

Press release

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## **Glenmark commences 1000 patients Post Marketing Surveillance study with COVID-19 who are administered FabiFlu®**

*Also, due to better yield and scale, Glenmark passes the benefits to patients by reducing the price of oral antiviral FabiFlu® by 27 % in India*

- The new MRP is INR 75 per tab from the earlier INR 103 per tab
- Glenmark's price reduction aims to make FabiFlu® further accessible for COVID-19 patients across the country

**Mumbai, India; July 13, 2020:** Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, has announced that it has commenced a Post Marketing Surveillance (PMS) study on FabiFlu® to closely monitor the efficacy and safety of the drug in 1000 patients that are prescribed with the oral antiviral, as part of an open label, multicenter, single arm study.

Further, Glenmark has announced a price reduction of **27%** for FabiFlu®. The new MRP is INR 75 per tab from the earlier INR 103 per tab. The price reduction has been made possible through benefits gained from higher yields and better scale, as both the API and formulations are made at Glenmark's facilities in India, the benefits of which are being passed on to patients in the country.

Glenmark has successfully developed the active pharmaceutical ingredient (API) and the formulation for FabiFlu® through its own in-house R&D team within the country, ensuring self-reliance with regard to long-term production and manufacturing. The API is manufactured at the Gujarat production facility which is USFDA & MHRA-UK approved. The formulation product is manufactured at the facility in Himachal Pradesh, which is also USFDA and MHRA-UK approved.

*Commenting on these developments, Mr. Alok Malik, Senior Vice President & Head – India business, Glenmark Pharmaceuticals Ltd., said, “We expect this post marketing surveillance study to shed more light on the drug’s clinical effectiveness and safety in a large cohort of patients prescribed FabiFlu®. Our priority from the start of this pandemic has been to offer patients in India an effective treatment for COVID-19, while also ensuring accessibility to the masses. Our internal research shows us that we launched FabiFlu® in India at the lowest market cost as compared to the cost of Favipiravir in other countries where it is approved. And now we hope that this further price reduction will make it even more accessible for patients across the country.”*

Despite investing significantly in R&D, clinical trials and the manufacturing of FabiFlu®(API and formulations), Glenmark has managed to keep the pricing of FabiFlu® lower as compared to its price in other countries. FabiFlu® in India was originally launched at INR 103/tab, while, its price as INR is higher in the remaining countries. (INR 600/tab in Russia, INR 378/tab in Japan, INR 350/tab in Bangladesh and INR 215/tab in China). \*Based on trade data available for 200mg /tab from the respective countries and currency rates in respective countries equivalent to INR recorded

On June 20th, Glenmark announced that it received manufacturing and marketing approval from India's drug regulator for FabiFlu®, making it the first oral Favipiravir-approved medication in India for the treatment of mild to moderate COVID-19. The manufacturing and marketing approval was granted as part of accelerated approval process, considering the emergency situation of the COVID-19 outbreak in India. The approval's restricted use entails responsible medication use where every patient must have signed informed consent before treatment initiation.

Most patients exhibiting mild to moderate symptoms can benefit from FabiFlu® use. Glenmark has also completed the phase 3 clinical trial with Favipiravir (FabiFlu®) in mild to moderate COVID-19 patients in India. The trial results will be available shortly.

Glenmark is also conducting another Phase 3 clinical trial to evaluate the efficacy of two antiviral drugs Favipiravir and Umifenovir as a combination therapy in moderate hospitalized adult COVID-19 patients in India. The combination study which is called the FAITH trial is looking to enroll 158 hospitalized patients of moderate COVID-19 in India. Early treatment with combination therapy will be evaluated for safety and efficacy as it is emerging as an effective approach in shortening duration of virus shedding, facilitating early clinical cure and discharge of patients.

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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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