

June 20, 2020

To,
**SINGAPORE EXCHANGE SECURITIES
TRADING LIMITED**
**11 North Buona Vista Drive,
#06-07 The Metropolis Tower 2,
Singapore – 138589**

Dear Sir,

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
DN: c=IN, st=Maharashtra,
2.5.4.20=cde2956f5be913821f9f991026d376afdaebf5b8838c3a71de2e75
255a782d, postalCode=400049, street=C21, Maker Kundan Garden,
serialNumber=fac79f9832e6525179ba771e8bf27e6f3c4c491160cbf2
71c804b16e6f, o=Personal, cn=HARISH VINAYAK KUBER
Date: 2020.06.20 15:04:18 +05'30'

**Harish Kuber
Company Secretary & Compliance Officer**

Encl: as above

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T: 91 22 4018 9999 F: 91 22 4018 9988 CIN No: L24299MH1977PLC019982 W: www.glenmarkpharma.com

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



Glenmark Pharmaceuticals
Limited

June 2020

Glenmark Pharmaceuticals – An Overview

Leading Integrated research-led **global pharmaceutical company**

Consolidated revenue: INR 9,865 Crores¹



Among the
Top 80 Pharma
companies
globally²



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



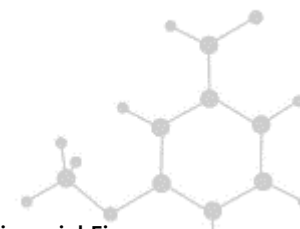
Established research
prowess in both
novel small molecule
and **biologics**
research with
molecules in different
stages of
development



