Pty Ltd	
leuprorelin acetate (ELIGARD)	Mundipharma Pty Ltd	
nivolumab (OPDIVO)	Bristol Myers Squibb Australia Pty Ltd	For adjuvant treatment of patients with muscle invasive urothelial carcinoma (MIUC).
pembrolizumab (KEYTRUDA)	Merck sharp and Dohme (Australia) Pty Ltd	For treatment of renal cell carcinoma.

pembrolizumab (KEYTRUDA)	Merck sharp and Dohme (Australia) Pty Ltd	For treatment of triple-negative breast cancer (TNBC)
ravulizumab (ULTOMIRIS)	Alexion Pharmaceuticals Australia Pty Ltd	For treatment of atypical haemolytic uraemic syndrome.

*These application types are published on the Prescription medicines: applications under evaluation page <https://www.tga.gov.au/prescription-medicines-applications-under-evaluation>

In addition to:

- Two seeking a major variation (change in dosage)
- One seeking input on a long-term application for consent to import, supply or export goods that do not conform with standards

Further details of the ACM discussion and advice associated with these items may be released within the Australian Public Assessment Reports (AusPARs). Please note that there is a delay from when an application was considered at ACM and the publication of the AusPAR. To browse all AusPARs see: <<https://www.tga.gov.au/browse-auspars-active-ingredient>>

Further information

For further information on the Advisory Committee on Medicines, please visit:

<https://www.tga.gov.au/committee/advisory-committee-medicines-acm> or contact the ACM Secretary by email: ACM@health.gov.au.