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BREAKING NEWS: COVID-19 Pill Receives First Authorisation in the World

U.K.'s Medicines and Healthcare Products Regulatory Agency has authorised the first oral antiviral medicine for treating mild-to-moderate COVID-19 in adults with a positive COVID-19 infection and at least one risk factor for developing severe illness.

Molnupiravir will be the first oral medicine authorised for COVID-19. This is a major achievement in Merck's legacy of bringing forward breakthrough medicines and vaccines to handle healthcare challenges. The new drug offers an important addition to the COVID-19 vaccines.

The authorisation is based on positive results from a Phase 3 MOVe-OUT clinical trial which evaluated molnupiravir 800 mg twice-daily in non-hospitalised, unvaccinated adult patients with confirmed COVID-19 infection, a symptom onset within five days of study randomisation and at least one risk factor associated with poor disease outcomes (e.g. heart disease, diabetes etc.).

Merck is committed to providing timely access to molnupiravir globally through a comprehensive supply and access approach. This will include production of millions of courses of therapy; tiered pricing, supply agreements with governments; and voluntary licenses to generic manufacturers and to the Medicines Patent Pool to make generic molnupiravir available in low- and middle-income countries.

The company expects to produce 10 million courses of treatment by the end of 2021 and 20 million courses in 2022.

Merck's application with the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of molnupiravir is still under review.

Dr Dean Y. Li, executive vice president and president, Merck Research Laboratories, says, "We are very grateful to the investigators, patients and their families for their critical contributions to the MOVe-OUT study that made this authorisation possible."

Source: Merck

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