July 21, 2020

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

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.

Scrip Name: GLENMARK

Ref: Your emails dated July 20, 2020

Dear Sirs,

Sub: Clarification on news item appeared in Media/Publication

Refer to your emails dated July 20, 2020 seeking clarification regarding News item appeared in the media, enclosed is the response submitted by Glenmark to Directorate General of Health Services.

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: 2020.07.21 08:47:03 +05'30'

Harish Kuber
Company Secretary & Compliance Officer

Glenmark
A new way for a new world

20 July 2020

To,
Dr. V.G. Somani
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, New Delhi – 110002

Ref : F.No. 12-01/20-DC (Pt.262)

Sub: Regarding representation by Hon'ble Member of Parliament forwarded under the above referenced letter dated 17th July 2020

Dear Sir,

We refer to your letter dated 17th July 2020 in relation to the captioned subject seeking clarifications on the concerns raised and allegations made by Hon'ble Member of the Parliament in the form of a representation in respect of the product Favipiravir tablets 200mg manufactured and marketed by Glenmark pursuant to permission dated 19th June 2020 granted by your kind office.

As you are aware, Glenmark is a global research-led pharmaceutical company with presence across Generics, Specialty and OTC business with operations in over 50 countries.

Our goal is to provide transformative, curative therapies that address unmet medical needs and help healthcare providers improve the lives of patients. With this in mind, we have been steadily investing in new drug discovery and development for over two decades. Glenmark has always made continuous investment in R&D roughly about 13% of our turnover for FY 19-20. We have developed several new chemical entities (NCEs) and new biological entities (NBEs) and many of them are part of clinical studies being conducted across the globe. Quickly upon the onset of pandemic and heeding to the clarion call of our Hon'ble Prime Minister, Glenmark swung into action with a view to make India self-reliant by finding an effective treatment option for COVID-19.

True to its spirit of research and development, Glenmark internally developed the API and the formulations for the product, Favipiravir. Soon after, Glenmark was one of the first companies to approach your office to seek approval to conduct clinical trials on Favipiravir tablets in mild to moderate COVID-19 patients, which approval was granted in late April 2020.

Having said the above, we now proceed in the following paragraphs to address specific concerns raised and allegations contained in the representation of Hon'ble Member of Parliament forwarded under the cover of the said letter.

Glenmark Pharmaceutical Ltd.
7-D, Atmaram House, 1 Tostoy Marg, New Delhi-110 001
T-2331 1870/71 F : 2331 1872 W: www.glenmarkpharma.com
Registered Office : B/2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road, Mumbai- 400 026

1. **Concern**: *Unaffordability to due to high Price*

Response:

Glenmark has successfully developed the active pharmaceutical ingredient (API) and the formulation for FabiFlu® through its own in-house R&D team within the country, ensuring self-reliance with regard to long-term production and manufacturing of the said Product. Moreover, Glenmark, up to the date hereof, remains the only company in India to conduct a randomized controlled trial for Favipiravir, naturally with significant investments in R&D and clinical trials.

Compared to other therapies approved for emergency use in COVID-19, FabiFlu® is much more economical and an effective treatment option as denoted by the below table:

	Favipiravir	**Remdesivir**	**Tocilizumab**	**Itolizumab**
Est. total cost of therapy for full course	~ INR 9,150	~ INR 24,000 - 30,000	~ INR 44,000	~ INR 32,000

Further, given that Favipiravir is an oral therapy, patients can be treated on an out-patient basis without incurring additional hospitalization expenses, unlike other approved drugs which are injectable and hence require administration at hospitals.

Favipiravir in India when launched was at the lowest market cost (₹103/tab) as compared to the cost of Favipiravir in other countries where it was approved. Despite investing significantly throughout the process of manufacturing, Glenmark has managed to keep the pricing of Favipiravir lower as compared to price of Favipiravir in other countries.

Country	**Price in ₹**
Russia	600 / tab
Japan	378 / tab
Bangladesh	350 / tab
China	215 / tab
India (FabiFlu)	103 / tab now reduced to ₹75/-
* Source trade data from respective countries and all tabs are 200mg	

Soon after the launch, with a view to make the Product even more accessible to larger section of the population, Glenmark proactively had committed in its letter dated 29th June 2020 that it was working to bring in further efficiencies in manufacturing with an intent to reduce the price of the Product.

Subsequently on 13th July 2020, Glenmark reduced price of FabiFlu® to INR 75/- per tablet. The price reduction was made possible through our efforts to obtain better yield and better scale, and with both API and formulations manufactured at Glenmark's own facilities in India.

Today, Favipiravir is a part of several state government protocols and thousands of COVID-19 patients have benefitted from the prescription of the product.

