

Press release

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## **No significant clinical benefit with Umifenovir addition in COVID-19 treatment: Glenmark clinical study**

- *Addition of Umifenovir did not demonstrate any additional benefit over Favipiravir alone in moderate COVID-19 patients*
- *Umifenovir did not show superior clinical outcomes when added to Favipiravir treatment. The trial did not meet key end-points*

**Mumbai, India; October 9, 2020:** Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, today announced results of its “FAITH” combination trial with antivirals Umifenovir and Favipiravir for the treatment of moderate hospitalized COVID-19 patients. This was the second clinical study after the successful Favipiravir monotherapy trial earlier this year that led the company to receiving the Emergency Use Authorisation for Favipiravir.

This second study titled the FAITH trial evaluated the possible superiority of the combination’s efficacy against Favipiravir monotherapy. As per the results that Glenmark today presented to the regulator, the study showed no superior clinical outcomes with the addition of Umifenovir.

The FAITH study enrolled a total of 158 hospitalized patients with moderate COVID-19 in India. The study’s primary end point (clinical outcome measured) was time taken from randomization to clinical cure, defined as resolution of baseline clinical signs and symptoms of COVID-19 infection and at least 2 point improvement on WHO Ordinal Scale for Clinical Improvement, within a time frame of 28 days. Median time to clinical cure improved by only 1 day (7 as compared to 8) in patients who received the two antiviral combination, which was not statistically significant and did not justify adding two antiviral agents.

*Commenting on the trial’s findings, Dr. Monika Tandon, Senior Vice President & Head, Clinical Development, Global Specialty/Branded Portfolio, Glenmark Pharmaceuticals Ltd., said, “Glenmark was the first company to provide patients an oral antiviral treatment for COVID-19 in India, and this combination study was yet another effort on our part to examine new treatment options to combat the health crisis. These latest findings confirm that the addition of Umifenovir does not show any incremental benefit in clinical outcomes. Thus Favipiravir therapy along with supportive care remains a suitable & effective choice for mild to moderate COVID-19 infection.”*

In June 2020, Glenmark became the first company in India to receive manufacturing and marketing approval for FabiFlu® as part of accelerated approval process, considering the emergency situation of the COVID-19 outbreak in the country. Glenmark successfully developed the active pharmaceutical ingredient (API) and the formulation for the oral antiviral through its own in-house R&D team.

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**About Glenmark Pharmaceuticals Ltd**

Glenmark Pharmaceuticals Ltd. (GPL) is a global research-led pharmaceutical company with presence across Generics, Specialty and OTC business with operations in over 50 countries. Glenmark's key therapy focus areas globally are respiratory, dermatology and oncology. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2019). For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com)

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