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 Sirs,

Sub: Glenmark unlocks the treatment for Mild to Moderate Covid-19 in India

Kindly find enclosed herewith the presentation on Glenmark unlocks the treatment for Mild to Moderate Covid-19 in India. The same will also be made available on our website.

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
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Date: 2020.06.20 14:42:02 +05'30'

Harish Kuber
Company Secretary & Compliance Officer

Encl: as above

UNLOCKING THE TREATMENT FOR MILD TO MODERATE COVID-19 IN INDIA

Glenmark Pharmaceuticals Limited

June 2020

glenmark
A new way for a new world

Glenmark Pharmaceuticals – An Overview

Leading Integrated research-led global pharmaceutical company

Consolidated revenue: INR 9,865 Crores[1]

Among the Top 80 Pharma companies globally[2]

Integrated across the pharmaceutical value chain with strong presence in drug discovery, API and finished dose formulations

Established research prowess in both novel small molecule and biologics research with molecules in different stages of development

15 facilities across formulations and API in 4 continents

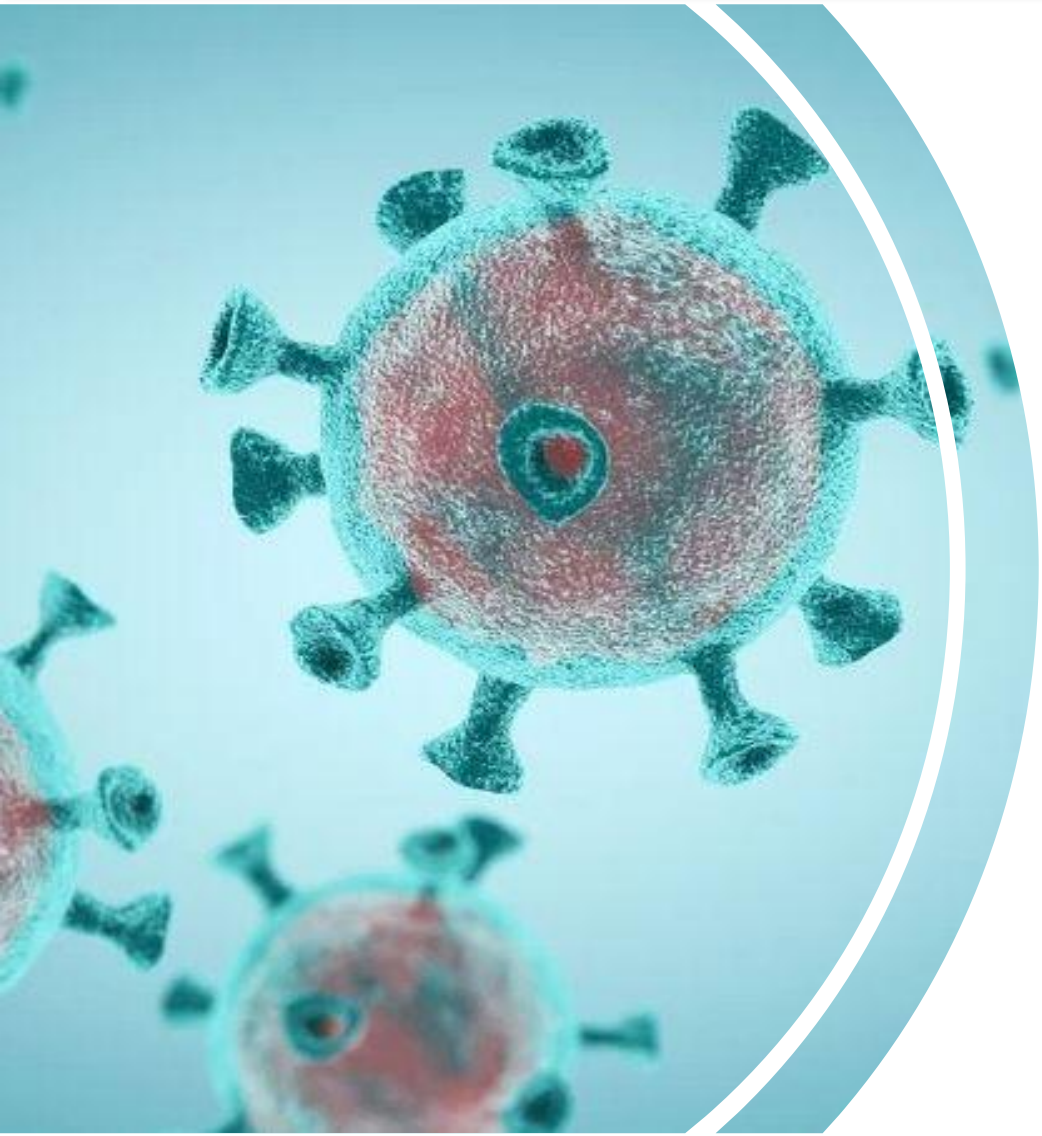
Global Operations in more than 80 countries with over 14000 employees

