Serum Institute Of India And Dynavax Announce First Participants Dosed In The Phase 1/2 Clinical Trial For A COVID-19 Vaccine

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PUNE, India and EMERYVILLE, Calif., Dec. 23, 2020 /PRNewswire/ -- Further strengthening its fight against COVID-19, Serum Institute of India (SIIPL), the world's largest vaccine manufacturer by volume, has partnered with Dynavax Technologies Corporation (Nasdaq: DVAX) a biopharmaceutical company focused on developing and commercializing novel vaccines, and today jointly announced that the first participants have been dosed in the Phase 1 part of the Phase 1/2 clinical trial evaluating SIIPL's vaccine candidate adjuvanted with CpG 1018 to prevent COVID-19.

The Phase 1/2 clinical trial will evaluate the safety and immunogenicity of SIIPL's vaccine candidate consisting of the SARS-COV-2 virus receptor binding domain (RBD) delivered as a virus-like particle (VPL), along with Dynavax's advanced adjuvant CpG 1018 plus alum. The Phase 1 portion of the clinical trial will enroll 39 healthy volunteers and post the completion of the study a decision will be taken regarding the dosing of up to 216 subjects in Phase 2.

Sharing his thoughts**,** Adar Poonawalla, Chief Executive Officer, Serum Institute of India, said*, "The collaboration with Dynavax is our effort in developing and exploring avenues to bolster our fight against the pandemic. We are hopeful that delivering the CpG 1018 adjuvant in the vaccine will enhance the immune response of the candidate. Through this we seek to provide our expertise and capability to produce large quantities of affordable vaccine to supply global needs."*

Ryan Spencer, Chief Executive Officer, Dynavax commented, *"We are pleased to be partnering with Serum Institute of India to advance their approach to leverage a VLP utilizing the receptor binding domain of the SARS-COV-2 spike protein. We believe continued development of multiple programs is critical to ensure the availability of safe and effective vaccines that can protect the global population from this devastating disease in the near term and for years to come."*

About Serum Institute of India Pvt. Ltd. (SIIPL):
Driven by the philanthropic philosophy of affordable vaccines, Serum Institute of India Pvt, Ltd. (SIIPL) is the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.5 billion doses), supplying the world's cheapest and WHO accredited vaccines to as many as 170 countries. It was founded in 1966 with the aim of manufacturing lifesaving immunobiological drugs including vaccines worldwide. With a strong commitment towards global health, the institute's objective has been proliferated by bringing down the prices of newer vaccines such as such as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines. SII is credited with bringing world-class technology to India, through its state-of-the-art equipped multifunctional production facility in Manjri, Pune; association with Zipline and government agencies to transform emergency medicine and critical care along with spearheading the race of vaccine development against the COVID-19 pandemic.

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.

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 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 Serum's antigen vaccine candidate will prove to be beneficial in clinical trials, whether use of CpG 1018 in the vaccine will enhance the immune response and help accelerate the development and large scale manufacturing of a COVID-19 vaccine, 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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