

Sun Pharma initiates Ph II trial on AQCH for COVID-19 treatment

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First phytopharmaceutical drug approved for clinical trial by DCGI for COVID-19



Sun Pharmaceutical Industries Ltd. has announced that it has commenced Phase II clinical trial on AQCH, a phytopharmaceutical (plant derived) drug for treatment of COVID-19. The Company received approval from the Drugs Controller General of India (DCGI) for conducting Phase II clinical trial in April this year.

The clinical trial will be conducted across 12 centers in India in 210 patients. The treatment duration for patients will be 10 days. The results of the clinical trial are expected by October 2020. Human safety study of AQCH has already been completed and the drug has been found safe at the recommended dose for Phase II study.

Dilip Shanghvi, Managing Director, Sun Pharma said, "This is the first phytopharmaceutical drug approved for clinical trials by the DCGI as a potential treatment for COVID-19. AQCH has shown anti-SARS-CoV-2 effects in in-vitro studies conducted in collaboration with ICGEB, Italy. These results combined with information on mechanism of action through in-vitro and small animal studies give us the confidence to evaluate this potential treatment option for COVID-19 patients."

AQCH, which is being developed for dengue, has shown broad antiviral effect in in vitro studies and hence is being tested as a potential treatment option for COVID-19. Since 2016, Sun Pharma has been working very closely with DBT-ICGEB, under the leadership of Dr. Navin Khanna and CSIR-IIIM, under the leadership of Dr. Ram Vishwakarma, to develop a phytopharmaceutical drug for dengue. The work on evaluation of plant-derived drugs for the treatment of dengue started in 2007 under the auspices of the Department of Biotechnology's (DBT) Task Force on Medicinal and Aromatic Plants.

Dr. Renu Swarup, Secretary of Department of Biotechnology, Ministry of Science and Technology, stated "Our efforts to develop a safe, effective and affordable drug against dengue started about 13 years ago. The collaborating team quickly initiated studies for the development of a drug against COVID-19. I wish the collaborating team success in the conduct of the clinical trial against COVID-19 and for the development of phytopharmaceutical drugs against other infectious diseases."

Dr Shekhar C Mande, Director General, CSIR commented that "CSIR has had a long-standing association with the pharmaceutical industry in India and welcomes this collaboration with Sun Pharma in taking forward AQCH into clinical trials

for COVID-19 patients. This collaboration aligns with our scientific rationale for the quickest way to develop drugs against SARS-CoV-2”.