1. FY 1819 Financial Figures
2. As per SCRIP 100 Rankings 2019

Glenmark Pharmaceuticals – India Business

- Among the fastest growing companies for the last 5 years*
- ₹2,788 Cr Sales
- 14th Rank (Value-wise)
- Leadership positions in Dermatology, Respiratory & Anti-Hypertensive therapies

*In Top 20 companies in Indian Pharmaceutical Market



COVID 19 – Situation Today

COVID19 – Global Situation

83,85,440
Confirmed Cases

216
Affected Countries*

4,50,686
Deaths

5.37%
Fatality Rate

*Countries/Regions as recognized by WHO

COVID 19 – Current Situation in India

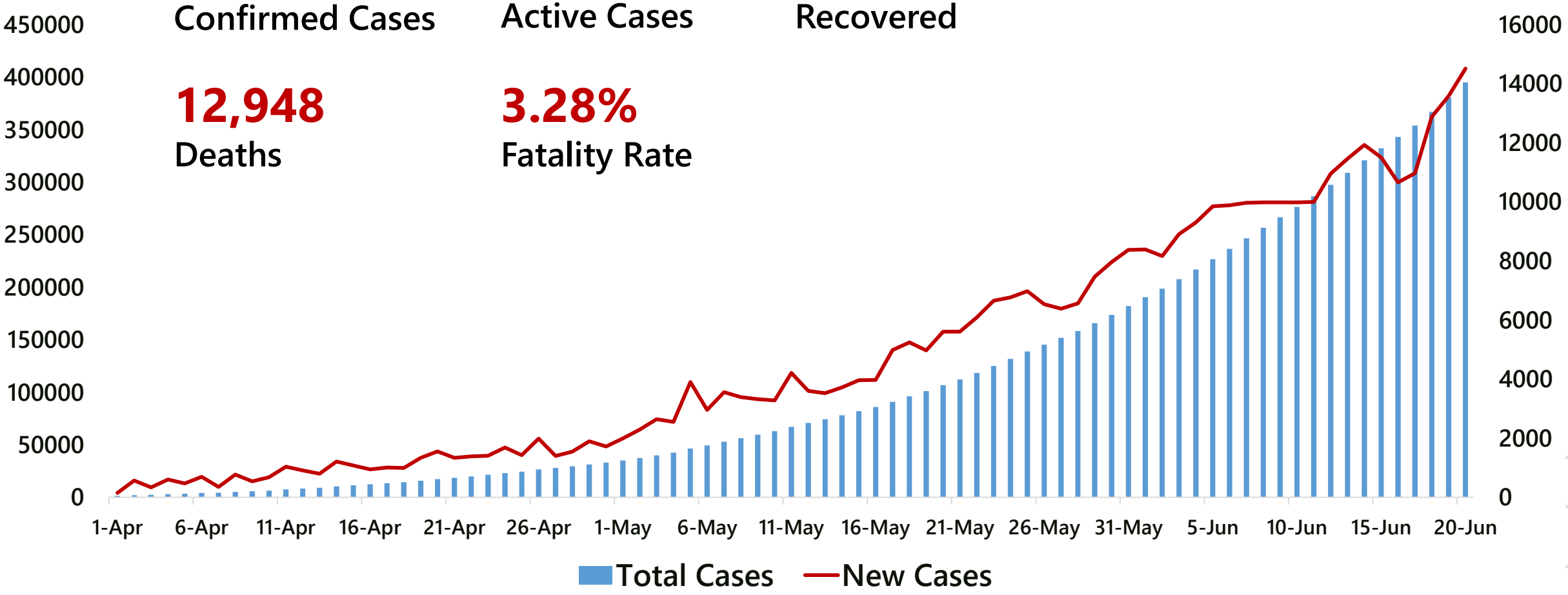
3,95,048
Confirmed Cases

1,68,269
Active Cases

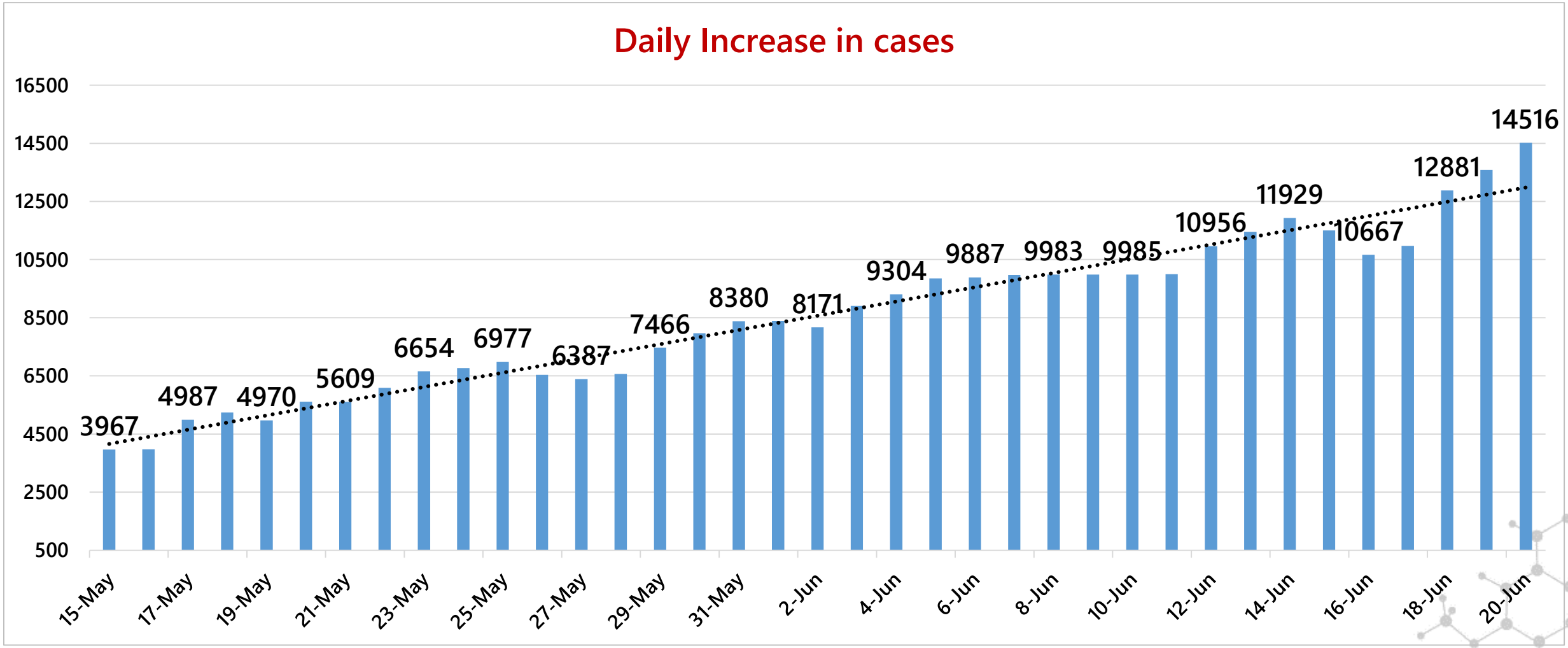
2,13,831
Recovered

12,948
Deaths

3.28%
Fatality Rate



COVID 19 – Current Situation in India




COVID-19
Need of the hour

Need of the hour…

1. Help the healthcare professionals to fight back
2. Help in faster recovery of patients & save lives

Glenmark

A new way for a new world

is at the forefront of

Leading the fight against COVID19

Glenmark

A new way for a new world

Initiated evaluation of treatment options for

COVID-19

and identified

Favipiravir

as a potential candidate.

Why did we initiate work on Favipiravir?

