Press release **For immediate distribution**

Glenmark to commence another new Phase 3 clinical trial on a combination of two anti-viral drugs Favipiravir and Umifenovir in hospitalized patients of moderate COVID-19 in India

- *Glenmark received approval from the Indian regulator to initiate the study*
- *The combination study which will be called the **FAITH** trial will look to enroll 158 hospitalized patients of moderate COVID-19 in India*
- *Early treatment with combination therapy will be evaluated for safety and efficacy as it is emerging as an effective approach in shortening duration of virus shedding, decreasing cytokine response, and facilitating early discharge of patients[1]*
- *Antivirals with different mechanisms of action could complement and enhance efficacy against COVID-19*
- ***Glenmark also continues its Phase 3 clinical trials on antiviral Favipiravir monotherapy for COVID-19 patients in India***

Mumbai, India; May 26, 2020: Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, has announced a new randomized, open-label study to test the combined efficacy of two antiviral drugs Favipiravir and Umifenovir as a potential COVID-19 treatment strategy. The two antiviral drugs have different mechanism of action, and their combination may demonstrate improved treatment efficacy by effectively tackling high viral loads in patients during early stage of disease.

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.[2] Thus combining antiviral drugs could result in greater clinical effectiveness and could also prevent, or delay, the emergence of resistance. Favipiravir is an oral antiviral drug approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections.[3] It has a unique mechanism of action by which it inhibits viral replication: it is converted into an active phosphoribosylated form (favipiravir-RTP) in cells and recognized as a substrate by viral RNA polymerase, thereby inhibiting RNA polymerase activity that is required for viral replication.[4] Umifenovir is another oral antiviral drug licensed for the treatment and prophylaxis of influenza A and B infections in Russia and China.[5] Umifenovir impedes the viral attachment to cells and acts as a viral entry inhibitor.[5] 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 vitro[5,6] and have shown efficacy in COVID-19 clinical trials. The current Glenmark study will examine whether early administration of a combination of Favipiravir and Umifenovir, both acting by different mechanisms, enhances antiviral efficacy on COVID-19 patients.

Commenting on this development, Dr. Monika Tandon, Vice President & Head, Clinical Development Global Specialty/Branded Portfolio, Glenmark Pharmaceuticals Ltd., said, "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 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."

Further, Mr. Sujesh Vasudevan, President, India Formulations, Middle East and Africa business, Glenmark Pharmaceuticals Ltd. mentioned "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."

The new combination clinical trial will be called **FAITH** – (**FA** vipiravir plus Um **I** fenovir (efficacy & safety) **T** rial in Indian **H** ospital setting). 158 hospitalized patients of moderate COVID-19 infection will be enrolled in the combination study and randomized in two groups: one group receiving Favipiravir and Umifenovir (with standard supportive care); and one group receiving Favipiravir along with standard supportive care. Patients in the arm receiving the drug will receive Faviprivir 1800mg bid and Umifenovir 800 mg bid on Day 1. Thereafter patients would receive Faviprivir 800mg bid and Unifenovir 800mg bid for the remaining course of the treatment. Duration of treatment will be 14 days and patients will be discharged after clinical cure and two consecutive negative tests for COVID-19 based on RT-PCR.

Simultaneously Glenmark is also conducting phase 3 clinical trials of Favipiravir as a COVID-19 monotherapy option with 150 patients, enrolled from 9 leading government and private hospitals across the country. So far 30 patients have been randomised. The monotherapy phase 3 clinical trial results are expected by July/August 2020. Glenmark was the first pharmaceutical

company to receive approval from drug regulator DCGI to conduct Favipiravir clinical trials against COVID-19 in India.

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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

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