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Clinical Trials to Combat Covid-19: Case Based Approach of a NSE Listed Indian Pharmaceutical Company

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ABSTRACT

Purpose

Clinical Trials to Combat Covid-19 (CTCC) case study had been developed on a National Stock Exchange (NSE) listed Indian pharmaceutical company. The main intention to develop this case study was to understand how the research and development (R&D) and innovative activities were being performed during crisis period to combat Covid-19.

Design / Methodology / Approach

The study period to develop this case was May 2020 to June 2020. Published official reports and press releases were considered for the study. Basic arithmetic and statistics had been incorporated for data driven analysis and interpretation. Microsoft Excel (most updated version) had been used for econometrics analysis and visual representation. Content Analysis Technique had been adopted to draw appropriate information, insights, and inferences. Trendline Analysis of the share price had been performed with the help of Y = mx + c regression equation with a univariate variable.

Findings

Clinical trial endeavor being rendered by the sample company subsequently made enable to obtain approval from the regulatory body Drug Controller General of India (DGCI), which impacted share price increase by 9% and this increment was supported by R Square value 1 (100%) followed by the increment value of 29.64x (where x was independent variable). There was a linear upward trend observed. It had been found that the company became 1st in India to initiate clinical trial to combat Covid-19 on two specific drugs Favipiravir and Umifenovir. The company's clinical trial study dubbed 'FAITH trial' would involve 158 hospitalized patients in India who had moderate symptoms of coronavirus infection. Leadership during the crisis period had also been observed with the dedicated activities of the R&D team of the company. At last, it had been found that the company is extremely optimistic and confident with their dedicated and painstaking efforts to provide the answer of the unknown through their innovative activities and serve the nation as well as the entire world with innovative healthcare solution to combat Covid-19 and finally the company would eagerly wait for those days to come.

Keywords: Econometrics, R&D, Drug, Jel Classification: B23, O32, L65

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INTRODUCTION

What is Covid-19?

OVID-19 is an infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. COVID-19 is now a pandemic affecting many countries globally.

Current context of Covid-19 in Indian Context

The COVID-19 pandemic in India is part of the worldwide pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first case of COVID-19

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in India, which originated from China, was reported on 30 January 2020. India's current statistics with regard to Covid-19 is mentioned in Table 1.

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Table 1: Covid 19 Statistics in Indian Context

Active Cases	Cured / Discharged	Deaths	Migrated
153106	169797	9520	1

[Source: https://www.mygov.in/covid-19]

Data extracted from COVID-19 Dashboard as on: 15 June 2020, 08:00 IST (GMT+5:30)

Symptoms of Covid-19

The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Other symptoms that are less common and may affect some patients include aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but only have very mild symptoms. Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 5 people who get COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart and lung problems, diabetes, or cancer, are at higher risk of developing a serious illness. However, anyone can catch COVID-19 and become seriously ill. People of all ages who experience fever and/or cough associated with difficulty breathing/ shortness of breath, chest pain/pressure, or loss of speech or movement should immediately seek medical attention. If possible, it is recommended to call the health care provider or facility first, so the patient can be directed to the right clinic.

Brief profile of the company Considered for Case Study (Sample Company) with respect to research and development (R&D) activities.

Mumbai, Indian based an Indian pharmaceutical company listed with National Stock Exchange (NSE) having unique identification number ISIN: INE935A01035 has become the first company in India to receive approval from DCGI to conduct clinical trials of Favipiravir antiviral tablets for the treatment of COVID-19 patients.

This Indian pharmaceutical company's research team across its R&D centres comprises of several highly qualified scientists with expertise in formulation and analytical development and discovery of NCEs (New Chemical Entities).

The Formulation R&D center based at Nashik, Maharashtra, India, is spread over 30,000 sq. ft. and is engaged in the research of specialty and branded formulations for global markets. It has a dedicated facility that is engaged in the research of HFA based MDI (Metered Dose Inhalers) products (Pressurized Metered Dose Inhalers). The center is equipped to research on a variety of dosage forms such as solid oral dosages, semi-solids, parenteral, and aerosols for various indications. The center also is engaged in the research and development of injection and Liposomal products.

Spread over 170,000 sq. ft. the R&D Centre in Taloja, on the outskirts of Mumbai, India is focused in identifying filing opportunities by doing effective product selection and patent landscaping with a vertical integration of active pharmaceutical ingredient (API). The R&D unit works in co-ordination with the Intellectual Property Management team to develop cost-effective and patent driven Generic Formulations that are bioequivalent to the original product but do not rely on any of the patents protecting the original formula.

