

# DYNAVAX

## Dynavax Announces First Participants Dosed in Phase 1 Clinical Trial Evaluating Clover Biopharmaceuticals' COVID-19 S-Trimer Vaccine Candidate with CpG 1018 Adjuvant

June 19, 2020

- Preclinical results demonstrated the ability of CpG 1018-adjuvanted SCB-2019 to elicit neutralizing antibodies in multiple animal species
- Clover expects to enroll 150 healthy adult and elderly participants in the Phase 1 study
- Preliminary safety and immunogenicity results expected in August 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 Clover's COVID-19 vaccine

EMERYVILLE, Calif., June 19, 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 to evaluate [Clover Biopharmaceuticals'](#) vaccine candidate to prevent COVID-19 that contains the Company's [CpG 1018 adjuvant](#).

In this previously announced collaboration, Clover is advancing its COVID-19 S-Trimer vaccine (SCB-2019), which is based on Clover's proprietary [Trimer-Tag<sup>®</sup>](#) vaccine technology platform, while Dynavax is providing the Company's proprietary toll-like receptor 9 (TLR9) agonist adjuvant, CpG 1018.

"We are proud to contribute CpG 1018 to this global effort to rapidly develop 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, an adjuvanted vaccine may be especially important for older adults and people with chronic conditions who are traditionally less responsive to vaccination and have the greatest risk of severe disease and death from COVID-19."

The study is a Phase 1 randomized, double blind, placebo controlled, first-in-human (FIH) study to assess safety, reactogenicity, and immunogenicity of SCB-2019 at multiple dose levels, administered as 2 intramuscular (IM) injections in approximately 90 adult healthy subjects 18 to 54 years of age and approximately 60 elderly healthy subjects 55 to 75 years of age. The trial and Clover's COVID-19 vaccine program are being supported by funding and collaboration with the [Coalition for Epidemic Preparedness Innovations \(CEPI\)](#).

The Phase 1 study will evaluate SCB-2019 alone, SCB-2019 in combination with Dynavax's CpG 1018 adjuvant combined with alum, and SCB-2019 in combination with a different adjuvant. Based on preclinical results demonstrating the ability of CpG 1018-adjuvanted SCB-2019 to elicit neutralizing antibodies in multiple animal species, the collaboration has been expanded to include clinical supply of CpG 1018 to Clover. Preliminary safety and immunogenicity results of the study are expected in August 2020.

### **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 8.2 million people and has caused over 445,000 reported deaths (as of June 18, 2020). It has been declared a pandemic by the [World Health Organization](#) (WHO). Currently there is no vaccine available for COVID-19.

### **About COVID-19 S-Trimer Vaccine**

Utilizing Trimer-Tag<sup>®</sup> technology, S-Trimer is a trimeric SARS-CoV-2 spike (S)-protein subunit vaccine candidate. Similar to other enveloped RNA viruses such as HIV, RSV and Influenza, SARS-CoV-2 is also an RNA virus that has a trimeric spike (S) protein on its viral envelope. The trimeric S protein of SARS-CoV-2 is responsible for binding to host cell surface receptor ACE2 and subsequent viral entry, making it the primary target antigen for vaccine development. S-Trimer resembles the native trimeric viral spike protein and is produced via a rapid mammalian cell-culture based expression system.

### **About Clover Biopharmaceuticals**

China based Clover Biopharmaceuticals is a global, clinical-stage, research-based biotechnology company focused on discovering, developing and commercializing transformative biologic therapies, with a focus on oncology and autoimmune diseases, as well as viral vaccines. Having raised more than US\$ 200 million in total capital since 2016, Clover is utilizing its proprietary Trimer-Tag<sup>®</sup> technology platform to develop novel biologics targeting trimerization-dependent pathways. Additionally, Clover is leveraging its in-house cGMP biomanufacturing capabilities to develop select biosimilars. For more information, please visit: [www.cloverbiopharma.com](http://www.cloverbiopharma.com).

### **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 minimizing 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<sup>®</sup>](#) [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 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](http://www.dynavax.com) and follow the company on [LinkedIn](#).

#### **Forward-Looking Statements**

This press release contains "forward-looking" statements, including statements regarding the potential to develop a COVID-19 vaccine 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, when clinical trial results will be obtained and what they will demonstrate, whether and when the vaccine will be approved for use, and whether the Company will be able to manufacture sufficient quantities of CpG 1018 to meet demand, 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 (SEC). 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](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

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Source: Dynavax Technologies Corporation