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Glenmark concludes largest post marketing study on FabiFlu in 1000+ COVID-19 patients

15 September 2021 | News

Results show no new safety signals or concerns to date and side effects reported are in line with the known safety profile of the drug



Glenmark Pharmaceuticals has 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. The time for fever resolution was four days, while the time for the clinical cure was seven 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. 13 sites - both government and private institutions - across Mumbai, Bengaluru, Hyderabad, Nashik, Nagpur, and Tiruvananthapuram took part. The study was conducted in patients in line with the approved indication of the drug.

Alok Malik, Group VP & 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."