Spread over 1,25,000 sq. ft, another R & D Center at Mahape on Mumbai's outskirts, India has end-to-end capabilities for discovery and development of new chemical entities (NCEs) from target selection to clinical development. The research facility is equipped with modern infrastructure to carry out research activities like medicinal chemistry, process and analytical chemistry, pharmacology, toxicology, and DMPK supported by project management.

LITERATURE REVIEW AND RESEARCH

A series of existing literature have been reviewed while developing this case study. None of the studies deal with the research work as proposed herewith, and an endeavor has taken to throw some light on the subject matter.

METHODOLOGY USED

The case study has been developed based on the published reports of reputed media (print, audio-visual, electronic and social media).

Case Study: Clinical Trials to Combat Covid-19

Global Context

Globally, as of 7:35 pm CEST, 15 June 2020, there have been 7,823,289 confirmed cases of COVID-19, including 431,541 deaths, reported to World Health Organization (WHO). Drugmakers across the world have been rushing to develop a treatment or vaccine for the



novel coronavirus, which has infected millions, people globally and killed lacs of people. In India, now (as of 7:35 pm CEST, 15 June 2020) among the 4th most-affected nations, the death toll reached 9520 as on 15 June 2020, 08:00 IST (GMT+5:30).

Indian Context Covid-19 Clinical Trial

Based in Mumbai, Glenmark Pharmaceuticals Limited has become the first company in India to receive approval from DCGI, the apex drug regulator body of India to conduct clinical trials of Favipiravir antiviral tablets for the treatment of COVID-19 patients. Glenmark Pharmaceuticals has received approval from the DCGI to evaluate antiviral drug favipiravir in clinical trials to treat patients with Covid-19. The company has obtained nod in very recent time (April 2020 as far as the company's press release statement dated 30 April 2020 is concerned) to conduct Favipiravir trials on COVID-19 patients.

Clinical Trial Protocol

As per the clinical trial protocol approved by DGCI, 150 subjects with mild to moderate COVID-19 will be randomized in the study in a 1:1 ratio to Favipiravir with standard supportive care or standalone standard supportive care. Treatment duration is a maximum of 14 days (2 weeks), and the total study duration will be a maximum of 28 days from randomization. The company estimates that the study would be completed by August 2020.

A highlight of the clinical trial is mentioned below.

- The company approval from the Indian regulator to initiate the clinical trial.
- The combination trial would enroll 158 hospitalized COVID-19 patients in India



- Antiviral with different mechanisms of action could complement and enhance efficacy against COVID-19
- The study dubbed 'FAITH trial' would involve 158 hospitalised patients who have moderate symptoms of corona virus infection.
- Clinical trials had commenced and over 10 leading government and private hospitals in India were being enrolled for the study.
- The company has developed the API (active pharmaceutical ingredients) and the product's formulations through its in-house and indigenous research and development team.

About the Generic-Favipiravir, Brand- Avigan

Favipiravir is made under the brand name *Avigan* by Japan's Fujifilm Holdings Corp, a subsidiary of Fujifilm Corporation and was approved for use as an anti-flu drug there in 2014, while Umifenovir is licensed as a treatment for some types of flu infections in Russia and China. Fujifilm would continue research on Avigan into June 2020, effectively dashing hopes that the drug would be approved as a COVID-19 treatment by the regulatory bodies (Figure 1).

Early administration of a combination of antiviral medications acting by different mechanisms is desirable for the treatment of COVID-19 since the viral load of SARS-CoV-2 peaks around the time of symptom onset. Thus, combining antiviral drugs could result in greater clinical effectiveness and could also prevent, or delay, the emergence of resistance, stated by this Indian pharmaceutical company.

Glenmark is also conducting clinical trials in India of just favipiravir as a potential COVID-19 treatment, for which it expects results by July or August 2020. Favipiravir is also undergoing trials in other countries.



Figure 1
[Source: Shutter stock]



According to the views of research and development (R&D) scientists, the two antiviral drugs have a different mechanism of action, and their combination may demonstrate improved treatment efficacy. Another Indian drugmaker - Strides Pharma - is also set to begin clinical trials of favipiravir as a potential COVID-19 treatment.