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 SCRIIP 100 Rankings 2019

Glenmark Pharmaceuticals – India Business



Among the fastest growing companies for the last 5 years*



₹2,788 Cr Sales

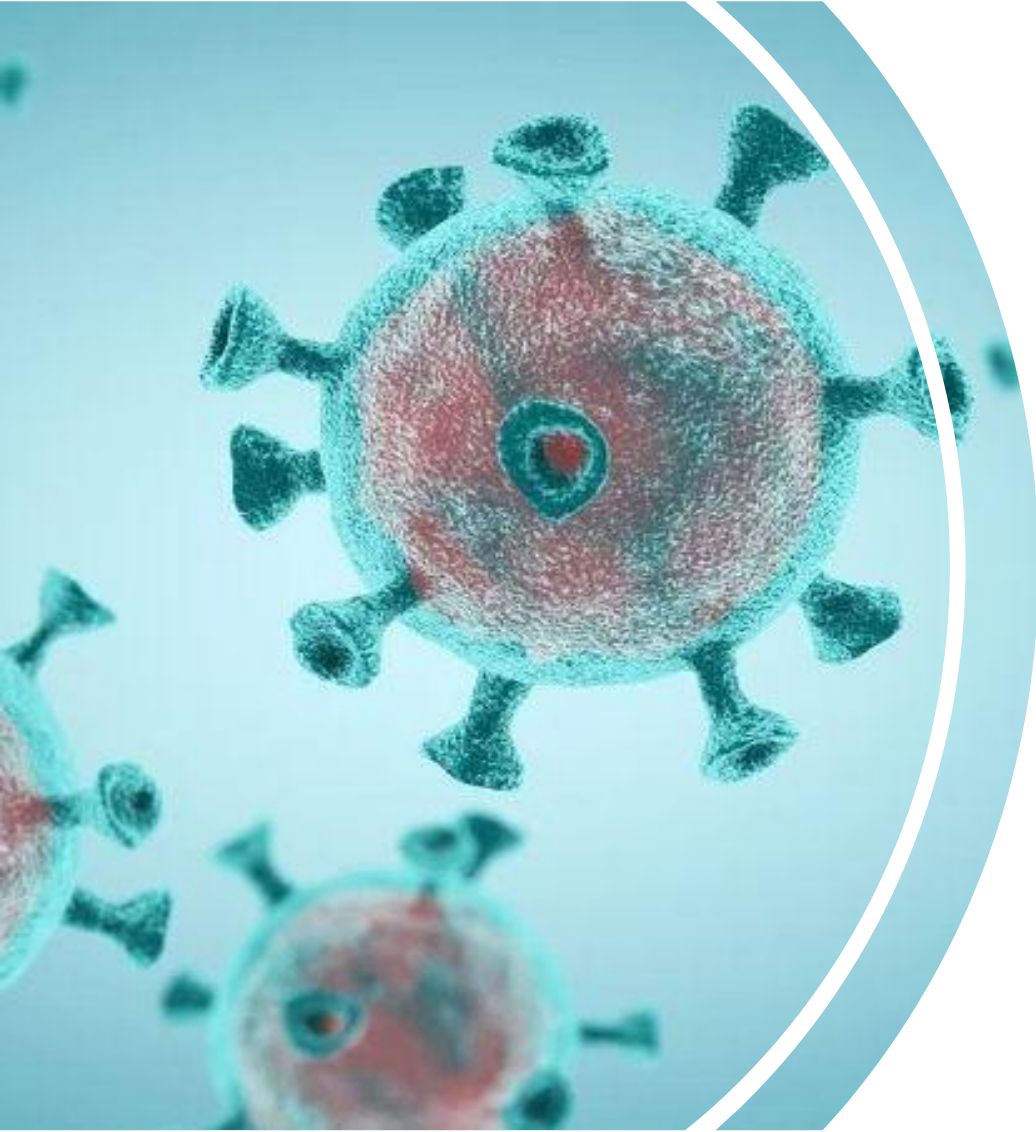


14th Rank (Value-wise)

