Anti-COVID drug ‘Colchicine’ cleared for phase 2 clinical trials

New Delhi, June 16 (India Science Wire): Council of Scientific & Industrial Research (CSIR), and Laxai Life Sciences Pvt. Ltd., Hyderabad, have been given the regulatory approval by the Drugs Controller General of India (DCGI) to undertake a two-arm phase-II clinical trial to assess the safety and efficacy of the drug Colchicine in the improvement of clinical outcomes during the treatment of COVID-19 patients. The partner CSIR institutes in this important clinical trial are the CSIR-Indian Institute of Chemical Technology (IICT), Hyderabad and CSIR-Indian Institute of Integrative Medicine (IIIM), Jammu.

Dr Shekhar C Mande, Director General of CSIR, expressed his happiness on the approval granted to conduct the clinical trial on this approved drug, used for treating gout and related inflammatory conditions.

Dr Ram Vishwakarma, advisor to DG-CSIR highlighted that colchicine in combination with standard of care will be an important therapeutic intervention for COVID patients with cardiac co-morbidities and also for reducing pro-inflammatory cytokines, leading to faster recovery. Several global studies have confirmed now that cardiac complications during the course of COVID-19 infections and post-COVID syndrome are leading to the loss of many lives, and it is essential to look for new or repurposed drugs.

“We are looking forward to the outcome of this Phase II clinical efficacy trial on Colchicine, which may lead to life-saving intervention in the management of hospitalized patients. Since, India is one of the largest producers of this key drug, and if successful, it will be made available to the patients at an affordable cost”, said Dr. S. Chandrasekhar Director CSIR-IICT, Hyderabad, and Dr. DS Reddy, Director, CSIR-IIIM, Jammu.

Dr Ram Upadhayay, CEO, Laxai Life Sciences, informed, that the enrollment of patients has already begun at multiple sites across India and the trial is likely to be completed in the next 8-10 weeks. He further added that this drug can be made available to a large population of India based on the results of this trial and regulatory approval.

Recent clinical studies have reported in leading medical journals about colchicine being associated with a significant reduction in the rates of recurrent pericarditis, post-pericardiotomy syndrome, and peri-procedural atrial fibrillation following cardiac surgery and atrial fibrillation ablation, CSIR statement said.

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Health checks in India (Photo: Gwydion M. Williams)