1. It has a proven in-vitro activity against SARS CoV2[1]

2. It has a wide therapeutic safety margin for COVID-19 dose[2]

3. It had shown promising results in a couple of studies in China[3,4]

4. It is an oral product & that is a big benefit especially when the hospital infrastructure is under strain

5. It already was approved for novel or re-emerging pandemic influenza virus infection in Japan[5]

1,2. Cell Research (2020) 0:1–3; https://doi.org/10.1038/s41422-020-0282-0)
3. Cai Q et al. Engineering (Beijing). 2020;10.1016/j.eng.2020.03.007.
4. Chen C et al. MedRxiv. 2020 Jan 1.
5. Avigan® Tablet 200 mg- Deliberation Results by PMDA. (2014). Favipiravir: Report on the Deliberation Results; Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau; Ministry of Health, Labour and Welfare; March 4, 2014. Avigan® is registered brand name of the innovator.

Favipiravir – Global status update

- COVID-19 therapeutic management guidelines include Favipiravir in Russia, Japan & Saudi Arabia
- ~18 global CTs in 3000+ subjects in clinical trials globally including India, USA, Canada, Italy, China, France, UK and other countries
- Compassionate Use in Japan: ~2050 patients already administered Favipiravir in Japan for clinical use – high recovery rates observed at both 7 and 14 days of therapy in both mild and moderate patients
- Approved by Italy & China for experimental use/compassionate use in COVID-19
- 760 patient trial of Favipiravir initiated in Canada recently in long term care centres

Favipiravir – Global status update

- Under regulatory licensing process in Turkey, expected to be made available to patients soon
- Commercially launched by many companies in Bangladesh
- Commercialization approval granted in UAE; protocol approved in Jordan
- Under registration approval process by more than 15 companies for launch in Egypt.
- Indonesia and Thailand approved clinical protocol; companies developing locally for launch
- Adopted in the COVID-19 treatment protocol in multiple CIS countries such as Ukraine, Kazakhstan, Uzbekistan and Moldova
- Evaluation ongoing in other middle eastern countries such as Iraq and Bahrain based on Saudi Arabia COVID-19 treatment guidelines

Glenmark demonstrated end-to-end development capabilities…

- Make In India -

1. Synthesized the **Active Pharmaceutical Ingredient (API)**
2. Developed the **Formulation**
3. Received approval to conduct **Clinical Trials** in India

The Approval Journey

Glenmark Favipiravir Clinical Trial – An Overview

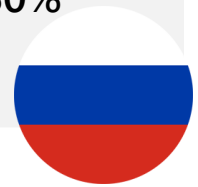
- Randomized, multi-centric study in Indian patients evaluating efficacy and safety of Favipiravir with standard of care vs. standard of care alone in mild to moderate COVID-19
- Sample size: 150 subjects (90 mild and 60 moderate patients)
- Dosing regimen: Favipiravir tablets; 3,600 mg (1,800 mg BID) (Day 1) + 1,600 mg (800 mg BID) (Day 2 or later) for up to maximum of 14 days, along with supportive care.
- Treatment duration: Maximum of 14 days
- Patient population: Hospitalized subjects with confirmed RT-PCR positivity
- Conducted in 11 sites across India.

Promising global evidence of safety & efficacy

Russian Study basis which approved by Russian Ministry of Health

- No. of patients: 390 (Part 1- 60 and Final part 360)
- Median elimination time for the SARS CoV-2 was 4 days with Favipiravir compared to 9 days with standard therapy.
- With Favipiravir, Day 4 of treatment 65% of patients turned RT-PCR negative for SARS CoV-2, Day 10 of treatment, 90% of patients turned RT-PCR negative for SARS CoV-2
- Favipiravir gr. 68% reached Fever resolution on day 3 vs Std. therapy on day 6
- Overall reported efficacy of favipiravir is >80%

(Ref: https://rdif.ru/Eng_fullNews/5224/)



Observational Study from Japan

- No. of patients: 2141

In Mild to Moderate COVID-19 patients-

- Clinical improvement with Favipiravir upto 74% by Day 7 of treatment
- Clinical improvement with Favipiravir upto 88% by Day 14 of treatment

(Ref: http://www.kansensho.or.jp/uploads/files/topics/2019ncov/covid19_casereport_en_200529.pdf)

Promising global evidence of safety & efficacy

Chinese Study 1 (Cai et al.)