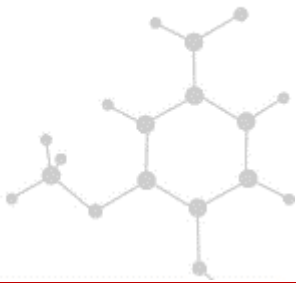


Leadership positions in Dermatology, Respiratory & Anti-Hypertensive therapies

*In Top 20 companies in Indian Pharmaceutical Market



COVID 19 – Situation Today



COVID19 – Global Situation

83,85,440

Confirmed Cases

216

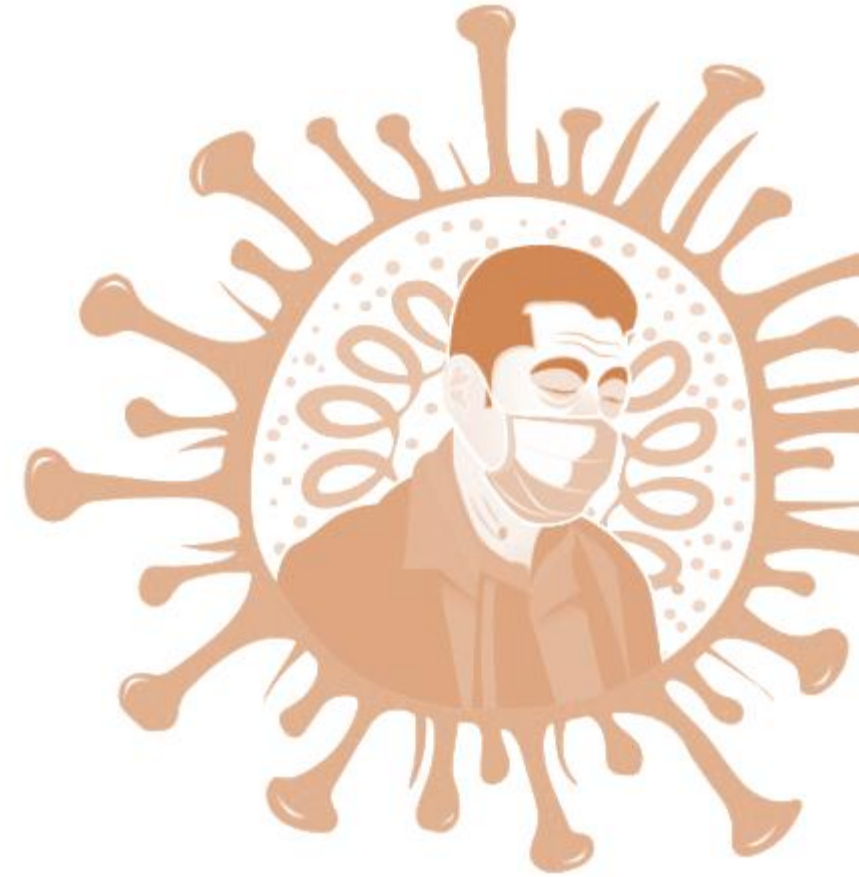
Affected Countries*

