SINGAPORE, 30 JUNE 2021

HSA UPDATES

"HSA UPDATES" addresses topics of current public interest and is subject to change as more information becomes available.

HSA UPDATES NO 1/2021

HSA GRANTS INTERIM AUTHORISATION FOR SOTROVIMAB FOR TREATMENT OF COVID-19 INFECTION

The Health Sciences Authority (HSA), in consultation with its Medicines Advisory Committee, has granted interim authorisation under the Pandemic Special Access Route (PSAR) for sotrovimab, a monoclonal antibody by GlaxoSmithKline Pte Ltd (GSK) and Vir Biotechnology, on 30 June 2021. This will allow infectious disease specialists to use this monoclonal antibody therapy for the treatment of mild-to-moderate COVID-19 in patients aged 18 years and older, who do not require oxygen supplementation and are at risk for progression to severe COVID-19. The at-risk factors include being aged 55 years and above, and / or having comorbidities such as chronic kidney disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes, moderate to severe asthma, and obesity.

EFFICACY AND SAFETY

2 HSA's review of the available clinical data based on rolling submission of the results from a Phase II/III study found that sotrovimab demonstrated a 79% reduction in the relative risk for progression to requiring acute treatment in hospital or death due to COVID-19 compared to placebo. There was also a smaller proportion of subjects who progressed to severe and/or critical respiratory disease requiring oxygen supplementation in the sotrovimab group (1%) compared to the placebo group (5%).

The efficacy data was based on an ongoing Phase II/III clinical trial conducted in more than 1,000 subjects aged 18 to 96 years, all of whom had risk factors for progression to severe disease. All subjects were enrolled within 5 days of onset of symptoms and did not require oxygen supplementation at baseline. As there was no data on the use of sotrovimab in individuals aged 18 years and below, and women who were pregnant and lactating, no recommendation for use was made for these sub-populations.

3 The safety data showed that sotrovimab is well-tolerated. The common adverse events reported in the clinical study were headache, dehydration, nausea and diarrhoea. The incidences of these adverse events were generally low and were reported at similar or lower incidences compared to the placebo group.

ACTIVE MONITORING AND CONTINUOUS REVIEW OF DATA

4 GSK is required to collect the relevant safety data and monitor the use of sotrovimab as a condition for interim authorisation under PSAR. HSA will also require GSK to continue submitting updated clinical and pharmacology data from ongoing clinical studies to ensure the continued safety and efficacy of the product. As there is currently insufficient clinical data to assess the efficacy of sotrovimab in the presence of circulating SARS-CoV-2 variants, GSK will also need to submit relevant data on this for HSA's continuous benefit-risk assessment.

5 HSA will actively review the data submitted by GSK to ensure that the benefits of sotrovimab continue to outweigh the known risks. When sufficient data is available, GSK will be required to file an application for full product registration. HSA may also terminate PSAR authorisation at any time; for example, if new data suggests that the benefits no longer outweigh the risks.

HEALTH SCIENCES AUTHORITY
SINGAPORE
30 JUNE 2021

- **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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