Biological E. Limited Starts Phase I/II Clinical Trial of its COVID-19 Vaccine Candidate

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HYDERABAD, India and HOUSTON and EMERYVILLE, Calif., Nov. 16, 2020 /PRNewswire/ -- **Biological E. Limited** (BE), a Hyderabad-based vaccines and pharmaceutical company, **Dynavax Technologies Corporation (NASDAQ: DVAX)**, a US-based vaccine focused biopharmaceutical company, and **Baylor College of Medicine**, a health sciences university in Houston, TX, today 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 commercialization 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 of the National School of Tropical Medicine at Baylor College of Medicine and co-director of Texas Children's Hospital Center 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 and dean of the National School of Tropical Medicine at Baylor and co-director of Texas Children's Hospital Center 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 Ms. 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 minimize the dose of antigen needed, enabling vaccination of a greater number of people," commented Ryan Spencer, Chief Executive Officer of Dynavax.

About Biological E. Limited
Biological E. Limited (BE), a Hyderabad-based Pharmaceuticals & Biologics Company founded in 1953, is the first private sector biological products company in India and the first pharmaceutical company in Southern India. BE develops, manufactures and supplies vaccines and therapeutics. BE supplies its vaccines to over 100 countries and its therapeutic products are sold in India and the USA. BE currently has 8 WHO-prequalified vaccines in its portfolio.

In recent years, BE has embarked on new initiatives for organisational expansion such as developing generic injectable products for the regulated markets, exploring synthetic biology and metabolic engineering as a means to manufacture APIs sustainably and developing novel vaccines for the global market.

For further details, please visit www.biologicale.com and follow us on Facebook, LinkedIn and Twitter.

About Baylor College of Medicine
Baylor College of Medicine (www.bcm.edu) in Houston is recognized as a health sciences university and is known for excellence in education, research and patient care. It is the only private medical school in the greater southwest and is ranked 22nd among medical schools for research and 4th for primary care by *U.S. News & World Report*. Baylor is listed 21th among all U.S. medical schools for National Institutes of Health funding and No. 1 in Texas. The Baylor pediatrics program ranked 6th among all pediatric programs, reflecting the strong affiliation with Texas Children's Hospital where our faculty care for pediatric patients and our students and residents train. Located in the Texas Medical Center, Baylor has affiliations with seven teaching hospitals and jointly owns and operates Baylor St. Luke's Medical Center, part of CHI St. Luke's Health. Currently, Baylor has more than 3,000 trainees in medical, graduate, nurse anesthesia, physician assistant, orthotics and genetic counseling as well as residents and postdoctoral fellows. Follow Baylor College of Medicine on Facebook and Twitter.

About BCM Ventures
Baylor College of Medicine Ventures is the commercial engine of the health sciences university, created to support the translation of academic knowledge and intellectual assets for the benefit of society. We do this by engaging university innovators, entrepreneurs and industry to fully develop ideas along their best commercial path. We foster a culture of commercialization and engage with industry to identify market opportunities for collaborative ventures. To learn more about partnering with BCM Ventures and accessing our available technologies, contact bcmventures@bcm.edu.

About CpG 1018
CpG 1018 is the adjuvant used in HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 provides a well- developed technology and a significant safety database, potentially accelerating the

development and large-scale manufacturing of a COVID-19 vaccine. Upon completion of on-going scale up activities, the existing equipment capacity for CpG 1018 will be 600 million to 1.2 billion adjuvant doses annually, depending on final dose selected.

About Dynavax

Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing CpG 1018 as a premier vaccine adjuvant through global research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Dynavax Forward-Looking Statements

This press release contains "forward-looking" statements, including statements regarding the potential to develop a COVID-19 vaccine containing CpG 1018. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in vaccine research and development, including the timing of completing development, whether CpG 1018 combined with the antigen in BE's subunit vaccine candidate will prove to be beneficial in clinical trials, whether use of CpG 1018 will reduce the amount of antigen required per dose, whether and when the vaccine will be approved for use, and whether sufficient quantities of CpG 1018 and of vaccine will be able to be manufactured, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

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