November 23, 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: Recently published data on Favipiravir as treatment for mild to moderate COVID-19 demonstrates significant improvement in time to clinical cure

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
Date: 2020.11.23 11:49:53 +05'30'

Harish Kuber
Company Secretary & Compliance Officer

Encl: as above

Press Release **For Immediate Release**

Recently published data on Favipiravir as treatment for mild to moderate COVID-19 demonstrates significant improvement in time to clinical cure

- *These findings were observed in a Phase 3 clinical trial conducted by Glenmark Pharmaceuticals and has been published by the globally reputed, peer reviewed* ***International Journal of Infectious Diseases.***

Mumbai, India; November 23, 2020: The oral antiviral medication Favipiravir, that prevents the replication phase of the virus life-cycle, leads to significant improvement in clinical cure in patients with mild to moderate COVID-19. These findings were observed in a randomized, controlled Phase 3 clinical study conducted by Glenmark Pharmaceuticals, and the results are now published online in The International Journal of Infectious Diseases (IJID). The IJID is a globally reputed, peer-reviewed, pubmed indexed, open access journal published monthly by the International Society for Infectious Diseases, USA. The published findings will also appear in the print edition of the journal in the coming weeks.

The publication on the study titled "Efficacy and Safety of Favipiravir, an Oral RNA-Dependent RNA Polymerase Inhibitor, in Mild-to-Moderate COVID-19: A Randomized, Comparative, Open-Label, Multicenter, Phase 3 Clinical Trial" was authored by Dr. Zarir .F. Udwadia and other co-authors .

The link to the article is mentioned below

https://authors.elsevier.com/sd/article/S1201-9712(20)32453-X

https://www.sciencedirect.com/science/article/pii/S120197122032453X

The Phase 3 study with antiviral drug Favipiravir, brand name FabiFlu®, was conducted in 150 patients as part of a randomised, open label, multicenter, Phase 3 study. The study aimed to evaluate the efficacy and safety of Favipiravir plus standard supportive care (Favipiravir treatment arm), versus standard supportive care alone (control arm), in mild to moderate patients, randomized within a 48 hour window of testing RT-PCR positive for COVID-19.

Favipiravir was found to provide multiple treatment benefits, demonstrated by faster time to clinical cure, and significantly delayed the need for supportive oxygen therapy. Additionally, patients of confirmed COVID-19 with moderate symptoms were discharged

from hospital earlier than those patients that did not receive Favipiravir, with the median time to clinical cure reduced by 2.5 days compared with the control group.

Dr Zarir F. Udwadia. MD, FRCP, FCCP, Breach Candy Hospital, Mumbai commented *"Every claim for the efficacy of a new drug in COVID-19 must be backed by evidence from a clinical trial. Glenmark has done just that with Favipiravir. Their well-designed trial in 150 patients showed Favipiravir resulted in a significantly improved time to clinical cure and rapid viral clearance. Based on this I would consider the use of this anti-viral drug in symptomatic patients with mild to moderate COVID-19. I eagerly await the results of similar trials presently being conducted in Boston and at Stanford".*

Since it was first pronounced a pandemic by the WHO in March, COVID-19 has continued to impact the lives of millions of people globally. As of date, over 50 mn. cases have been reported, with over 1 mn. deaths attributed to this disease. The virus has reportedly spread to all around the world and territories across the globe.[i] Most disease cases are mild to moderate, with symptoms including fever, cough and breathlessness. In severe cases, COVID-19 can cause pneumonia, severe acute respiratory syndrome, kidney failure and death.[ii]

Favipiravir is an antiviral medication that works by inhibiting a viral enzyme called RdRP (RNA dependent RNA polymerase), thereby halting the virus's replication cycle. This helps control the multiplication of the virus and prevents its spread in the patient. This mechanism of action of Favipiravir is novel compared to most antivirals that primarily prevent entry and exit of the virus from cells. Several published reports are now available of the drug's effectiveness against COVID-19.

Mr. Robert Crockart, Chief Commercial Officer *Glenmark Pharmaceuticals said, "From the first reported case of COVID-19, our every effort was to bring a viable, safe and effective treatment option to patients in a timely manner. It is encouraging to see our trial results now published in a reputed global medical journal, which we hope will support other countries in their fight against this disease."*

Patients in the Glenmark clinical trial received Favipiravir tablets 3,600 mg (1,800 mg BID) (Day 1) + 1,600 mg (800 mg BID) (Day 2 or later) for up to maximum of 14 days, along with standard supportive care. Randomization was stratified based on disease severity into mild and moderate. Favipiravir was well tolerated with no serious adverse events (SAEs) or deaths in the Favipiravir treated arm.

The pre-specified primary endpoint, time from randomisation to cessation of oral shedding of the SARS-CoV-2 virus, demonstrated a 2 day earlier virological cure in the Favipiravir treatment group, though not statistically significant. However, significant improvement in time to clinical cure and other secondary end-points suggest Favipiravir may be beneficial in the treatment of mild-to-moderate COVID-19.

"The study, which was undertaken by Glenmark Pharmaceuticals, at a time when the number of cases for infections were dramatically increasing around the globe, demonstrates Glenmark's commitment to ensuring all patients have access to affordable medication, to make a positive impact on their quality of life," said ***Dr. Monika Tandon, Sr. Vice President & Head - Clinical Development, Global Specialty/Branded Portfolio*** *at Glenmark.*

In June 2020, Glenmark received manufacturing and marketing approval from India's drug regulator for Favipiravir (FabiFlu®), making it the first oral approved medication in India for the treatment of mild to moderate COVID-19. The manufacturing and marketing approval was granted as part of an 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.

—End—

About The International Journal of Infectious Diseases

The International Journal of Infectious Diseases (IJID) is a peer-reviewed, pubmed indexed, open access journal that publishes original clinical and laboratory-based research, together with reports of clinical trials, reviews, and some case reports dealing with the epidemiology, clinical diagnosis, treatment, and control of infectious diseases with particular emphasis placed on those diseases that are most common in under-resourced countries. IJID is published monthly by the International Society for Infectious Diseases, USA

About Favipiravir

Favipiravir is an RNA-dependent RNA polymerase (RdRp) inhibitor approved for the treatment of novel influenza viruses in Japan and China, with approvals for use in the pandemic across several countries in Asia, Latin America, and the Middle East. Reports of in-vitro studies have demonstrated that Favipiravir can have an effective concentration against the SARS-CoV-2 infection within safe therapeutic dose. Additionally, Favipiravir being an oral formulation – and considering that ~80% of COVID-19 cases are categorized as mild to moderate – is likely to address unmet clinical needs of a sizeable majority of patient population, which can mostly be treated on an outpatient basis.

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

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "promising," "provides treatment benefit," may reduce," "suggest," or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Favipiravir, regarding potential future revenues from Favipiravir, or regarding the long- term impact of a patient's use of Favipiravir. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Favipiravir to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Favipiravir will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Favipiravir will achieve any particular levels of revenue in the future. Neither can there be any guarantee regarding the long-term impact of a patient's use of Favipiravir. In particular, management's expectations regarding Favipiravir could be affected by, among other things, unexpected clinical trial results, including unexpected NEW clinical data and unexpected additional analysis of existing clinical trial data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Glenmark Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Glenmark Pharmaceutical current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Glenmark Pharmaceuticals is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

For more information:

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[i] BMJ Best Practices 2020.
[ii] WHO 2020