Sri Lanka awaiting regulatory approval of molnupiravir anti-COVID drug

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ECONOMYNEXT – Sri Lanka's health ministry is waiting for the Advisory Committee of Communicable Diseases and the National Medicine Regulatory Authority (NMRA) to approve the recently developed molnupiravir anti-COVID drug.

State Minister of Pharmaceutical Production, Supply and Regulation Channa Jayasumana said a written request has been sent to the Director General of Health to give a recommendation for the pill that was jointly developed by U.S.-based Merck & Co Inc (MRK.N) and Ridgeback Biotherapeutics.

"We hope to get a recommendation by next week," Jayasumana told the privatel owned Derana network on Friday (05).

Molnupiravir is the first antiviral medication for COVID-19 which can be taken as a pill rather than injected or given intravenously.

The drug needs to be given within five days of the onset of symptoms to be most effective.

International media quoted Merck & Co Inc that the phase three of the drug was studied with the participation of 1,550 patients globally in more than 170 planned sites in Argentina, Brazil, Canada, Chile, Colombia, Egypt, France, Germany, Guatemala, Israel, Italy, Japan, Mexico, Philippines, Poland, Russia, South Africa, Spain, Sweden, Taiwan, Ukraine, the United Kingdom and the United States.

Merk said the study showed that Molnupiravir reduced the risk of hospitalisation and/or death across all key subgroups. Efficacy was not affected by timing of symptom onset or underlying risk factor, the company said.

The most common risk factors for poor disease outcome included obesity, older age (>60 years), diabetes mellitus, and heart disease.

Additionally, based on participants with available viral sequencing data (approximately 40 percent of participants), molnupiravir demonstrated consistent efficacy across viral variants Gamma, Delta, and Mu variants.

To date, the Delta, Gamma, and Mu variants have accounted for nearly 80 percent of the evaluable cases in the trial. Recruitment in Latin America, Europe, and Africa accounted for 55 percent, 23 percent and 15 percent of the study population, respectively.

Even though approval has not yet been granted by the World Health Organisation (WHO) or the US Food and Drug Administration (FDA), the United Kingdom gave approval for the drug on Thursday (04) and placed an order for 480,000 courses, with the first deliveries expected in November.

Merik said it expects to produce 10 million courses of treatment by the end of 2021, with more doses expected to be produced in 2022.

Earlier this year, Merck entered into a procurement agreement with the US government under which Merck will supply approximately 1.7 million courses of molnupiravir to the country, upon EUA or approval from the FDA, media reports said.

Meanwhile, the Technical Advisory Group of the WHO on Wednesday (03) approved Covaxin, the the second COVID-19 vaccine produced in India, by the Bharat Biotech pharmaceuticals company.

The vaccine is said to have 78 percent efficacy against COVID-19 of any severity, 14 or more days after the second dose, and is extremely suitable for low- and middle-income countries due to easy storage requirements.

The advisory Committee said the vaccine is suitable to use for all age groups 18 years and above. (Colombo/Nov05/2021)