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HSA UPDATES

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HSA UPDATES NO 7/2020

HSA GRANTS CONDITIONAL APPROVAL OF REMDESIVIR FOR TREATMENT OF COVID-19 INFECTION

The Health Sciences Authority (HSA), in consultation with its Medicines Advisory Committee, has today granted conditional approval for Gilead Sciences Singapore Pte Ltd’s (Gilead) Veklury® (remdesivir). This will allow infectious diseases specialists to administer remdesivir for the treatment of adult patients with COVID-19 infection, who:

- Have oxygen saturation less than or equal to 94%, or;
- Require supplemental oxygen, or;
- Require more intensive breathing support such as extracorporeal membrane oxygenation or invasive mechanical ventilation.

2 To optimise the use of remdesivir in COVID-19 management, HSA is working with the Ministry of Health and relevant experts to further define the subcategory of patients who are likely to benefit most from this medicine.

3 Although the data on its efficacy and safety is very limited at this point in time, HSA has expedited the review of remdesivir given the urgent public health need during the COVID-19 pandemic. As part of the conditional approval, Gilead is required to collect the relevant safety data and to monitor the use of remdesivir. HSA

will also require data from ongoing clinical studies to be submitted post-approval to ensure the continued safety and efficacy of the product.

4 Since March 2020, HSA had facilitated the early access of remdesivir to COVID-19 patients in Singapore through the expeditious evaluation and approval of its use in clinical trials. HSA has been working closely with Gilead on the conditional approval of remdesivir in Singapore. Gilead filed for registration of remdesivir in Singapore on 22 May and obtained HSA's conditional approval on 10 June 2020. Singapore is among the earliest countries to grant an approval for the medicine.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
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▪ **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

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