



**Press Release**

**Hetero Announces Interim Clinical Results  
from Phase III Clinical Trials of Molnupiravir  
conducted in India.**

**~ Phase 3 Trial Demonstrates Statistically Significant fewer hospital admissions, Faster Time to Clinical Improvement and early negative SARS CoV-2 RT PCR with Molnupiravir Treatment in Mild COVID 19 Patients Compared to Standard of Care alone~**

**~ Hetero has approached the Drug Controller General of India (DCGI) to seek Emergency Use Authorization for Molnupiravir in India ~**

**India, Hyderabad, 9<sup>th</sup> July 2021:** Hetero, a globally renowned vertically integrated pharmaceutical organization, today announced the interim clinical results from Phase III Clinical trials of Molnupiravir in mild Covid-19 patients conducted across multiple COVID-19 dedicated hospital sites across India.

In April this year, Hetero had entered into a non-exclusive licensing agreement with MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA (NYSE: MRK), to manufacture and supply Molnupiravir in India and over 100 low and middle-income countries (LMICs). Molnupiravir is an investigational, orally administered form of a potent ribonucleoside analog, being developed globally by MSD, that inhibits the replication of multiple RNA viruses including SARS-CoV-2, the causative agent of COVID-19 with demonstrated activity against SARS-CoV-2 in human airway epithelial cell cultures and potential to completely eliminate SARS CoV-2 from the body within 5 days.

Hetero had commenced a phase-III, comparative, randomized, multicenter clinical trial on mild Covid-19 patients (N=1218). These clinical trials were aimed at evaluating the efficacy and safety of Molnupiravir plus standard of care (test arm) versus standard of care alone (control

arm), in mild Covid-19 patients with a positive SARS CoV-2 RT PCR test for COVID-19 and randomized within 5 days of onset of symptoms.

Patients in the clinical trial were randomized to receive either Hetero's Molnupiravir capsules 800 mg (4 x 200 mg) every 12 hours (twice daily) for 5 days along with standard of care as per the Indian Council of Medical Research (ICMR) guidelines or, in the control arm, to receive standard of care alone.

The interim results from mild COVID-19 patients (N=741) revealed the following encouraging outcomes:

- Earlier clinical improvement (2-point decrease in WHO Clinical Progression Scale) observed in Molnupiravir group compared to standard of care (Day 5 (63.43% vs 22.33%;  $p < 0.0001$ ), Day 10 (78.96% vs 49.49%;  $p < 0.0001$ ) and Day 14 (81.55% vs 73.22%;  $p = 0.0150$ ))
- Median time to clinical improvement as early as 8 days in Molnupiravir group compared to 12 days in SOC alone group ( $p = 0.0001$ )
- Earlier SARS CoV-2 RT-PCR negativity observed in Molnupiravir group compared standard of care (Day 5 (77.35% vs 26.07%;  $p < 0.0001$ ) Day 10 (94.03% vs 57.20%;  $p < 0.0001$ ) and Day 14 (97.01% vs 85.21%;  $p < 0.0001$ )).
- Fewer hospital admissions in Molnupiravir group compared to standard of care alone (7 (1.89%) Vs 23 (6.22%)  $p = 0.0027$ ) over 14 days of observation.
- There was no mortality in either groups. All adverse events were non-serious, mild in severity, and none led to drug discontinuation. Most common adverse events reported were nausea, diarrhoea and headache which were resolved completely.

In addition to the above clinical trial studies, Hetero is also undertaking a separate Molnupiravir study on moderate Covid-19 patients approved by CDSCO. The interim and final clinical results on the same will be shared in due course.

### **About Molnupiravir**

MSD is developing Molnupiravir in collaboration with Ridgeback Biotherapeutics. Molnupiravir (EIDD-2801/MK-4482) is an investigational, orally bioavailable form of a potent ribonucleoside analog that inhibits the replication of multiple RNA viruses including SARS-CoV-2, the causative agent of COVID-19. Molnupiravir has been shown to be active in several models of SARS-CoV-2, including for prophylaxis, treatment, and prevention of transmission, as well as SARS-CoV-1 and MERS. EIDD-2801 was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University. EIDD-

2801/MK-4482 was licensed by Ridgeback Biotherapeutics. MSD, through a subsidiary, acquired exclusive worldwide rights to develop EIDD-2801/MK-4482 and related molecules in collaboration with Ridgeback. Since licensed by Ridgeback, all funds used for the development of EIDD-2801/MK-4482 by Ridgeback have been provided by Wayne and Wendy Holman and MSD.

### **About Hetero**

Hetero is a globally renowned vertically integrated pharmaceutical organization engaged in research and development, manufacturing, and marketing of high-quality chemical and biologic medicines across diverse therapeutic areas. Backed by 27+ years of expertise in the pharmaceutical industry, Hetero's strategic business areas spread across APIs, Global Generics, Biosimilars and Custom Pharmaceutical Services. The company is among the largest producers of Active Pharmaceutical Ingredients (APIs) in the world.

Hetero has 36 state-of-the-art manufacturing facilities strategically located worldwide, which has been approved by top pharma regulatory bodies of the world. Our portfolio includes 300+ products encompassing major therapeutic categories such as HIV/AIDS, Oncology, Cardiovascular, Neurology, Hepatitis, Nephrology etc. Hetero has a strong global presence in over 126 countries and focusses on making affordable medicines accessible to patients worldwide.

Over the years, Hetero has established its strong leadership in ARVs and Antiviral therapies and caters to 40% of existing global demand for Anti-Retroviral (ARV) APIs and Finished Dosage Forms (FDFs) used in HIV/AIDS treatment.

For more information on Hetero, please visit [www.heteroworld.com](http://www.heteroworld.com).

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