

Press release

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Glenmark concludes post marketing surveillance (PMS) study on Favipiravir (FabiFlu®) in 1000+ COVID-19 patients, findings reinforce the drug's safety and efficacy in real world settings

- *Glenmark's PMS study is the first and largest post marketing study conducted in India on Favipiravir in mild to moderate COVID-19 patients.*
- *The study was initiated after Glenmark received restricted emergency use approval for Favipiravir (FabiFlu®) for mild to moderate COVID-19*
- *Results show no new safety signals or concerns till date and side effects reported are in line with known safety profile of the drug*
- *Glenmark is the only organization in India to conduct a Phase 3 study and the first to receive restricted emergency use approval for Favipiravir (FabiFlu®)*

Mumbai, India; September 15, 2021: Glenmark Pharmaceuticals, a research-led, global integrated pharmaceutical company, today announced the successful completion of its Post Marketing Surveillance (PMS) study on Favipiravir (FabiFlu®) in India. The PMS study commenced in July 2020 to evaluate the safety and efficacy of Favipiravir in mild to moderate COVID-19 patients. A total of 1083 patients were enrolled in the prospective, open label, multicentre, single arm study. Results showed no new safety signals or concerns with the use of Favipiravir, and already-known side effects such as weakness, gastritis, diarrhoea, vomiting etc., were found to be mild in nature. The time for fever resolution was 4 days, while time for clinical cure was 7 days.

Glenmark's PMS study is the first and largest post marketing study conducted in India on Favipiravir in mild to moderate COVID-19 patients. Thirteen sites – both Government and private institutions – across Mumbai, Bangalore, Hyderabad, Nashik, Nagpur, and Trivandrum took part. The study was conducted in patients in line with the approved indication of the drug.

Commenting on these findings, Mr. Alok Malik, Group Vice President & Head, India Formulations, said, "This study was crucial as it examined the safety and efficacy of FabiFlu® in real-world settings, where multiple variables can impact the results. Despite these factors, the PMS study demonstrated FabiFlu®'s consistent ability to provide symptomatic relief and improve clinical outcomes in patients with mild to moderate COVID-19. It is a step forward both for Glenmark and the medical community, as it reinforces the oral antiviral's multiple benefits in tackling the pandemic."

On June 19, 2020, Glenmark became the first company in India to receive restricted emergency use approval from India's drug regulator for Favipiravir (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.

This PMS study continued to evaluate the safety and efficacy of Favipiravir (FabiFlu®) post its launch in the market. The average age of patients in the study was 40 years, with women comprising 40%, while men 60% of the study population. Hypertension (11%) and diabetes (8%) were the two most common comorbidities noted in these patients. Fever was present in all patients at baseline, followed by cough (81%), fatigue (46.2%), and new loss of taste (41%).

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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 ranks among the world's top 50 Generics and Biosimilars companies (Top 50 Company Rankings, 2020, from Informa's Generics Bulletin). 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
Deputy General Manager, Corporate Communications
+91 9960377617
corpcomm@glenmarkpharma.com