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Biological E to initiate Ph III trial of COVID-19 vaccine candidate

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The Phase III clinical study is to be conducted in 15 sites across India

Biological E. Limited (BE), a Hyderabad-based vaccine and pharmaceutical company, has announced that it has successfully completed the Phase I/II clinical trial of its COVID-19 subunit vaccine candidate in India and received the approval to start the Phase III clinical trial from the Central Drugs Standard Control Organization (CDSCO) - Subject Expert Committee (SEC).

BE started the Phase I/II Clinical Trial of its COVID-19 Vaccine Candidate in the second week of November 2020. Its candidate includes an antigen developed by Texas Children's Hospital Center for Vaccine Development and in-licensed from BCM Ventures, Baylor College of Medicine's integrated commercialization team, along with Dynavax Technologies Corporation's (Nasdaq: DVAX) advanced adjuvant CpG 1018™.

The Coalition for Epidemic Preparedness Innovations (CEPI) and the Biotechnology Industry Research Assistance Council (BIRAC) have provided support for the Phase I/II clinical trials and also for the upcoming Phase III trial of this vaccine candidate.

BE's Phase I/II clinical trial evaluated the safety and immunogenicity of the vaccine candidate consisting of the Receptor Binding Domain of the Spike Protein of SARS-CoV-2 at three-dose level adjuvanted with CpG 1018 plus alum, in about 360 healthy subjects in the age range of 18 to 65 years.

The vaccination schedule consisted of two doses for each study participant, administered via intramuscular injection 28 days apart. BE's novel Covid-19 vaccine was found to be safe and well tolerated and immunogenic.

The Phase III clinical study to be conducted in 15 sites across India will evaluate the Immunogenicity and Safety of Biological E's SARS-CoV-2 COVID-19 vaccine for protection against COVID-19 disease in about 1268 healthy subjects in the age range of 18 to 80 years. It is intended to be part of a larger global Phase III study.