- No. of patients: 80
- Significantly shorter viral clearance time with Favipiravir (4 days) compared to 11 days for LPV/RTV (Lopinavir/Ritonavir)
- Significantly higher improvement in chest CT changes with Favipiravir (91.4%) compared to LPV/RTV(62.2 %)
- Favipiravir has better Safety profile than LPV/RTV

(Ref: Cai Q et al. Engineering (Beijing), 2020;10.1016/j.eng.2020.03.007.)

Chinese Study 2 (Chen et al.)

- No. of patients: 236
- Significantly superior clinical recovery rate (71.4%) at day 7 with favipiravir than that of umifenovir (55.8%) in moderate COVID-19 patients
- Favipiravir had significantly shorter time to relief from fever and cough than umifenovir

(Ref: Chen C et al. MedRxiv. 2020 Jan 1.)

All these studies point to the following…

- Rapid reduction in viral load[1,2]
- Faster fever resolution[1,3]
- Faster resolution of Chest CT changes[4]
- Faster clinical recovery[2,3]

References:

1. https://rdif.ru/Eng_fullNews/5224/
2. http://www.kansensho.or.jp/uploads/files/topics/ 2019ncov/covid19_casereport_en_200529.pdf
3. Chen C et al. MedRxiv. 2020 Jan 1
4. Cai Q et al. Engineering (Beijing), 2020;10.1016/j.eng.2020.03.007

Glenmark
A new way for a new world

has received permission from the
Indian drug regulator

To Manufacture and Market Favipiravir in India for treatment of Mild to Moderate COVID-19*

*Under the Accelerated Approval Process

Favipiravir – Accelerated Approval Process

- Accelerated approval process takes into account the disease severity, rarity, and the availability or lack of alternative treatment.
- Glenmark has received approval to manufacture and market Favipiravir in India for mild to moderate COVID-19 cases.
- Emergency Use Authorization is a provision that allows countries to use drugs urgently needed in an emergency situation or healthcare crisis. (COVID-19 pandemic)
- "Emergency" here does not refer to patients in an emergency status of the disease, but refers to the emergency pandemic situation prevalent in the country and the need for effective and timely treatment.
- Restricted use entails "responsible medication" use where every patient must have signed informed consent before treatment initiation

