

Optimus Pharma to conduct Ph III trials for Molnupiravir capsules on COVID-19 patients

19 May 2021 | News

2500 subjects with mild to moderate COVID-19 will be randomised in the study in a 1:1 ratio to Molnupiravir

Optimus Pharma, based in Hyderabad, has received the nod from the Drugs Controller General of India (DCGI) for conducting Phase III Clinical Trials for orally administered Molnupiravir capsules on patients with Mild to Moderate Covid-19.

With severe shortage of antiviral drugs in the market against the SARS-CoV-2 infection, it is imperative that more drugs with potent antiviral activity against SARS-CoV-2 be introduced.

Optimus Pharma having internally developed the active pharmaceutical ingredient (API) and the formulations for the product, it had filed for clinical trials with the DCGI. The regulator gave the nod for conducting the trial on mild to moderate patients.

As per the clinical trial protocol approved, 2500 subjects with mild to moderate COVID-19 will be randomised in the study in a 1:1 ratio to Molnupiravir with standard supportive care or standalone standard supportive care. The treatment duration is a maximum of 5 days and the total study duration will be maximum for 29 days from randomisation, the release said.

“Optimus is all geared to immediately begin clinical trials on Molnupiravir on COVID-19 patients in India. The clinical trial will let us know the efficacy of this molecule,” Chairman & Managing Director – Dr D Srinivas Reddy said.