Historical Background of Favipiravir and Umifenovir

The two drugs have different mechanisms of action Favipiravir is known to inhibit virus replication, thus killing the virus, while Umifenovir doesn't allow the virus to enter cells, as it impedes viral attachment and acts as a viral entry inhibitor. This results in an ideal combination for effectively tackling high viral loads in patients during the disease's early stage. Favipiravir is an oral antiviral drug approved in Japan since 2014 for treating novel or re-emerging influenza virus infections.

Favipiravir, manufactured under the brand name Avigan by a unit of Japan's Fujifilm Holdings Corp and approved for use as an anti-flu drug in the Asian island country in 2014, has been effective, with no obvious side-effects, in helping coronavirus patients recover as experienced by China. Favipiravir has demonstrated activity against influenza viruses and has been approved in Japan to treat novel influenza virus infections. Recently in the past few months, post the outbreak of COVID-19, multiple clinical trials have been initiated on COVID-19 patients in China, Japan, and the US.

Umifenovir is another oral antiviral drug licensed for the treatment and prophylaxis of influenza A and B infections in Russia and China. Umifenovir impedes the viral attachment to cells and acts as a viral entry inhibitory. Additionally, it exhibits modulatory effects on the immune system and induces interferon-production. Hence a combined use of Favipiravir and Umifenovir acting on different mechanisms offers a comprehensive antiviral cover on pre-entry and post-entry life-cycle of the SARS-CoV-2 virus. Both Favipiravir and Umifenovir inhibited virus infection in vitro5, 6, and have shown efficacy in COVID-19 clinical trials. The current Glenmark study will examine whether early administration of a

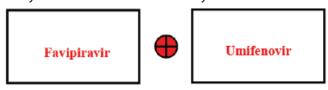


Figure 2: Clinical trial with combination therapy [Source: Author's Own]

combination of Favipiravir and Umifenovir, both acting by different mechanisms, enhances antiviral efficacy on COVID-19 patients.

Glenmark's Phase-III Trial with Favipiravir and Umifenovir

The company began phase 3 trial on a combination of two antiviral drugs, favipiravir, and umifenovir in COVID-19 patients in India. In this clinical trial, a new randomized, open-label study would be conducted to test the combined efficacy of two antiviral drugs Favipiravir and Umifenovir as a potential COVID-19 treatment strategy. The two antiviral drugs have a different mechanism of action, and their combination may demonstrate improved treatment efficacy by effectively tackling high viral loads in patients during an early stage of the disease, according to the reputed press/media reports.

As far as the statement of the company's research and development (R&D) team is concerned, combining antiviral agents that have a good safety profile and act on different and safe treatments against COVID-19 in India. Beyond its many potential patient treatment benefits. The company hopes that combination therapy will reduce infection risk amongst medical professionals and healthcare workers by reducing the duration of the virus. This endeavor of the company steps in their effort is to launch a treatment for COVID-19 patient fraternities, and they are looking at every possibility.

Impact of Clinical Trial on Share Price

With this Covid-19 clinical trial endeavor, the company's stock went up by 9%. The stock surged nearly 9 percent (%) to INR ₹ 359 posts the announcement of DGCI approval (Figure 2).

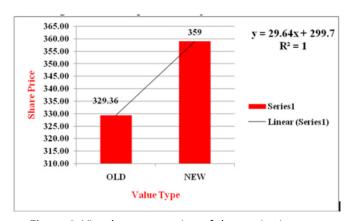


Figure 3: Visual representation of share price increase [Source: Author's Own]

Market Reuters Updated: 30 April, 2020 10:31 am IST.



X Axis = Share value type: Old (Before DGCI Approval), New (After DGCI Approval)

Y Axis= Share price of glenmark pharmaceuticals limited

From Figure 3 we can visualize the share price of Glenmark Pharmaceuticals Limited before and after the company obtained Drug Controller General of India approval for conducting clinical trial for Covid-19 drugs. We can find out from the equation that there was a share increase of INR ₹ 29.64 after the DGCI's approval. The stock surged nearly 9 percent (%) to Rs 359 post the announcement made by the DGCI. We can also find out the upward linear trend of the company's share price, and R Square value 1 supports the linearity 100% in the equation and explains the increment of a share price over time. In the later stage, we can also find out the upward share price trend of this pharmaceutical company in the National Stock Exchange (NSE) online portal and the same is presented in Figure 4 (Table 2).