Favipiravir

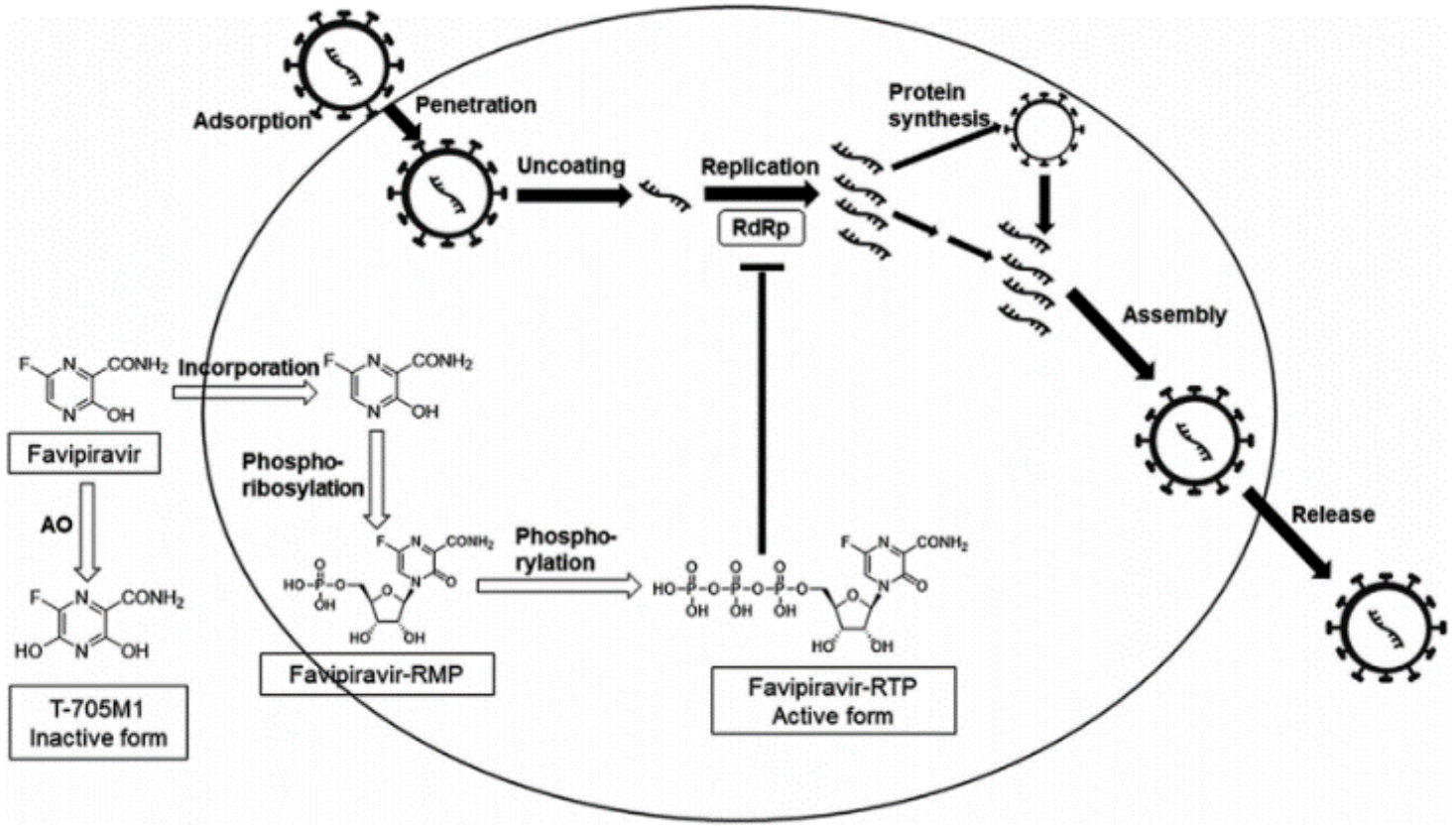
An important step for

