FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
3 FEBRUARY 2022

HSA GRANTS INTERIM AUTHORISATION FOR PAXLOVID™, THE FIRST ORAL MEDICINE FOR TREATMENT OF COVID-19 INFECTION

The Health Sciences Authority (HSA), in consultation with its Medicines Advisory Committee, has on 31 January 2022, granted interim authorisation under the Pandemic Special Access Route (PSAR) for Pfizer's PAXLOVID™, a combination of two medicines, nirmatrelvir (the antiviral medicine) and ritonavir (to maintain the blood level of nirmatrelvir for antiviral efficacy). This is the first oral tablet approved in Singapore for the treatment of mild to moderate COVID-19 in adult patients who are at high risk of progression to severe disease, to reduce the risk of hospitalisation and death. PAXLOVID™ is to be taken twice daily for 5 days, and the treatment should be initiated as soon as possible after a diagnosis has been made, within 5 days of the onset of COVID-19 symptoms. It will be prescribed and prioritised to those at higher risk of severe COVID illness, as directed by the Ministry of Health.

EFFICACY AND SAFETY

2 HSA's review of the available clinical data based on rolling submission of the results from an ongoing Phase II/III study found that PAXLOVID™ reduced the risk of COVID-19 related hospitalisation or death as compared to the placebo group by 88.9% when treatment was given within 3 days of onset of symptoms and 87.8% when given within 5 days of onset of symptoms. The efficacy analysis included patients infected with the Delta variant. In vitro data has shown that PAXLOVID™ is active against the prevailing variants of concern, including the Delta and Omicron variants.

3 The randomised, placebo-controlled study recruited more than 2,000 participants aged 18 to 88 years with mild to moderate COVID-19 and who had one or more risk factors for progression to severe COVID-19. 1,039 participants received PAXLOVID™ and 1,046 received placebo. The results showed that 0.8% (8 / 1,039)

of patients who received PAXLOVID™ and 6.3 % (66 / 1,046) of those who received placebo were hospitalised. There was no death in the PAXLOVID™ arm, compared to 12 deaths in the placebo arm.

4 The safety data showed that PAXLOVID™ is well-tolerated. The incidences of adverse events reported in the clinical study were generally low. The common adverse events reported were mild to moderate, such as altered sense of taste, diarrhoea, vomiting, hypertension, muscle pain (myalgia) and chills.

5 PAXLOVID™ may interact with various medications, such as medicines for irregular heart rate, migraine, cholesterol, etc., and could increase the amount of these medications in the blood, leading to serious adverse events. On the other hand, some medicines such as those for epileptic seizures could reduce the levels of PAXLOVID™ resulting in a loss of anti-viral efficacy. The potential for drug interactions should be carefully considered by the prescribing doctor prior to treatment initiation.

6 Based on the available clinical evidence, the benefits of PAXLOVID™ outweigh the risks, and there is a favourable benefit-risk profile for the treatment of mild to moderate COVID-19 in adults who are at high risk of progression to severe COVID-19.

ACTIVE MONITORING AND CONTINUOUS REVIEW OF DATA

7 Pfizer is required to collect the relevant safety data and monitor the use of PAXLOVID™ as a condition for interim authorisation under PSAR. HSA will also require Pfizer to continue submitting updated data from ongoing clinical studies to ensure the continued safety and efficacy of PAXLOVID™, such as its efficacy against prevailing variants, for HSA's continual benefit-risk assessment.

8 HSA will actively review the data submitted by Pfizer to ensure that the benefits of PAXLOVID™ continue to outweigh the known risks. As PSAR is an interim authorisation, the company is required to submit the complete dataset based on prevailing international standards[1] to obtain a full registration. The PSAR interim

[1] HSA's current requirements are based on the scientific standards set out by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

authorisation may also be terminated at any time; for example, if new data suggests that the benefits no longer outweigh the risks.

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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/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.