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

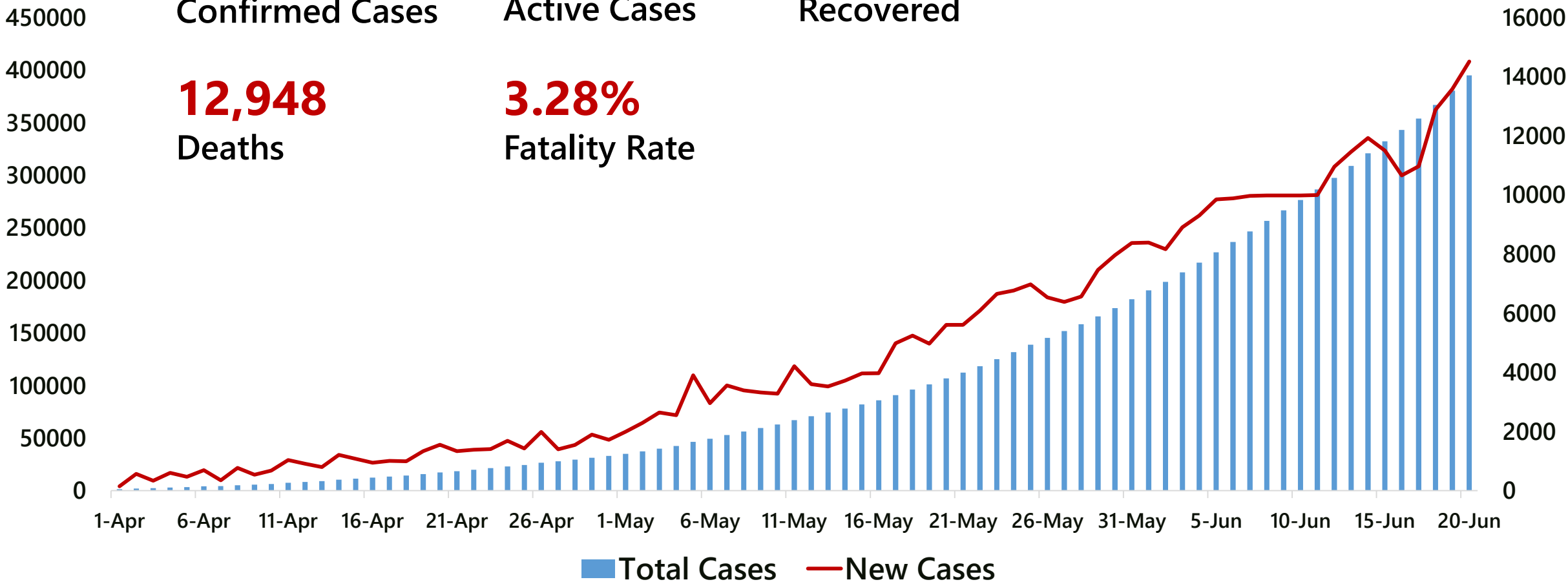
Recovered

12,948

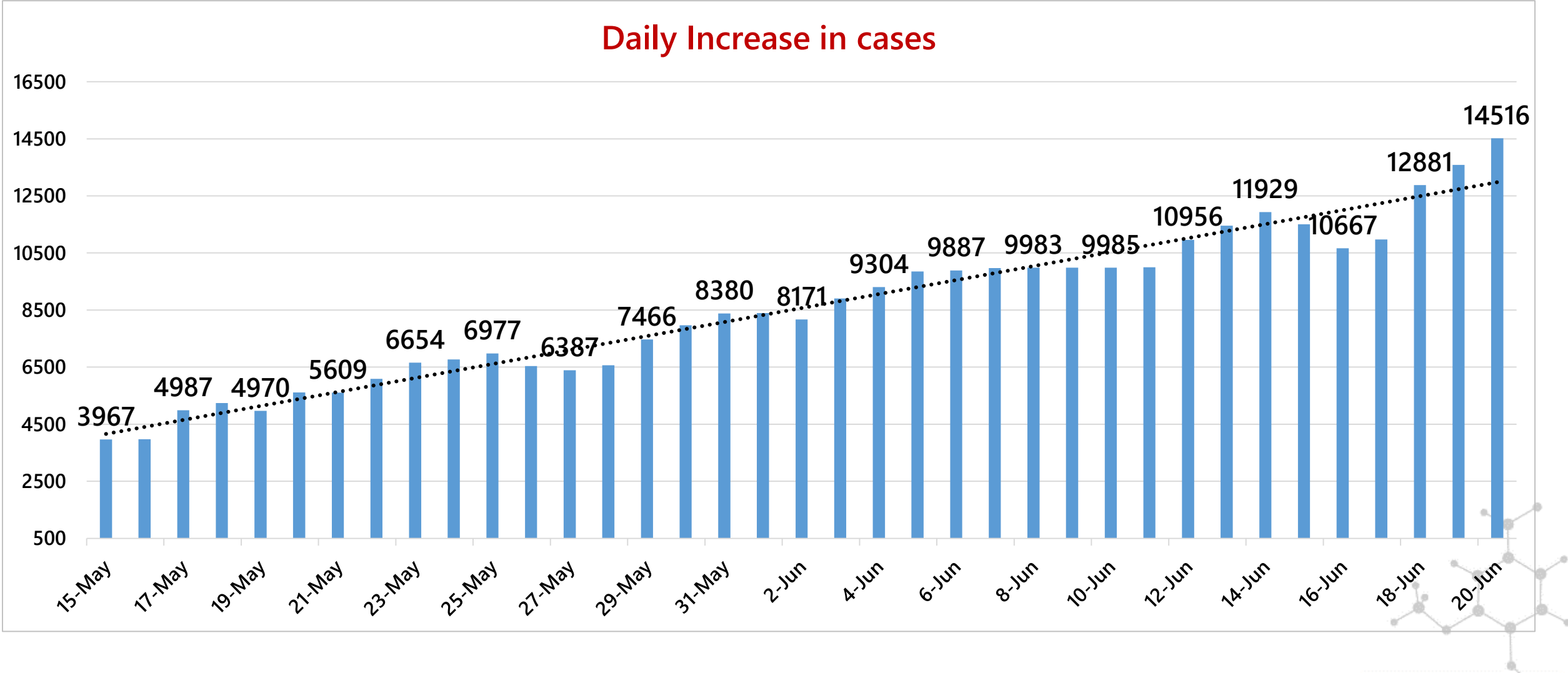
Deaths

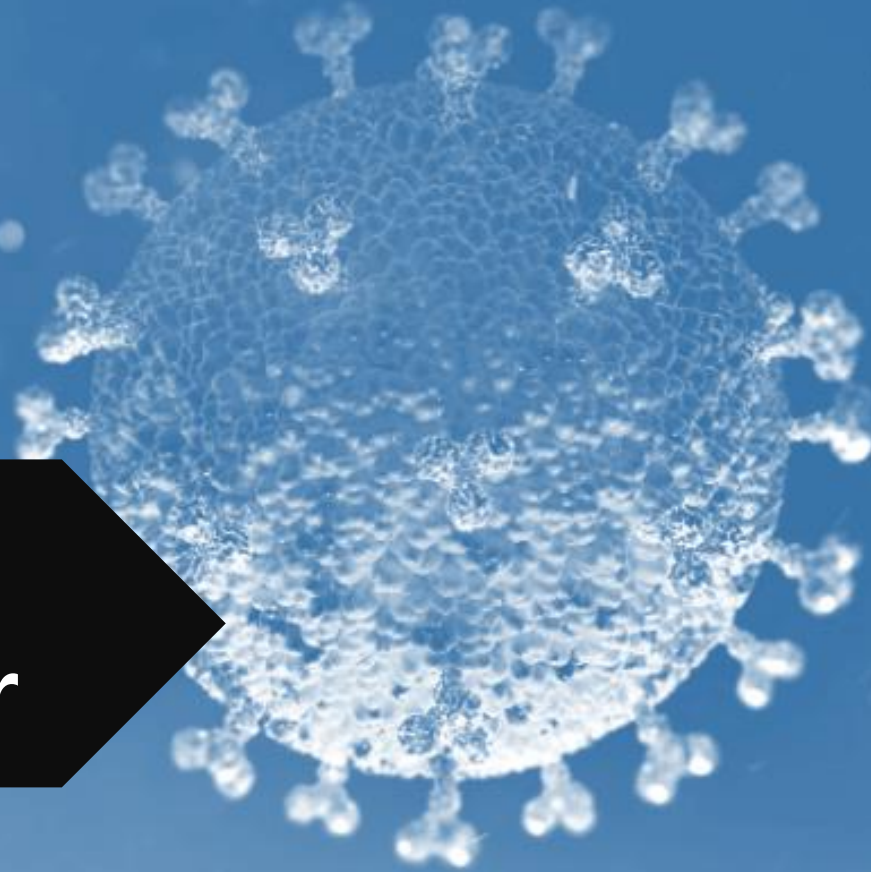
3.28%

Fatality Rate



COVID 19 – Current Situation in India





COVID-19

Need of the hour

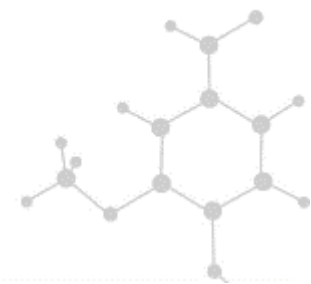
Need of the hour...