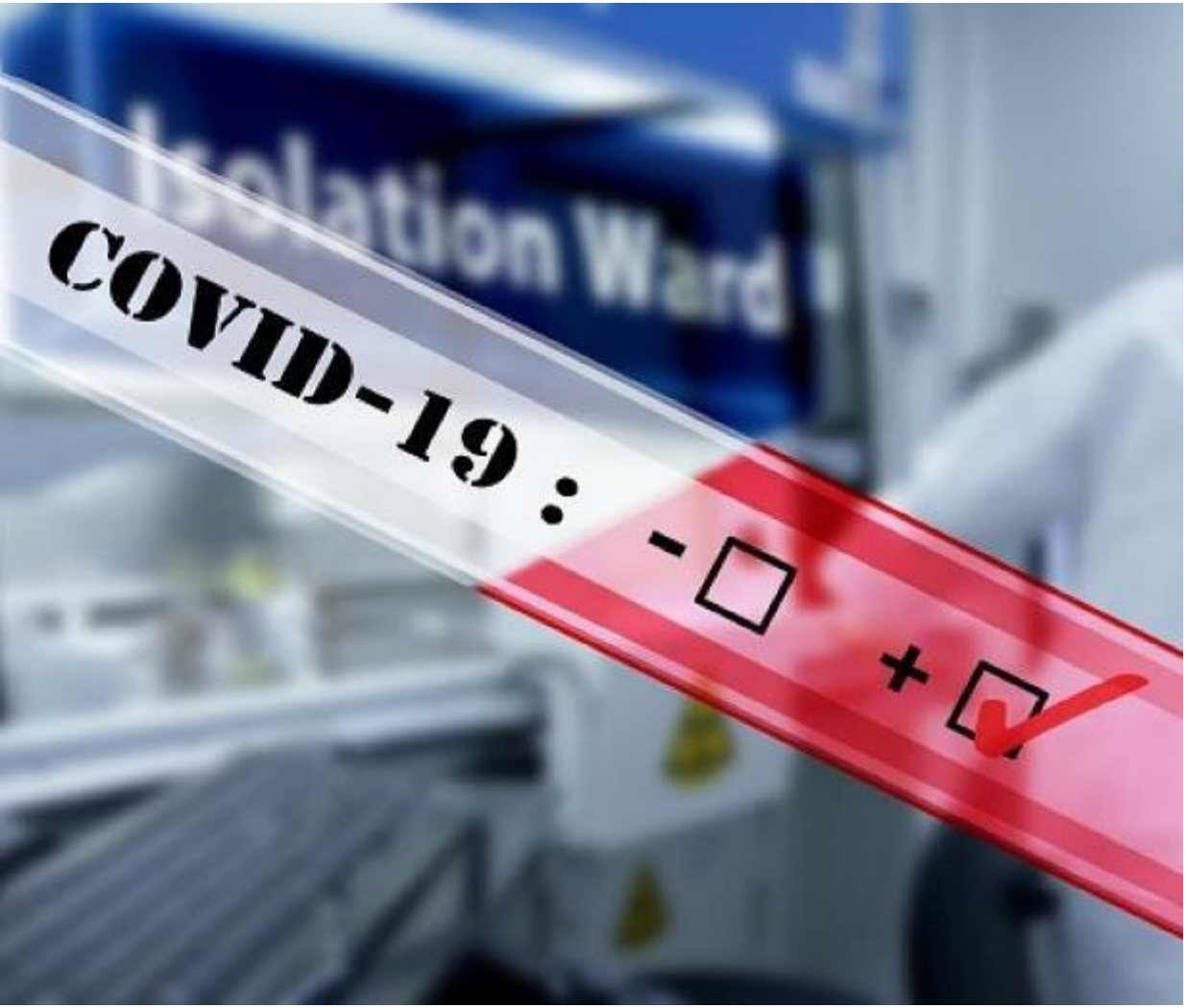
Oral Treatment of Mild to Moderate COVID-19*

