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Glenmark to conduct clinical trials with Favipiravir

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Glenmark Pharmaceuticals has announced that it has received approval from the DCGI (Drug Controller General of India), the regulator in India to conduct clinical trials on Favipiravir Antiviral tablets on COVID-19 patients.

The product is a generic version of Avigan® of Fujifilm Toyama Chemical Co. Ltd., Japan, a subsidiary of Fujifilm Corporation. Favipiravir has demonstrated activity against influenza viruses and has been approved in Japan for the treatment of novel influenza virus infections. Recently in the past few months, post the outbreak of COVID-19, multiple clinical trials have been initiated on COVID-19 patients in China, Japan and in the US.

Having internally developed the API and the formulations for the product, Glenmark filed the product for clinical trials with the DCGI and has received approval for conducting the trial on mild to moderate patients. As on date, Glenmark is the first pharmaceutical company in India to be given an approval by the regulator to start the trial on COVID-19 patients in India.

Sushrut Kulkarni, Executive Vice President – Global R&D, Glenmark Pharmaceuticals Limited said, “After having successfully developed the API and the formulations through its in-house R&D team, Glenmark is all geared to immediately begin clinical trials on Favipiravir on COVID-19 patients in India. The clinical trial will let us know the efficacy of this molecule on COVID-19 patients.”

He also added, “If the clinical trials are successful, Favipiravir could become a potential treatment for COVID-19 patients.”

As per the clinical trial protocol approved, 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 maximum for 28 days from randomization.