June 20, 2020

**To,**
**Dy. General Manager**
**Department of Corporate Services,**
**BSE Ltd.,**
**P. J. Towers, Dalal Street,**
**Fort, Mumbai – 400 001.**

**Ref: Scrip Code: 532296**

**To,**
**The Manager – Listing,**
**The National Stock Exchange of India Ltd.,**
**Plot No. C/1, G Block,**
**Bandra Kurla Complex,**
**Bandra (E), Mumbai – 400 051.**

**Ref: Scrip Name: GLENMARK**

Dear Sir,

**Sub: Glenmark becomes the first pharmaceutical company in India to receive regulatory approval for oral antiviral Favipiravir, for the treatment of mild to moderate COVID-19**

With reference to the subject mentioned above, kindly find attached media release which is self-explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,
**For Glenmark Pharmaceuticals Limited**

HARISH VINAYAK KUBER

Digitally signed by HARISH VINAYAK KUBER
DN: c=IN, st=Maharashtra, 2.5.4.20=cde2956f5be913821f9f9f91026d376afdaebf5fb8838c3a71de2e75255a782d, postalCode=400049, street=C21, Maker Kundan Garden, serialNumber=afdac79f9832ea525179ba4771e8bfb76ef0e3cac49116 0cbf271c80d4b16e4f, o=Personal, cn=HARISH VINAYAK KUBER
Date: 2020.06.20 11:55:20 +05'30'

**Harish Kuber**
**Company Secretary & Compliance Officer**

**Encl:** as above

**Press release** **For immediate distribution**

# Glenmark becomes the first pharmaceutical company in India to receive regulatory approval for oral antiviral Favipiravir, for the treatment of mild to moderate COVID-19

- *Manufacturing and marketing approval 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*
- *Favipiravir shows clinical improvements of up to 88% in COVID-19, with rapid reduction in viral load by 4 days*
- *Clinical improvement noted across age groups 20 to >90 years, including in patients with co-morbid conditions like diabetes and heart disease suffering from mild to moderate COVID-19*
- *Glenmark to market the antiviral under the brand name 'FabiFlu®'*

**Mumbai, India; June 20, 2020:** In a landmark development for COVID-19 patients in India, Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, today announced the launch of antiviral drug Favipiravir (brand name FabiFlu®) for the treatment of mild to moderate COVID-19 patients. Glenmark has received manufacturing and marketing approval from India's drug regulator, making FabiFlu® the first oral Favipiravir-approved medication in India for the treatment of COVID-19.

Favipiravir is backed by strong clinical evidence showing encouraging results in patients with mild to moderate COVID-19. The antiviral offers broad spectrum RNA virus coverage[2] with clinical improvement noted across age groups 20 to >90 years.[3] Favipiravir can be used in COVID-19 patients with co-morbid conditions such as diabetes and heart disease with mild to moderate COVID 19 symptoms.[3] It offers rapid reduction in viral load within 4 days[1,4] and provides faster symptomatic and radiological improvement.[1,4,5] Of most importance, Favipiravir has shown clinical improvement of up to 88% in COVID-19 mild to moderate COVID 19 cases.[3]

**Glenmark successfully developed the active pharmaceutical ingredient (API) and the formulation for FabiFlu® through its own in-house R&D team.** Glenmark filed the product for clinical trial with India's drug regulator DCGI and became the first pharmaceutical company in India to receive approval for conducting phase 3 clinical trial on mild to moderate COVID-19 patients.

***Commenting on the significance of this development, Mr. Glenn Saldanha, Chairman and Managing Director of Glenmark Pharmaceuticals Ltd., said, "This approval comes at a time when cases in India are spiralling like never before, putting a tremendous pressure on our healthcare system. We hope the availability of an effective treatment such as FabiFlu® will considerably help assuage this pressure, and offer patients in India a much needed and timely therapy option."***

***He added, "FabiFlu® has demonstrated an encouraging response in mild to moderate COVID-19 patients during clinical trials. Moreover, it is orally administered, and so it serves as a more convenient treatment option over other intravenously administered medications. Glenmark will work closely with the government and medical community to make FabiFlu® quickly accessible to patients across the country."***

Favipiravir is approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections. It has a unique mechanism of action: it is converted into an active phosphoribosylated form (favipiravir-RTP) in cells and recognized as a substrate by viral RNA polymerase, thereby inhibiting RNA polymerase activity.

Most patients exhibiting mild to moderate symptoms can benefit from FabiFlu® use. The drug will be available as a prescription-based medication for INR 103/tablet, with recommended dose being 1800 mg twice daily on day 1, followed by 800 mg twice daily up to day 14.

Earlier last month, Glenmark also announced that it is conducting another clinical trial to evaluate the efficacy of two antivirals Favipiravir and Umifenovir as a combination therapy in moderate hospitalized adult COVID-19 patients in India.

—End—

**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

**For more information:**

**Glenmark Media Contacts**

Madhurima Gupta Jain
Senior Manager, Corporate Communications
+91 9819382087
corpcomm@glenmarkpharma.com

Udaykumar Murthy
Senior Manager, Corporate Communications
+91 9960377617

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