Press release



For immediate distribution

Glenmark introduces higher strength (400 mg) of FabiFlu® to reduce pill burden of COVID-19 treatment

- Glenmark is the first company in India to have received the regulator's approval for 400 mg dosage form
- Increased strength of FabiFlu[®] yet another milestone effort by Glenmark's in-house R&D
- Patients can now opt for a more relaxed dosage regimen when compared to 200 mg tablet and now need to take half the number of pills due to the introduction of 400 mg
- *Glenmark remains the only company in India to successfully complete an* randomized, controlled, open-labelled, multi-center Phase 3 clinical trial on Indian patients with mild to moderate Covid-19

Mumbai, India; August 6, 2020: Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, today announced that it will introduce a 400 mg version of oral antiviral FabiFlu®, for the treatment of mild to moderate COVID-19 in India. The higher strength will improve patient compliance and experience, by effectively reducing the number of tablets that patients require per day.

A higher pill burden has been associated with lower adherence to therapy, the latter affecting viral suppression and overall treatment outcomes. Also reducing the pill burden has been a demand from doctors and patients to enable adherence. The 200 mg dosage of FabiFlu® required patients to take 18 tablets on Day 1 (nine in the morning and nine in the evening), followed by 8 tablets each day thereafter for a maximum of 14 days. With the new 400 mg version, patients will now have a more relaxed dosage regimen, with 9 tablets required on Day 1(4.5 in the morning and 4.5 in the evening), and thereafter 2 tablets twice a day from Day 2 till end of the course.

Explaining the significance of this development, Dr. Monika Tandon, Vice President & Head, Clinical Development, Global Specialty/Branded Portfolio, Glenmark Pharmaceuticals Ltd., said, "Being the first company to launch Favipiravir in India, we continue to innovate and seek new treatment options for Covid-19 patients. Introducing this higher strength of FabiFlu[®] is in line with these efforts to ensure a smoother experience for patients, by reducing their daily pill burden."

"The 200 mg dosage of FabiFlu[®] was developed in line with global formulations of the drug Favipiravir, which had similar strength. The 400 mg version is a result of Glenmark's own R&D efforts to improve treatment experience for patients in India," she added.

Glenmark has also commenced a Post Marketing Surveillance (PMS) study on FabiFlu® to closely monitor the efficacy and safety of the drug in a large pool of patients prescribed with the oral antiviral Favipiravir, as part of an open label, multicenter, single arm study. Glenmark is also conducting another Phase 3 clinical



trial to evaluate the efficacy of two antivirals 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 enrol 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

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