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Biological E initiates Ph I/II trial of COVID-19 vaccine candidate

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The results of this clinical trial are expected to be available by February 2021.



Biological E Limited (BE), a Hyderabad-based vaccines and pharmaceutical company, Dynavax Technologies Corporation, US-based vaccine focused biopharmaceutical company, and Baylor College of Medicine, a health sciences university in Houston, TX, have announced that BE has initiated a Phase I/II clinical trial of its COVID-19 subunit vaccine candidate in India following approval from the Drugs Controller General of India (DGCI).

The vaccine candidate includes an antigen in-licensed from BCM Ventures, Baylor College of Medicine's integrated commercialisation team, along with Dynavax's advanced adjuvant CpG 1018.

BE's Phase I/II clinical trial will evaluate 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 levels adjuvanted with CpG 1018 plus alum, in about 360 healthy subjects in the age range of 18 to 65 years. The vaccination schedule consists of two doses for each study participant, administered via intramuscular injection 28 days apart.

The results of this clinical trial are expected to be available by February 2021.

"The transition of our vaccine candidate into human trials is an important milestone, and exemplifies a successful transfer of technology with BE, that could lead to a safe, effective and affordable vaccine," said Dr Maria Elena Bottazzi, Associate Dean, National School of Tropical Medicine, Baylor College of Medicine and Co-Director, Texas Children's Hospital Centre for Vaccine Development.

"This vaccine represents an urgent biotechnology innovation for ensuring health equity and combating the COVID-19 pandemic," said Dr Peter Hotez, Professor, Dean, National School of Tropical Medicine, Baylor and Co-Director, Texas Children's Hospital Centre for Vaccine Development.

"We are very happy indeed to transition our potential vaccine candidate to clinical trials and offer one more potential option for the prophylaxis of COVID-19," said Mahima Datla, Managing Director, Biological E Limited.

"We are proud to contribute CpG 1018 to support development of an adjuvanted vaccine to prevent COVID-19. CpG 1018's potential to boost the immune response to produce more antibodies and longer lasting immunity may also minimise the dose of antigen needed, enabling vaccination of a greater number of people," commented Ryan Spencer, Chief Executive Officer, Dynavax.