Dengue drug enters Phase II clinical trial for COVID-19

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New Delhi, 05 Jun (India Science Wire): Sun Pharma 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 research is being done in association with the Council of Scientific and Industrial Research (CSIR) and Department of Biotechnology (DBT).

The clinical trial will be conducted across 12 centres in 210 patients located in Delhi, Mumbai, Ahmedabad, and other places spread across the country. 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.

Since 2016, Sun Pharma has been working closely with DBT-International Centre for Genetic Engineering and Biotechnology (ICGEB), under the leadership of Dr. Navin Khanna, and CSIR-Indian Institute of Integrative Medicine (IIIM), Jammu, under the leadership of Dr. Ram Vishwakarma, to develop a phytopharmaceutical drug for dengue.

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."

"Preclinical development and IND enabling (Investigational New Drug Application) studies have been done by IIIM Jammu. After that, Sun Pharma carried out IND submission and clinical trial work. This is a perfect example of synergy among public institutions, R&D organisations, and private companies," said Dr Ram Vishwakarma, Director, IIIM Jammu, while speaking with *India Science Wire*.

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.

The work on evaluation of plant-derived drugs for the treatment of dengue started in 2007 under the auspices of the DBT Task Force on Medicinal and Aromatic Plants.

Dr. Renu Swarup, Secretary, DBT, 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". (India Science Wire)

Keywords: Phase II trials, AQCH, COVID_19, Sun Pharma, CSIR-IIIIM, DBT-ICGEB