

CSIR India and Laxai Life Sciences initiate clinical trials of promising repurposed drug Niclosamide for treatment of Covid-19

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CSIR in collaboration with Laxai Life Sciences Pvt. Ltd., has initiated Phase-II clinical trial with anti-helminthic drug Niclosamide for treatment of Covid-19. The trial is a multi-centric, phase-II, randomized, open label clinical study to evaluate efficacy, safety and tolerability of Niclosamide for the treatment of hospitalized Covid-19 patients. Niclosamide has been extensively used in past for treatment of tapeworm's infection in adults as well as children. The safety profile of this drug has been tested over time and has been found safe for human consumption at different dose levels.

Dr Shekhar C Mande, Director General, CSIR expressed his happiness over the SEC recommendations to conduct this Phase II clinical trial using Niclosamide, which is generic, affordable drug and easily available in India and therefore can be made available to our population. Dr Ram Vishwakarma, Advisor to DG-CSIR pointed out that

a) in a screen to identify drugs that can inhibit syncytia formation, Niclosamide was identified as a promising repurposed drug by research group from King's College, London, who collaborated in this project. The syncytia or fused cells observed in the lungs of patients with COVID-19 probably results from the fusogenic activity of the SARS-CoV-2 spike protein and Niclosamide can inhibit syncytia formation.

b) Independently, collaborative research between CSIR-IIIM, Jammu and NCBS, Bangalore has recently demonstrated that Niclosamide is also a potential SARS-CoV2 entry inhibitor blocking the viral entry through pH dependent endocytic pathway. Given these two independent experimental studies, Niclosamide has now emerged as a promising drug candidate for clinical trial in Covid-19 patients.

Dr Srivari Chandrashekhar, Director CSIR-IICT Hyderabad, highlighted that the Active Pharmaceutical Ingredient (API) is being made by Laxai Life Sciences based on improved technology developed at IICT and the lab is a partner in this important clinical trial which could provide cost effective therapeutic options for patients if trial is successful.

Dr Ram Upadhayaya, CEO, Laxai informed, that realizing the potential of Niclosamide, efforts were initiated last year itself to undertake clinical trials. Having received approval from drug regulator, the clinical trial has been initiated this week at different sites and is expected that the trial will be completed within 8-12 weeks. Based on successful clinical evidence generated during clinical trials in Indian studies, emergency use authorization may be sought so that more treatment options are available to COVID-19 patients.

SS/RP/ (CSIR)

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