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Sanofi, GSK to conduct Ph 3 trial of COVID-19 vaccine in India

08 July 2021 | News

Phase 3 clinical trial will include more than 35,000 volunteers from several countries, including sites in the US, Asia, Africa and Latin America

Sanofi and GSK have received approval for their Phase 3 clinical study in India, to assess the safety, efficacy and immunogenicity of their adjuvanted recombinant-protein COVID-19 vaccine candidate.

The global, randomised, double-blind Phase 3 study will include more than 35,000 volunteers aged 18 and older across sites in the US, Asia, Africa, and Latin America.

As COVID-19 vaccination becomes available, study participants are encouraged to receive an approved COVID-19 vaccine during the study, if they wish to do so. As part of the study design, all participants including the control group will be offered the study vaccine as soon as it is determined to be safe and effective.

Annapurna Das, Country Head, Sanofi Pasteur India said, "India is participating in Sanofi Pasteur's pivotal Phase 3 study, and subject to subsequent approvals, we should soon begin enrollment of study participants in the country. As the virus continues to evolve, we are anticipating what will be needed in the coming months and years, and accordingly, have adapted our vaccine development programme. We believe our COVID-19 adjuvanted, recombinant vaccine can make a significant contribution to the ongoing fight against COVID-19 and are committed to initiating our clinical programme in India, at the earliest."