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Australia approves remdesivir as first treatment option for COVID-19

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Provisional approval from TGA for use of remdesivir is limited to a maximum of six years



The Therapeutic Goods Administration (TGA), Division of the Australian Department of Health, has granted provisional approval to remdesivir ("Veklury", Gilead Sciences Pty Ltd) as the first treatment option for COVID-19. It has received provisional approval for use in adults and adolescent patients with severe COVID-19 symptoms who have been hospitalised.

Remdesivir is the most promising treatment option so far to reduce hospitalisation time for those suffering from severe coronavirus infections. Remdesivir offers the potential to reduce the strain on Australia's health care system. By reducing recovery times patients will be able to leave the hospital earlier, freeing beds for those in need. Remdesivir will not be available to Australians unless they are severely unwell, requiring oxygen or high-level support to breathe, and in-hospital care.

While this is a major milestone in Australia's struggle against the pandemic, it is important to emphasize that the product has not been shown to prevent coronavirus infection or relieve milder cases of infection.

Australia is one of the first regulators to authorize the use of remdesivir for the treatment of COVID-19, following on from recent approvals in European Union, Japan, and Singapore. International regulatory cooperation played a significant role, as the European Medicines Agency and the Singapore Health Sciences Authority generously shared their review reports with TGA at an early stage.

TGA's approval was able to be made within 2 weeks of the receipt of the submission with a large multidisciplinary review team at TGA working around the clock.

Provisional approval, which is limited to a maximum of six years, was made on the basis of preliminary clinical data, as there is the potential for substantial benefit to Australian patients. The sponsor, Gilead Sciences Pty Ltd may apply for full registration when additional clinical data required by the TGA to confirm the safety and efficacy of the medicine are available.