

Five pharma cos collaborate for clinical trial of Molnupiravir for COVID-19 treatment

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The companies will jointly sponsor, supervise and monitor the clinical trial in India



Cipla, Dr Reddy's, Emcure, Sun Pharma and Torrent will collaborate for the clinical trial of the investigational oral anti-viral drug Molnupiravir for the treatment of mild COVID-19 in an outpatient setting in India.

Between March and April this year, these five pharma companies had individually entered into a non-exclusive voluntary licensing agreement with Merck Sharpe Dohme (MSD) to manufacture and supply Molnupiravir to India and over 100 low and middle-income countries (LMICs).

The five pharma companies have entered into a collaboration agreement, wherein the parties will jointly sponsor, supervise and monitor the clinical trial in India. As per the directive of the Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization, Dr Reddy's will conduct the clinical trial using its product, and the other four pharma companies will be required to demonstrate equivalence of their product to the product used by Dr Reddy's in its clinical trial.

Following the clinical trial protocol approval given by the Drugs Controller General of India, the clinical trial will be conducted for the treatment of mild COVID-19 in an outpatient setting. It is expected to take place between June and September this year across India with the recruitment of 1,200 patients. Such collaboration for a clinical trial is a first-of-its-kind within the Indian pharma industry and will aim to investigate yet another line of treatment in the collective fight against the COVID-19 pandemic. On successful completion of the clinical trial, each company will independently approach the regulatory authorities for approval to manufacture and supply Molnupiravir for the treatment of COVID-19 in India.

Molnupiravir is an oral antiviral that inhibits the replication of multiple RNA viruses including SARS-CoV-2. It is presently being studied by MSD, through a collaboration with Ridgeback Biotherapeutics, in a Phase III trial for the treatment of non-hospitalized patients with confirmed COVID-19 globally.