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



is at the forefront of
**Leading the fight against
COVID19**



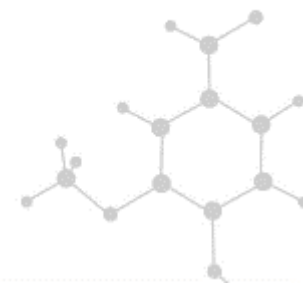


Initiated evaluation of treatment options for
COVID-19

and identified

Favipiravir

as a potential candidate.



Why did we initiate work on Favipiravir?

1

It has a proven in-vitro activity against SARS CoV2¹



2

It has a wide therapeutic safety margin for COVID-19 dose²



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 Japan⁵



1,2. Cell Research (2020) 0:1–3; <https://doi.org/10.1038/s41422-020-0282-0>

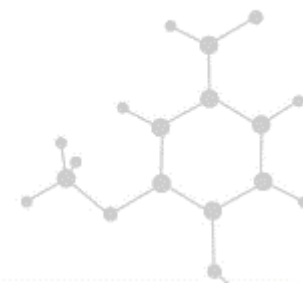
3. Cai Q et al. Engineering (Beijing). 2020;10.1016/j.eng.2020.03.007.

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



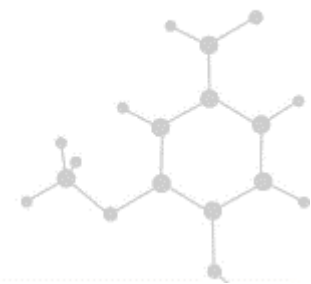
3

Received approval to
conduct **Clinical Trials**
in India



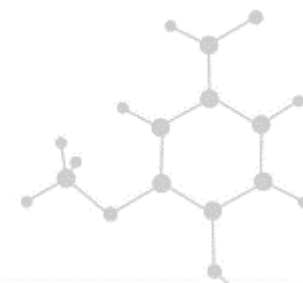


The Approval Journey



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.