Crisis Management

The coronavirus outbreak has impacted every business worldwide, and the pharmaceutical industry has been no exception. As a leading global pharmaceutical company, the sample company on which the case study is being made has remained committed to fulfilling its responsibility towards patients worldwide. Despite of the many evolving and unforeseen challenges, the company met with every day and has ensured no breaks to its medicine supply chain-both in India and the world. The company's employees at the manufacturing sites are dedicatedly working on a rotational basis to continue producing our essential medicines and products, while those in its offices and research and development centers were working from home to ensure smooth back-end business processes continue to operate to meet patient healthcare needs.

Covid-19 Clinical Trial Leadership

Glenmark Pharmaceuticals Global R&D executive vicepresident Sushrut Kulkarni said the following statements as reported and published in the reputed medias. "After having successfully developed the API and the formulations through its in-house R&D team, Glenmark is all geared to immediately begin clinical trials on favipiravir on Covid-19 patients in India (I)

"The clinical trial will let us know the efficacy of this molecule on Covid-19 patients. If the clinical trials are successful, favipiravir could become a potential treatment for Covid-19 patients."

Monika Tandon, vice-president & head, clinical development, global specialty/branded portfolio, Glenmark Pharmaceuticals Ltd., said the following statements as reported and published in different Indian and International reputed media and press releases.

"Several health and medical experts, both in and outside of Glenmark are eager to see the effect that Favipiravir has on COVID-19 cases." (I)

"We believe the study results will be significant as there is currently no effective treatment for the virus," (II)

"The data we get from these trials will point us in a clearer direction with regard to COVID-19 treatment and management" (III)

"Combining antiviral agents that have a good safety profile and act on different stages of viral life-cycle is an effective treatment approach to rapidly suppress initial high viral load and lead to overall improvement in clinical parameters. We consider Glenmark's study will be pivotal in leading to identification of highly effective

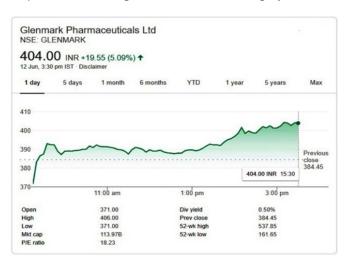


Figure 4: Share Price Trend with Clinical Trial Impact
[Source: National Stock Exchange]

**Share price extracted from NSE Database as on 12 June
2020, IST 3:30 pm.

Table 2: Trend Line Interpretation of R & D Expenditure

Model no.	Model name	Trend/ regression type	Equation	R Square
1	Glenmark Share Price	Linear	y = 29.64x + 299.7	$R^2 = 1$

[Source: Researchers own calculation in microsoft Excel]



and safe treatments against COVID-19 in India. Beyond its many potential patient treatment benefits, we also hope the combination therapy will reduce infection risk amongst medical professionals and healthcare workers by reducing the duration of virus shedding from treated patients." (IV)

"We consider Glenmark's study will be pivotal in leading to identification of highly effective and safe treatments against COVID-19 in India. Beyond its many potential patient treatment benefits, we also hope the combination therapy will reduce infection risk amongst medical professionals and healthcare workers by reducing the duration of virus shedding from treated patients (V)

"This is another step in our effort is to launch a treatment for COVID-19 patients and we are looking at every possibility. We will do all it takes to ensure accessibility of the product across the country if the clinical trials are successful." (VI)

"Favipiravir has demonstrated activity against influenza viruses and has been approved in Japan for the treatment of novel influenza virus infections. The molecule, if commercialised, will be marketed under the brand name 'FabiFlu' in India" (VII)

On the other hand Sujesh Vasudevan, president, India Formulations, Middle East and Africa, Glenmark Pharmaceuticals Ltd. said the following statements as reported and published in the different media:

"Our effort is to launch a treatment for COVID-19 patients as soon as possible and control the spread of the pandemic." (I)

"We will do all it takes to ensure accessibility of the product across the country if the clinical trials are successful." (II)

CONCLUSION-WAY FORWARD

This Indian pharmaceutical company has been rendering all possible efforts to ensure the accessibility of the product across the country as well as in the globe if the clinical trials are successful with the painstaking and dedicated efforts being rendered by the dedicated research and development in house team of knowledge based and highly skilled scientists working tirelessly to search for the answer of unknown for taking away the pain of sufferings from the pandemic Covid-19 of millions of patient fraternities not only in India by across the globe.

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