

Press release

For immediate distribution

Glenmark's interim data from PMS Study on Favipiravir (FabiFlu®) supports its safety and effectiveness in real world settings with no new safety signals or concerns in Covid-19 patients

- *Glenmark is the only organization from India to conduct a Phase 3 study and the first to receive restricted emergency use approval for Favipiravir (FabiFlu®) in mild to moderate Covid-19*
- *Glenmark commenced a 1000+ patients PMS study in mild to moderate Covid-19 after receiving restricted emergency use approval for Favipiravir (FabiFlu®)*
- *PMS interim data revealed no new safety signals or concerns till date and safety is in line with known side effects of the drug*

Mumbai, India; June 08, 2021: Glenmark Pharmaceuticals, a research-led, global integrated pharmaceutical company, today announced interim data of 503 patients from its Post Marketing Surveillance (PMS) study on Favipiravir in India. The PMS study commenced in July 2020 aimed to evaluate safety and efficacy of Favipiravir in mild to moderate Covid-19 patients. This PMS is the first and large post marketing study being conducted in India on Favipiravir in mild to moderate Covid-19 patients and as on date, a total of 1083 patients have been enrolled in the prospective, open label, multicenter, single arm study. A total of 13 sites – both Government and private institutions – across Mumbai, Bangalore, Hyderabad, Nashik, Nagpur, and Trivandrum took part.

Interim data presented by Glenmark to the regulator reveals no new safety signals or concerns with the use of Favipiravir and already-known side effects such as weakness, gastritis, diarrhoea, vomiting etc., which were found to be mild in nature. The time to fever resolution was seen on day 3, while two-third of the patients achieved clinical cure on day 7.

The study was conducted in patients with mild to moderate COVID-19, in line with the approved indication of the drug. The mean age of patients was 40 years, with the most common age group being 30-45 years. Women comprised 40%, while men 60% of the study population. Hypertension and Diabetes were the two most common comorbidities noted in these patients. Fever was present in all patients at baseline followed by cough (84.6%), fatigue (55%), new loss of taste (38.1%).

Commenting on these findings, Mr. Alok Malik, Group Vice President & Head, India Formulations, said, "It is encouraging to note that our interim data supports the safety and effectiveness of FabiFlu® in real-world settings. Since its launch last year, FabiFlu® has provided immense relief to millions of patients in India and the world, while also reducing the overall burden on healthcare infrastructure. We will soon submit the final study findings to the regulator and continue to deliver FabiFlu®'s multiple benefits to patients all over."

On June 19th 2020, Glenmark became the first company in India to receive restricted emergency use 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 approval was granted as part of accelerated approval process, considering the emergency situation of the COVID-19 outbreak in India.

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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). The company has been listed in the Dow Jones Sustainability Index (DJSI), under the category of emerging markets for the third consecutive year in a row. DJSI is one of the world's most respected and widely accepted sustainability benchmarks globally with only the top ranked companies in terms of Corporate Sustainability within each industry are featured in the index. For more information, visit www.glenmarkpharma.com

For more information, please contact:

Udaykumar Murthy
Senior Manager, Corporate Communications
+91 9960377617
corpcomm@glenmarkpharma.com