*Under the Accelerated Approval Process

Favipiravir – Mechanism of Action

- Favipiravir is incorporated into cells and converted to favipiravir ribofuranosyl-5′-triphosphate (favipiravir-RTP) by host cells.
- Favipiravir-RTP, inhibits the activity of RNA dependent RNA polymerase (RdRp) of SARS CoV2.
- The inhibition of RdRp leads to inhibition of the viral replication.

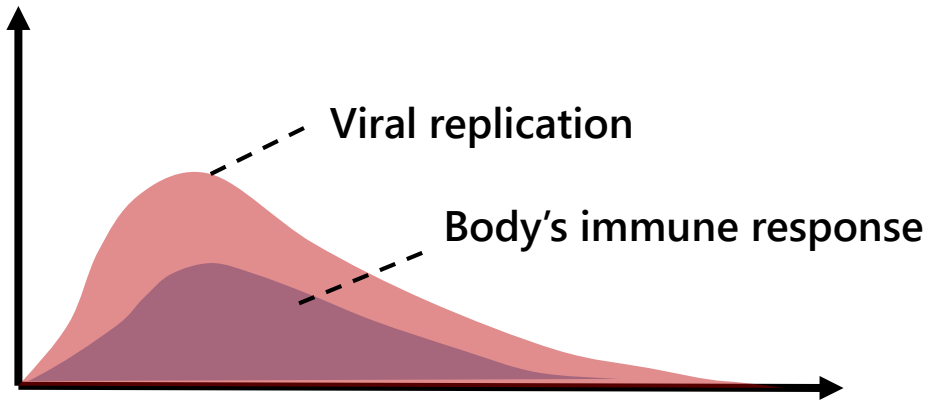




Starting early is the key…

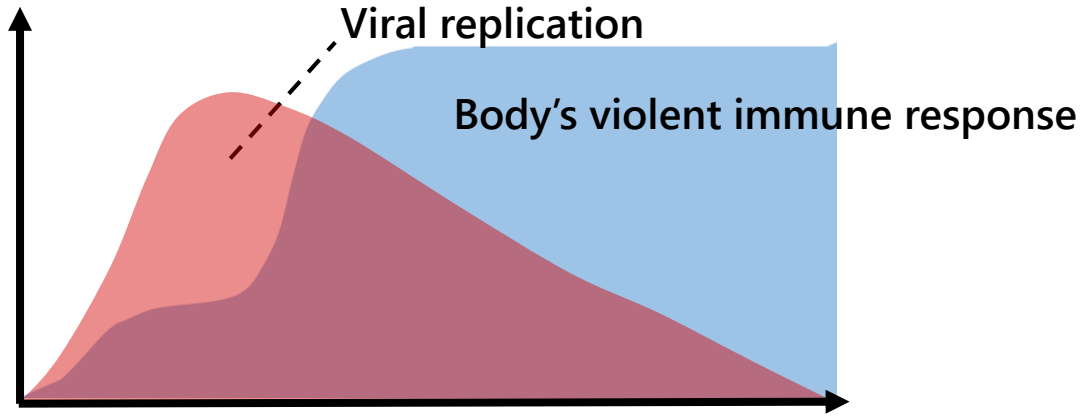
Favipiravir – Starting early is a key in COV

