

Press release

For immediate distribution

Glenmark initiates Phase 3 clinical trials on antiviral Favipiravir for COVID-19 patients in India

- COVID-19 patients from over 10 leading government and private hospitals in India are being enrolled for the study
- Trial completion and study results expected by July/August 2020
- Glenmark was the first pharmaceutical company in India to be given an approval by the regulator to conduct Phase 3 clinical trials in India on Favipiravir Antiviral tablets for COVID -19 patients

Mumbai, India; May 12, 2020: Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company has initiated Phase 3 clinical trials in India on Antiviral tablet Favipiravir, for which it received approval from India's drug regulator DCGI in late April. Glenmark is the first company in India to initiate Phase 3 clinical trials on Favipiravir for COVID-19 patients in India. Favipiravir is a generic version of Avigan® of Fujifilm Toyama Chemical Co. Ltd., Japan, a subsidiary of Fujifilm Corporation. Clinical trials have commenced and over 10 leading government & private hospitals in India are being enrolled for the study. Glenmark estimates study completion by July/August 2020.

Glenmark has successfully developed the API and the formulations for the product through its in-house R&D team. Favipiravir has demonstrated activity against influenza viruses and has been approved in Japan for the treatment of novel influenza virus infections. The molecule if commercialized, will be marketed under the brand name 'FabiFlu®' in India.

Commenting on this development, Dr. Monika Tandon, Vice President & Head, Clinical Development, Global Specialty/Branded Portfolio, Glenmark Pharmaceuticals Ltd., said, "Several health and medical experts, both in and outside of Glenmark are eager to see the effect that Favipiravir has on COVID-19 cases. We believe the study results will be significant as there is currently no effective treatment for the virus." She added, "The data we get from these trials will point us in a clearer direction with regard to COVID-19 treatment and management."

Further, Mr. Sujesh Vasudevan, President, India Formulations, Middle East and Africa, Glenmark Pharmaceuticals Ltd. mentioned "Our effort is to launch a treatment for COVID-19 patients as soon as possible and control the spread of the pandemic. We will do all it takes to ensure accessibility of the product across the country if the clinical trials are successful."

Glenmark was the first pharmaceutical company in India to be given an approval by the regulator to start the trial on COVID-19 patients in India. As per the approved clinical trial protocol, 150 subjects with mild to moderate COVID-19 will be randomized in the study in a 1:1 ratio to Favipiravir with standard supportive care or standalone standard supportive care. Treatment duration is a maximum of 14 days and the total study duration will be a maximum of 28 days from randomization.

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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

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