Dynavax and Serum Institute of India Announce First Participant Dosed in a Phase 1 Clinical Trial Evaluating an Improved Tdap Vaccine Adjuvanted with CpG 1018

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- Tdap vaccine adjuvanted with CpG 1018 is focused on addressing rising incidence of pertussis since the change to acellular vaccines in the 1990s

- CpG 1018 adjuvant has the potential to increase durability of the immune responses to pertussis and reduce transmission in previously vaccinated asymptomatic individuals

EMERYVILLE, Calif. and PUNE, India, Feb. 4, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, and Serum Institute of India (SIIPL), the largest vaccine manufacturer in the world by doses, today jointly announced that the first participant has been dosed in a Phase 1 clinical trial evaluating a tetanus, diphtheria, and acellular pertussis (Tdap) booster vaccine candidate adjuvanted with CpG 1018.

Dynavax and SIIPL are collaborating to develop an adjuvanted Tdap vaccine to address the shortcomings of the currently marketed acellular pertussis vaccines. Incidence of pertussis infection in the U.S. and other industrialized countries has been rising since the switch from whole cell pertussis to acellular pertussis vaccines in the 1990s. Although currently marketed acellular pertussis vaccines are effective at providing initial protection from disease, rates of pertussis continue to rise due to waning immunity over time. These vaccines may not prevent the pertussis bacteria from colonizing in the patient, potentially allowing previously vaccinated, asymptomatic individuals to spread the disease. This vaccine candidate has the potential to provide an alternative to the current booster dose given at 10 years of age and older with the goal of increasing the durability of the immune response and reducing transmission from vaccinated individuals who may still spread the disease even if they are asymptomatic.

"The development of a CpG 1018 adjuvanted Tdap vaccine is an important pipeline product for Dynavax which continues to leverage the value of CpG 1018, the adjuvant included in our FDA licensed 2-dose adult hepatitis B vaccine," commented Ryan Spencer, Chief Executive Officer of Dynavax. "With our proven adjuvant technology and SIIPL's antigen manufacturing capabilities, this program provides a unique opportunity to advance our goal of developing improved vaccines to address important unmet needs globally."

Sharing his thoughts, Mr. Adar Poonawalla, CEO, Serum Institute of India, said, "Our partnership with Dynavax is an important step towards addressing the resurgence of Pertussis. Addition of CpG 1018 adjuvant to our Tdap vaccine will ensure the development of this much needed improved Acellular pertussis-based combination vaccine to protect the children, adolescents and adults in the developed world. Even though there is a lot to be done before the vaccine is fully developed, this marks a key step towards a promising and healthy future."

The Phase 1 randomized, open label, active-controlled, dose escalation clinical trial will evaluate the safety, tolerability, and immunogenicity of the vaccine candidate, adjuvanted with CpG 1018, in healthy volunteers 10 to 22 years of age. Dynavax anticipates results from the Phase 1 study to be available in the fourth quarter of 2021.

Under the collaboration, Dynavax has exclusive world-wide rights to commercialize the vaccine, except that SII has exclusive rights to distribute in India and to fulfill WHO/UNICEF tender contracts. The parties are responsible for clinical development cost in their respective territories.

About Pertussis

Pertussis (whooping cough) is a highly contagious respiratory disease that affects the lungs, making it hard to breathe. Pertussis can affect people of all ages, and is particularly serious, even deadly, for babies less than a year old[i] Pertussis spreads from human to human by coughing, sneezing or sharing breathing space.

Reported pertussis incidence has been increasing in the United States and other industrialized countries using the acellular vaccine since the late 1980s and early 1990s, with large epidemic peaks in disease observed since the mid-2000s. A total of 48,277 US pertussis cases were reported in 2012, the largest number reported since the mid-1950s. There are likely many factors contributing to the observed increase in reported disease. These include changes in diagnostic testing, heightened recognition and reporting of pertussis cases, and molecular changes in the organism. However, waning of vaccine-induced immunity and asymptomatic transmission from vaccinated individuals is thought to play a key role in countries, including the United States, that transitioned to acellular vaccines in the 1990s. [iii]

The U.S. Centers for Disease Control (CDC) recommends the Tdap vaccine for all children 7 years and older, adolescents from 11-12 years of age, pregnant women (during the 3rd trimester) and adults who have never been received Tdap, also adults should receive a booster dose every 10 years, because they are often the source of infection for infants.[iv]

[i]CDC https://www.cdc.gov/pertussis/index.html

[iii]NCBI https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-015-0382-8

[iv]CDC https://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html

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 applied for Marketing Authorization Approval in Europe for HEPLISAV-B in December 2020 the Company received a positive opinion issued from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP). 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, Tdap and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

About Serum Institute of India Pvt. Ltd.
Serum Institute is now the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.6 billion doses). Vaccines manufactured by Serum Institute are accredited by the World Health Organization and are being used in around 170 countries across the globe in their national immunization programs, saving millions of lives throughout the world.

Serum Institute is developing biosimilars of existing antibody immunotherapies for a range of diseases, and in 2017 launched a novel monoclonal antibody against rabies.

Dynavax Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the potential to develop an improved Tdap-1018 booster vaccine and anticipated timing for results of the Phase 1 clinical trial. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent vaccine research and development, including, whether clinical trial results will support advancing the vaccine candidate, whether and when clinical trials will be completed, whether and when the Tdap-1018 booster vaccine candidate will receive regulatory approval, and if approved, whether we will successfully manufacture and commercialize the vaccine candidate, 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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