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GSK Australia receives provisional nod for COVID-19 mAb treatment

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The provisional pathway provides a formal and transparent mechanism for speeding up the registration of promising new medicines

The Therapeutic Goods Administration (TGA), part of the Department of Health in Australia, has granted a provisional determination to GlaxoSmithKline Australia Pty Ltd (GSK) in relation to the monoclonal antibody (mAb) treatment, SOTROVIMAB.

The granting of a provisional determination means that the TGA has made a decision that GSK is now eligible to apply for provisional registration for the treatment in the Australian Register of Therapeutic Goods (ARTG).

Provisional determination is the first step in the process and does not mean that an application has or will be made, or that the treatment will be provisionally approved for inclusion in the ARTG.

The provisional pathway provides a formal and transparent mechanism for speeding up the registration of promising new medicines with preliminary clinical data. In order to apply for provisional registration, the sponsor must first apply for a provisional determination. Further information on eligibility criteria can be found at Provisional registration process.

In making its decision to grant GSK a provisional determination, the TGA considered all eligibility criteria, including factors such as the evidence of a plan to submit comprehensive clinical data and the seriousness of the current COVID-19 pandemic.