Early stages – Mild and Moderate



- High rate of viral replication
- Can be controlled with early use of Antiviral drugs
- Limited immune response mediated damage - Immune response subsides quickly

Later stages- Severe and Critical



- Viral replication slows down
- Body's violent immune response drives disease leading to complications and organ failure
- Diminishing effects of Antiviral drugs
- Higher dependence on other drugs and ventilators for survival

Favipiravir – Contraindications & Cautions

Contraindications:

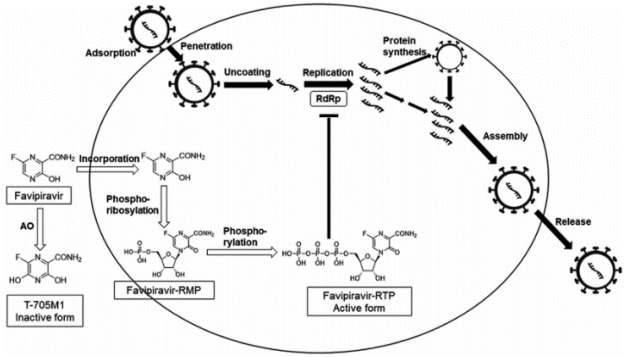
- The drug is contraindicated in patients with severe renal, hepatic impairment, pregnant & lactating women.
- The drug is contraindicated in patients with history of hypersensitivity to Favipiravir.

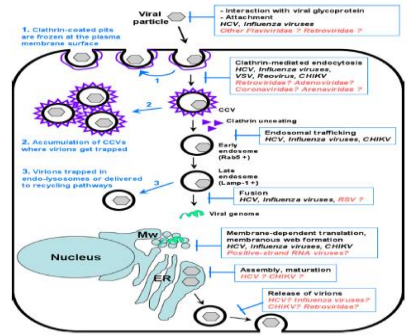
Cautions:

- The drug should be used with caution in patient with history of abnormalities in metabolism of uric acid or having Gout.

Favipiravir and Umifenovir Combination – An update

- COVID-19 patients show high viral load at time of symptom onset suggests treating with combination of antiviral drugs- highly effective and minimize the emergence of resistance.
- In line with this strategy, Glenmark proposes to combine two anti-viral drugs Favipiravir (Approved drug for novel flu pandemics) with Umifenovir (Approved drug for Influenza) – safety well established.
- Both drugs acting on different mechanisms the combined use of Favipiravir and Umifenovir offers a comprehensive antiviral cover on pre-entry and post-entry life-cycle of SARS-CoV-2 virus.





- Favipiravir: Prevention of viral replication by inhibition of RNA dependent RNA polymerase
- Umifenovir: Interaction with viral attachment, fusion with infected cell

The Next Step…

Glenmark
A new way for a new world

proudly introduces

Fabiflu®
Favipiravir 200 mgTablets

The First Oral Anti-viral Treatment Option for Mild to Moderate COVID-19 cases*

*Under the Accelerated Approval Process

Fabiflu®
Favipiravir 200 mgTablets

Available as a tablet of 200mg

It will be available in a strip of 34 tabs

Fabiflu®
Favipiravir 200 mgTablets

Dosage:

	Day 1	Day 2 to max 14 days
Total Daily Dose	1800 mg BID	800 mg BID
Morning	200 mg x 9 tabs	200 mg x 4 tabs each day
Evening	200 mg x 9 tabs	200 mg x 4 tabs each day

Price:

MRP ₹3500 for a pack of 34 tablets
(Approx. ₹ 103 per tablet)

Fabiflu®*

Favipiravir 200 mg Tablets

A significant step in the fight against **Mild to Moderate COVID-19 cases***

WITH AN ORAL ADVANTAGE

*Under the Accelerated Approval Process

Fabiflu®

Favipiravir 200 mgTablets

Thank you!


Glenmark
A new way for a new world