

DYNAVAX

Dynavax Announces First Participants Dosed in Phase 1 Clinical Trial Evaluating Medicago's COVID-19 Vaccine Candidate with Dynavax's CpG 1018 Adjuvant

July 14, 2020

- Medicago expects to enroll 180 healthy adult participants
- Preliminary safety and immunogenicity results are expected in October 2020
- Dynavax is providing CpG 1018, the adjuvant contained in its U.S. FDA-approved adult hepatitis B vaccine, to enhance the immune response of Medicago's COVID-19 vaccine candidate

EMERYVILLE, Calif., July 14, 2020 (GLOBE NEWSWIRE) -- [Dynavax Technologies Corporation](#) (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, announced today that the first participants have been dosed in the [Phase 1 clinical trial](#) evaluating [Medicago's](#) plant-derived vaccine candidate adjuvanted with CpG 1018 to prevent COVID-19.

The previously announced collaboration is evaluating the combination of Medicago's Coronavirus Virus-Like Particle (CoVLP) with Dynavax's CpG 1018, the adjuvant contained in Dynavax's U.S. FDA-approved adult hepatitis B vaccine. Adding CpG 1018 is intended to enhance the immune response of Medicago's COVID-19 vaccine which may reduce the amount of antigen required per dose, providing more doses to help protect a greater number of people.

"We are committed to supporting the development of an adjuvanted vaccine to prevent COVID-19," commented [Ryan Spencer](#), Chief Executive Officer of Dynavax. "CpG 1018's ability to enhance the immune response, as successfully demonstrated in HEPLISAV-B, is expected to reduce the dose of antigen needed, helping ensure broader availability to patients. Additionally, the unique mechanism of action of CpG 1018 may provide important enhancements including increased protection in populations traditionally less responsive to vaccination such as older adults who are at greatest risk for severe disease from COVID-19."

The study is a Phase 1 randomized, partially-blinded, prime-boost, staggered dose-escalation study intended to assess the safety, tolerability, and immunogenicity of the Coronavirus-Like Particle COVID-19 Vaccine at three dose levels (3.75 µg, 7.5 µg, and 15 µg VLP) unadjuvanted or adjuvanted with either CpG 1018, or another company's adjuvant, in approximately 180 healthy subjects 18 to 55 years of age, who have been tested for the absence of SARS-CoV-2 antibodies. Preliminary safety and immunogenicity results are expected in October 2020. Medicago is also planning a Phase 2/3 trial to be initiated this October.

Medicago's innovative plant-based production platform will be used to manufacture the COVID-19 vaccine antigen. This platform uses plants as mini-factories which create proteins that self-assemble into the virus-like particles that are used in the CoVLP vaccine candidate. Combining Medicago's technology with Dynavax's CpG 1018 adjuvant, the companies expect to be able to deliver up to 100 million doses by the end of 2021. By the end of 2023, Medicago expects to complete the construction of a large-scale manufacturing facility in Quebec City, Canada that Medicago anticipates will have the capacity to produce up to 1 billion vaccine doses annually.

About Vaccine Adjuvants

An adjuvant is a pharmacological or immunological agent that modifies the effect of other agents. Adjuvants are added to a vaccine to boost the immune response to produce more antibodies and longer-lasting immunity, thus reducing the dose of antigen needed. Adjuvants may also be used to enhance the efficacy of a vaccine by helping to modify the immune response by particular types of immune system cells.

About CpG 1018 Adjuvant

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. In pre-clinical and clinical studies, results demonstrated that the addition of CpG 1018 increases antibody concentrations, stimulates helper (CD4+) and cytotoxic (CD8+) T cell populations and generates robust T and B cell memory responses. Additionally, CpG 1018 strongly favors development of the Th1 subset of helper T cells, the type of helper T cell that is essential for protection from infections with viruses and intracellular bacteria. CpG 1018 targets a single, well defined receptor (TLR9) expressed on only a few key cell types and the mechanisms of action as an adjuvant are quite well understood. 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 launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also further developing CpG 1018 as an advanced vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19 and pertussis. For more information, visit www.dynavax.com and follow the company on [LinkedIn](#).

About Medicago

Medicago is a biopharmaceutical company headquartered in Quebec City with production sites in Quebec, Canada and Durham, North Carolina, USA. Medicago's mission is to improve global health outcomes by leveraging innovative plant-based technologies for rapid responses to emerging global health challenges. Medicago is committed to advancing therapeutics against life-threatening diseases worldwide. For more information please visit www.medicago.com.

About the Novel Coronavirus SARS-CoV-2 (and COVID-19 Disease)

SARS-CoV-2 is a new coronavirus identified in late 2019 which belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of the respiratory system. The virus causes a disease named COVID-19. Since this outbreak was first reported in late 2019, the virus has infected over 12.7 million people and has caused over 566,000 reported deaths (as of July 13, 2020). It has been declared a pandemic by the [World Health Organization](#) (WHO). Currently there is no vaccine available for COVID-19.

Forward-Looking Statements

This press release contains "forward-looking" statements, including statements regarding the potential to develop a COVID-19 vaccine containing CpG 1018, and to do so on an accelerated basis. 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, the timing and results of clinical trials, whether CpG 1018 is proven to be beneficial when combined with Medicago's CoVLP, whether and when the vaccine will be approved for use, and whether sufficient quantities of CpG 1018 and of vaccine timely 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.

Contacts - Dynavax

Nicole Arndt, Senior Manager, Investor Relations
narndt@dynavax.com
510-665-7264

Derek Cole, President
Investor Relations Advisory Solutions
derek.cole@IRadvisory.com

The logo for Dynavax, featuring the word "DYNVAVAX" in a stylized, multi-colored font. The letters are in various shades of green and blue.

Source: Dynavax Technologies Corporation