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Serum Institute announces first-in-human trial of COVI-VAC

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With the Phase 1 trial now initiated, Codagenix and Serum Institute of India expect to begin advanced clinicaltesting in mid-2021.

US-based Codagenix and Serum Institute of India Pvt. Ltd. have announced that a Phase 1 clinical trial of COVI-VAC received regulatory approval by the Medicines and Healthcare Products Regulatory Agency (MHRA) and has commenced in London, UK. COVI-VAC is a single-dose intranasal, live attenuated vaccine against SARS-CoV-2, the virus that causes COVID-19, that was shown to be safe and efficacious in preclinical animal studies.

COVI-VAC was developed with Codagenix's Synthetic Attenuated Virus Engineering (*SAVE*) platform that uses synthetic biology to re-code the genes of viruses into safe and stable vaccines. COVI-VAC is designed to deliver a safe, live attenuated version of SARS-CoV-2 that may induce a more robust immune response and long-lasting cellular immunity against SARS-CoV-2 compared to other vaccines against the virus.

COVI-VAC has the potential to address several key logistical challenges to immunization against SARS-CoV-2 at a global scale. As a single-dose, intranasally-delivered vaccine, COVI-VAC will not require a needle and syringe, nor ultra-low temperature freezers. COVI-VAC can be manufactured at large scale and supports ease of administration in a mass vaccination campaign.

The Phase 1 trial of COVI-VAC is designed as a randomized, double-blind, placebo-controlled, dose-escalation study to evaluate the safety and tolerability of a single dose of COVI-VAC administered by nose drops. The secondary objective of the study is to evaluate immunogenicity, or the vaccine's ability to provoke an immune response, measured as neutralizing antibody, mucosal IgA and cellular immune responses. The trial will be conducted by hVIVO in London, UK, a subsidiary of Open Orphan. Patient recruitment has begun and dosing of the first trial participants will commence in the first week of January 2021.

With the Phase 1 trial now initiated, Codagenix and Serum Institute of India expect to begin advanced clinical testing in mid-2021.

"We at SIIPL are pleased with the MHRA approval for initiating the first-in-human clinical trial for the novel intranasal product against COVID-19, developed by Codagenix in collaboration with SIIPL. The product is promising with many unique features and will make our fight against the virus stronger, and therefore, this news is surely welcoming," said Dr.Rajeev Dhere, Executive Director of SIIPL.