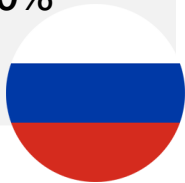


Promising global evidence of safety & efficacy

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}



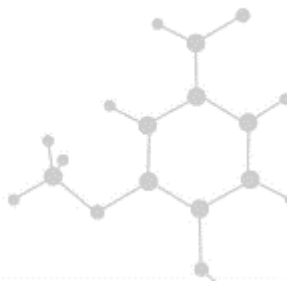
Faster resolution of Chest CT changes⁴



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





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

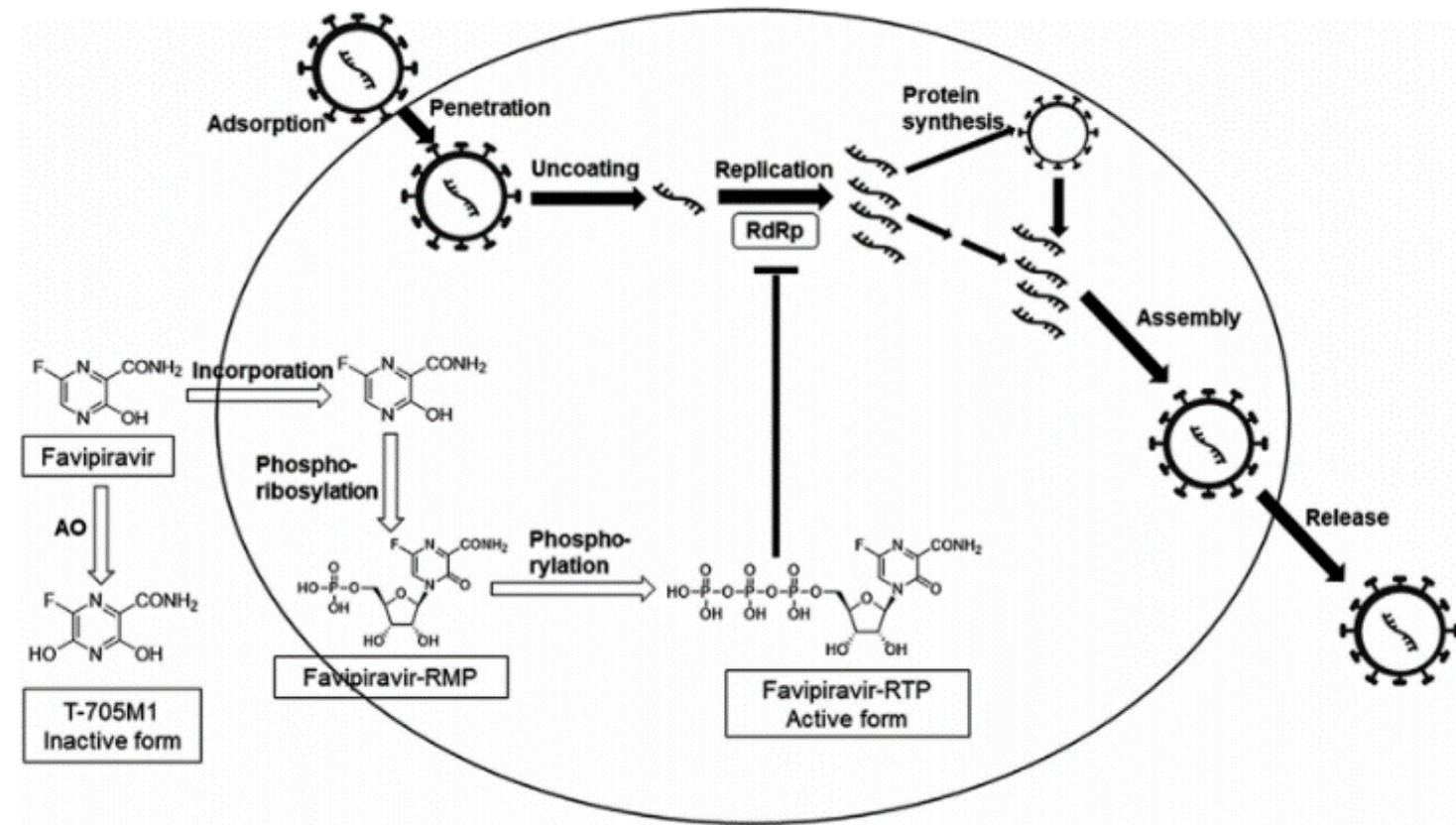
**Oral Treatment of
Mild to Moderate COVID-19***