2. Concern: *Allegation of misleading/false claim that Favipiravir is effective in COVID-19 patients with comorbidities like diabetes, hypertension as Phase 3 clinical trial was designed to evaluate the efficacy in these co-morbidities*

Response:

The alleged statement pertaining to co-morbidity in the press release dated 20 June 2020 was not derived from or alluded to Glenmark's ongoing Phase 3 clinical trial. On the contrary, the reference to co-morbidity was clearly based on data from Japanese registry – the largest collection of real-world evidence on clinical use of Favipiravir in COVID-19.

Our bonafide are further corroborated by the fact that none of the product promotional literature, Summary of Product Characteristics (SmPC) or Product Information leaflet makes any such claim that Favipiravir can be used in mild to moderate COVID-19 patients with co-morbid conditions such as diabetes and heart disease.

In Feb 2020, Favipiravir was incorporated in the Guidance[1] of antiviral drug treatment for COVID-19 in Japan wherein Favipiravir was used on compassionate basis in Japan in adult patients of all age groups including with co-morbidities. The report of registry on Favipiravir published by Japanese Infectious Disease Society[2] had 2,158 patients across 407 hospitals which included 49% of the patients with co-morbidities (including diabetes, hypertension) and 52% aged above 60 years. The results showed clinical improvement in 84.5% and 87.8% patients with Favipiravir in moderate and mild COVID-19 patients respectively at the 14 day evaluation period. The 88% clinical improvement mentioned is derived from the published Japanese clinical use in the large cohort of >2100 patients.

In fact what is surprising is that the allegation of false claim is being made that when Glenmark, being a responsible corporate citizen, explicitly referenced upfront the Japanese registry , and at no point linked it to our India Phase 3 clinical trial.

In view of the above, it is clear that Glenmark's communication at the launch of the said Product has been completely misread and/or quoted out of context which is harming our reputation.

1. *Guidance of antiviral drug treatment for COVID-19 1st edition (26 Feb. 2020). The Japanese Association for Infectious Diseases.*
2. *http://www.kansensho.or.jp/uploads/files/topics/2019ncov/covid19_casereport_en_200529.pdf*

3. Concern: *Favipiravir is not tested as Monotherapy in Phase 3 clinical trial in India.*

Response:

At the outset, Glenmark denies having made any such claim at any point in time that "Favipiravir alone" is effective in treatment of Covid-19 patients with mild to moderate disease.

In the light of the pandemic, in all COVID-19 trials being proposed/conducted across India, all patients receive standard supportive care as per the guidance of MoH & FW as giving the patients placebo alone in such a situation would be unethical as it would deprive the patients of any care at all . Globally, similar approach i.e. including standard supportive care is adopted in clinical trials that are being conducted to consider treatment options for COVID-19 patients.

Similarly, in the Glenmark Study, as per the guidelines issued by ICMR/ MoH&FW, patients with mild to moderate COVID 19 symptoms were treated with Favipiravir plus recommended standard supportive care versus standard supportive care alone.

It is pertinent to note that the standard supportive care in Glenmark Study did not include HCQ or any other anti-viral drug. Consequently, since both arms of the Glenmark Study received standard supportive care under this design, any advantage observed in the treatment arm can solely be attributed to the administration of Favipiravir.

It is further important to note that the protocol of Glenmark Study was duly approved by SEC after subjecting the draft protocol to much interrogatories and challenge. Therefore, we submit that concerns raised by Hon'ble Member of Parliament that Fabiflu was not tested as a monotherapy i.e. only Fabiflu in any of the mild to moderate patient in Glenmark study is wholly misplaced and devoid of understandings of the clinical trial principles in a pandemic situation.

As you are well aware, the clinical trial permission and the restricted use approval both were preceded by multiple dialogues, deliberations and consideration before the Subject Expert Committee ("SEC") constituted by the Ministry of Health & Family Welfare (MoH&FW). All approvals to Glenmark were granted in accordance with the extant law and with stringent conditions.

In conclusion, what has dismayed us the most is that despite Glenmark –

- **bringing an oral anti-viral agent in less than 3 months of the pandemic setting in to India; with end-to-end synthesis and API and formulation catering to Indian populace and even export markets;**
- **being the first and only company to conduct a robust 150-patient randomized controlled trial;**

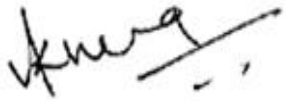
- **launching the drug at a affordable price and making it even more accessible in 15 days post launch with a voluntary price reduction being passed on to the patients;**
- **ensuring continuous availability of the drug to various state governments**

…Glenmark has been at the receiving end of such careless, unsubstantiated allegations that are devoid of merits whatsoever as amply demonstrated above.

We would like to end by assuring you that Glenmark will continue to work tirelessly towards bringing relief to COVID-19 patients.

Yours faithfully,

For **Glenmark Pharmaceuticals Ltd.**



Anurag Khera
Sr. Vice President - Corporate Affairs

E-mail: anurag.khera@glenmarkpharma.com

Encl: As above.