First oral Covid-19 medicine authorised in the UK

The first oral Covid-19 medicine, Molnupiravir, for treatment of mild to moderate Covid-19 in adults, who have at least one risk factor for developing severe illness has been authorised by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA).

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Producd by Merck & Co (MSD) and Ridgeback Biotherapeutics, Molnupiravir's will trade as Lagevior in the UK.

"The first global authorisation of Molnupiravir is a major achievement in MSD's singular legacy of bringing forward breakthrough medicines and vaccines to address the world's greatest health challenges," says Robert M Davis, chief executive officer and president, MSD.

"As an oral therapeutic, Molnupiravir offers an important addition to the vaccines and medicines deployed so far to counter the Covid-19 pandemic," says Dr. Dean Y. Li, executive vice president and president, MSD Research Laboratories.

Phase 3 MOVe-OUT clinical trial

The authorisation is based on positive results from a planned interim analysis from the Phase 3 MOVe-OUT clinical trial.

The MOVe-OUT trial (MK-4482-002) (NCT04575597) is a global Phase 3, randomised, placebo-controlled, double-blind,

multi-site study of non-hospitalised adult patients with laboratory-confirmed mild-to-moderate Covid

Patients enrolled in the study were unvaccinated against SARS-CoV-2, had at least one risk factor associated with poor disease outcomes, and symptom onset within five days prior to randomisation.

The primary efficacy objective of MOVe-OUT is to evaluate the efficacy of molnupiravir compared to placebo as assessed by the percentage of participants who are hospitalised and/or die from the time of randomisation through Day 29.

The Phase 3 portion of the MOVe-OUT trial was conducted globally in countries including Brazil, Canada, Chile, Colombia, France, Germany, Guatemala, Mexico, Philippines, Russia, South Africa, Spain, Taiwan, Ukraine, the UK and US.

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

Delta, Gamma and Mu variants accounted for nearly 80% of the baseline viral variants that had been sequenced at the time of the interim analysis.

Recruitment in Latin America, Europe and Africa accounted for 56%, 23% and 15% of the study population, respectively.

About Molnupiravir

Molnupiravir (MK-4482, EIDD-2801) is an investigational, orally administered form of a potent ribonucleoside analog that inhibits the replication of SARS-CoV-2, the causative agent of Covid-19.

Molnupiravir is also being evaluated for post-exposure prophylaxis in MOVe-AHEAD, a global, multicenter, randomised, double-blind, placebo-controlled Phase 3 study, which is evaluating the efficacy and safety of molnupiravir in preventing the spread of Covid-19 within households.

Molnupiravir’s application is still under review by the US Food and Drug Administration and the European Medicines Agency.

MSD is actively working to submit applications to other regulatory agencies around the world.

Supply

In anticipation of the results from MOVe-OUT and the potential for regulatory authorisation or approval, MSD has been producing molnupiravir at risk and expects to produce 10 million courses of treatment by the end of 2021, with at least 20 million courses to be produced in 2022.

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

Additionally, MSD has entered into supply and advance purchase agreements for molnupiravir with governments worldwide, including the UK government for 480,000 courses of therapy, pending regulatory authorisation, and is currently in discussions with additional governments.

MSD plans to implement a tiered pricing approach based on World Bank country income criteria to reflect countries’ relative ability to finance their health response to the pandemic.