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Sun Pharma receives approval from DCGI to initiate clinical trial with Nafamostat in Covid-19 patients

- Nafamostat identified as a potential candidate for Covid-19 patients by scientists at University of Tokyo and Leibniz Institute for Primate Research, Germany

Mumbai, India, May 29, 2020: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) has announced that it has received approval from the Drugs Controller General of India (DCGI) to initiate a clinical trial with Nafamostat Mesilate in Covid-19 patients. Nafamostat is approved in Japan for improvement of acute symptoms of pancreatitis and treatment of Disseminated Intravascular Coagulation (DIC).

A group of scientists from the University of Tokyo, Japan and Leibniz Institute for Primate Research, Germany have recently demonstrated that Nafamostat, at very low concentrations, suppresses a protein (TMPRSS2) that the Covid-19 virus uses to enter human lung cells^{1,2}. Another group from Institut Pasteur, South Korea, also published data comparing antiviral efficacy of 24 drugs and Nafamostat, against SARS-CoV-2 in *in-vitro* studies in human lung epithelial derived cells. In this research, Nafamostat was found to be the most potent drug and was able to inhibit virus entry at very low concentrations, consistent with findings from Japan and German labs³.

Globally, there are three clinical trials currently underway to test Nafamostat in Covid-19 patients. These trials are being led by the University of Tokyo Hospital, Japan; Gyeongsang National University Hospital (South Korea); and a collaborative trial by University Hospital, Padova, Italy, University of Zurich, Switzerland and Yokohama City University, Japan (RACONA study).

Dilip Shanghvi, Managing Director, Sun Pharma said, "Sun Pharma is constantly evaluating potential targets that can be explored for treating Covid-19 patients. Nafamostat has shown promising data against SARS-CoV-2 virus in *in vitro* studies conducted by three independent groups of scientists in Europe, Japan and South Korea. We believe it holds promise in the treatment of COVID-19 patients."

Considering the pandemic situation and urgent need for newer treatment options, Sun Pharma plans to initiate the clinical trials at the earliest. The company has initiated manufacturing of both, the API and the finished product of Nafamostat in India, using technology from its subsidiary, Pola Pharma Japan.

References:

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2. Yamamoto Me et al. BioRxiv preprint April 23, 2020: <https://doi.org/10.1101/2020.04.22.054981>
3. Ko M et al. May 12, 2020, bioRxiv preprint <https://doi.org/10.1101/2020.05.12.090035>

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Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

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