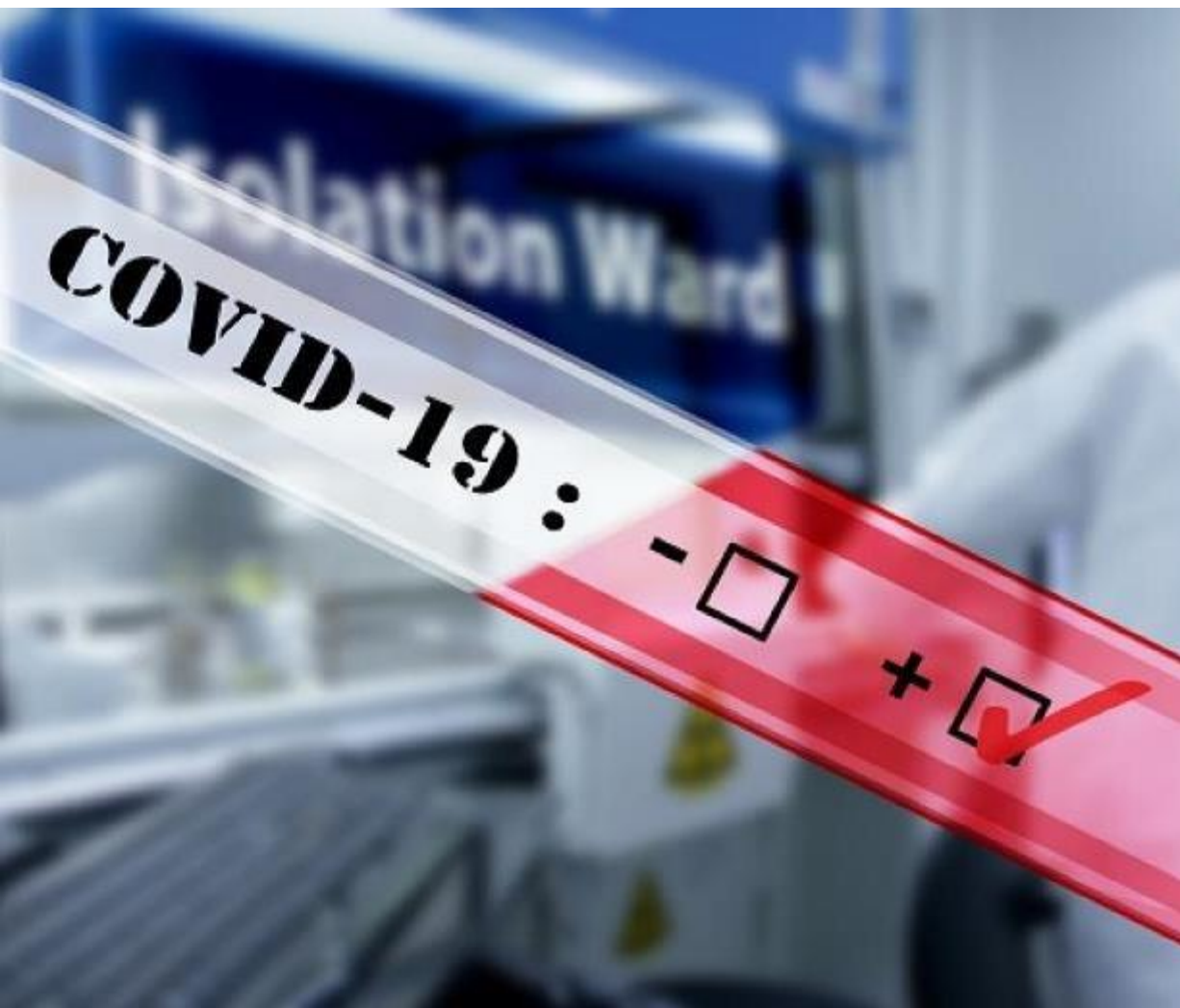


*Under the Accelerated Approval Process

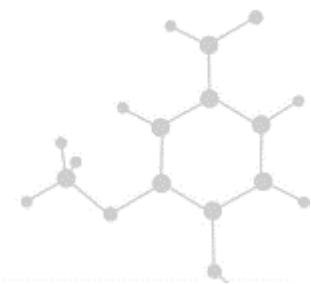
Favipiravir – Mechanism of Action

- 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.



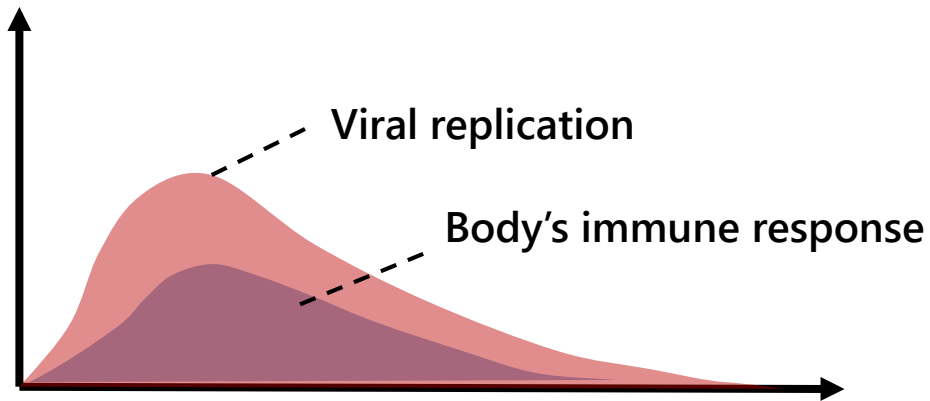


Starting early is the key...



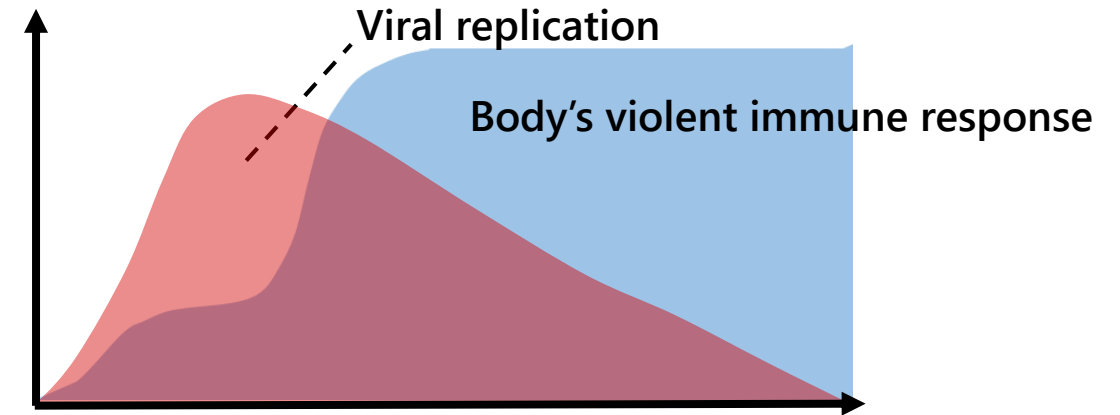
Favipiravir – Starting early is a key in COV

