SINGAPORE, 21 SEPTEMBER 2021

HSA UPDATES

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HSA UPDATES NO 5/2021

HSA GRANTS INTERIM AUTHORISATION FOR CASIRIVIMAB AND IMDEVIMAB FOR TREATMENT OF COVID-19 INFECTION

The Health Sciences Authority (HSA), in consultation with its Medicines Advisory Committee, has on 21 September 2021 granted interim authorisation under the Pandemic Special Access Route (PSAR) for casirivimab and imdevimab, by Roche-Regeneron, to be administered together for the treatment of mild to moderate COVID-19. This will allow infectious diseases specialists to use the combination monoclonal antibodies therapy for the treatment of COVID-19 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 50 years and above, being immunocompromised or having comorbidities such as cardiovascular disease, chronic lung disease, chronic liver disease, chronic kidney disease, diabetes, and obesity.

EFFICACY AND SAFETY

2 HSA's review of the available clinical data based on rolling submission of the results from an ongoing Phase III study found that casirivimab-imdevimab demonstrated a 70% reduction in the relative risk for progression to requiring acute treatment in hospital or death due to COVID-19 as compared to the placebo group. Treatment with casirivimab-imdevimab also led to faster resolution of COVID-19 symptoms, 4 days earlier than the placebo group. There was also a smaller proportion

of subjects who progressed to severe and/or critical respiratory disease requiring oxygen supplementation in the casirivimab-imdevimab group (0.5%) as compared to the placebo group (2.1%). The clinical trial was conducted in more than 4,000 subjects aged 18 to 96 years, all of whom had risk factors for progression to severe disease. All subjects were enrolled within 7 days of onset of symptoms and did not require oxygen supplementation at baseline. As there was no data on the use of casirivimab-imdevimab in individuals aged below 18 years, and women who were pregnant and lactating, HSA is not recommending its use in these sub-populations.

3 The safety data showed that casirivimab-imdevimab is well-tolerated. The incidences of adverse events reported in the clinical study were generally low and were mostly reported at lower incidences as compared to the placebo group. The common adverse events reported were infusion-related reactions or hypersensitivity reactions.

ACTIVE MONITORING AND CONTINUOUS REVIEW OF DATA

4 Roche is required to collect the relevant safety data and monitor the use of casirivimab-imdevimab as a condition for interim authorisation under PSAR. HSA will also require Roche to continue submitting updated clinical 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 the treatment in the presence of circulating SARS-CoV-2 variants, Roche will also need to submit relevant data on this for HSA's continual benefit-risk assessment.

5 HSA will actively review the data submitted by Roche to ensure that the benefits of casirivimab-imdevimab continue to outweigh the known risks. When sufficient data is available, Roche 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
21 SEPTEMBER 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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