Early stages – Mild and Moderate

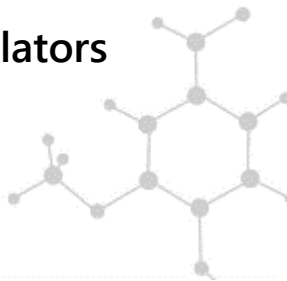


- High rate of viral replication
- Can be controlled with early use of Antiviral drugs
- Limited immune response mediated damage - Immune response subsides quickly

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



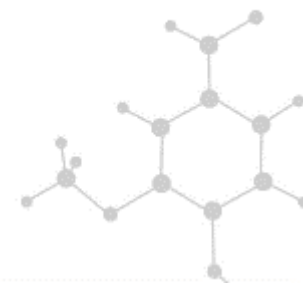
Favipiravir – Contraindications & Cautions

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.

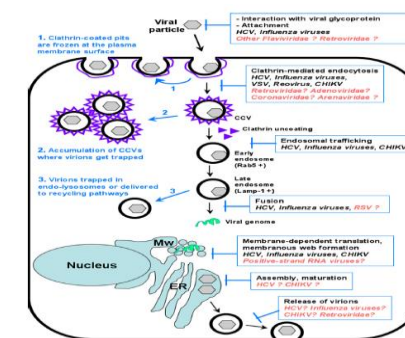
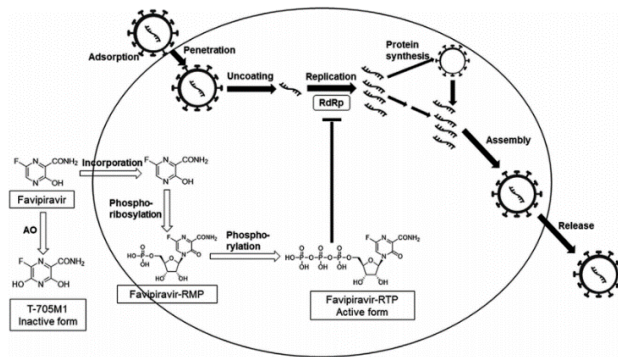
Cautions:

- 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

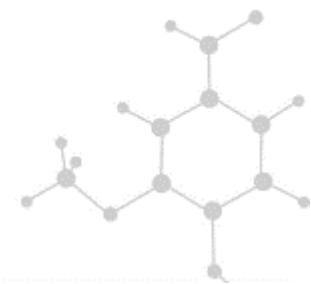
- COVID-19 patients show high viral load at time of symptom onset suggests treating with combination of antiviral drugs- highly effective and minimize the emergence of resistance.
- In line with this strategy, Glenmark proposes to combine two anti-viral drugs **Favipiravir** (Approved drug for novel 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 mg Tablets

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

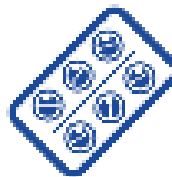
*Under the Accelerated Approval Process



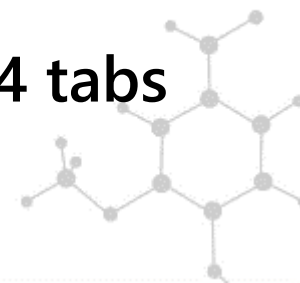
Fabiflu®
Favipiravir 200 mg Tablets



Available as a tablet of 200mg



It will be available in a strip of 34 tabs





Fabiflu®
Favipiravir 200 mg Tablets



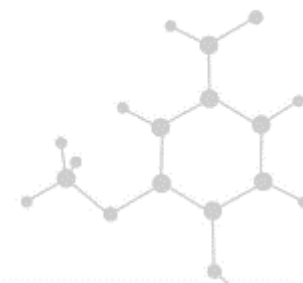
Dosage:

	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***



*Under the Accelerated Approval Process

Fabi^{flu}®

Favipiravir 200 mg Tablets



Thank you!



glenmark

A new way for a new world