

DYNAVAX

Clover Biopharmaceuticals and Dynavax Announce First Participants Dosed in SPECTRA, a Global Phase 2/3 Clinical Trial for Adjuvanted S-Trimer COVID-19 Vaccine Candidate

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- Over 22,000 participants aged 18 years or older are expected to be enrolled in SPECTRA across Latin America, Asia, Europe and Africa
- Interim analysis of the primary endpoint expected in the middle of 2021

CHENGDU, China and EMERYVILLE, Calif., March 24, 2021 /PRNewswire/ -- [Clover Biopharmaceuticals \(Clover\)](#), a global clinical-stage biotechnology company developing transformative biologics such as vaccines and therapeutics for the world's most debilitating diseases, and [Dynavax Technologies Corporation](#) (Dynavax, Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced the first participants have been dosed in Clover's SPECTRA trial (Study Evaluating Protective-Efficacy and Safety of Clover's Trimeric Recombinant Protein-based and Adjuvanted COVID-19 Vaccine), a global Phase 2/3 clinical trial evaluating the efficacy, safety and immunogenicity of Clover's protein-based S-Trimer COVID-19 vaccine candidate adjuvanted with Dynavax's CpG 1018 plus alum.

The global Phase 2/3 trial is a double-blind, randomized, controlled study of the adjuvanted S-Trimer COVID-19 vaccine candidate in a two-dose regimen, given 21 days apart. The study is expected to enroll over 22,000 adult and elderly participants at multiple sites across Latin America, Asia, Europe and Africa. An independent external Data Safety Monitoring Board (DSMB) will provide safety oversight throughout the program by regular review of available efficacy and safety data. An interim analysis of the primary endpoint is expected in the middle of 2021, depending on trial enrollment and occurrence of COVID-19 cases in the study.

Joshua Liang, Chief Executive Officer of Clover Biopharmaceuticals, said, "Dosing the first participants in SPECTRA marks another significant milestone in our journey to develop a COVID-19 vaccine. There is still a significant need in many global communities for COVID-19 vaccines and should the Phase 2/3 interim analysis be favorable, we will work closely with regulatory authorities worldwide to make our S-Trimer COVID-19 vaccine candidate available as soon as possible."

[Ryan Spencer](#), Chief Executive Officer of Dynavax, commented, "We are excited to see the first participants dosed in SPECTRA, providing an opportunity for Clover's protein subunit vaccine candidate adjuvanted with CpG 1018 to demonstrate safety and efficacy. Clover's adjuvanted vaccine candidate has the potential to be an important additional solution to address worldwide demand since it can be manufactured at large scale and stored at standard refrigeration temperature. We are proud to be collaborating with Clover on the development of this vaccine for COVID-19 and committed to supporting Clover in making the vaccine available globally."

SPECTRA is fully funded by the [Coalition for Epidemic Preparedness Innovations](#) (CEPI). Through this collaboration, hundreds of millions of adjuvanted S-Trimer vaccine doses will potentially be made available for procurement and allocation through the [COVAX Facility](#) to protect the most at-risk populations in participating countries.

Dr. Richard Hatchett, Chief Executive Officer of CEPI commented: "This is an important step forward in the development of Clover's promising vaccine candidate, which could give us a much-needed additional tool to help control the spread of COVID-19. If the vaccine is proven to be safe and effective, we hope to make hundreds of millions of doses globally accessible through COVAX."

In December 2020, Clover reported positive clinical data from its Phase 1 trial demonstrating that its protein-based COVID-19 S-Trimer vaccine candidate in combination with Dynavax's CpG 1018 induces strong immune response, including neutralizing antibodies and cell-mediated immunity, as well as favorable safety and tolerability profiles in the adult and elderly participants. The vaccine candidate is expected to be stable long term under standard refrigeration conditions and has demonstrated stability at room temperature for at least two months, making it suitable for global distribution.

The Phase 1 data was shared in [The Lancet](#) in early 2021.

About S-Trimer COVID-19 Vaccine Candidate

Utilizing Clover's proprietary Trimer-Tag[®] 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. S-Trimer is intended to be adjuvanted.

About Trimer-Tag[®] Technology

Trimer-Tag[®] is an innovative drug development platform which allows the production of novel, covalently-trimerized fusion proteins. Many major disease targets are trimerization-dependent such as the tumor necrosis factor (TNF) superfamily (involved in extrinsic apoptosis, immune co-stimulation and inflammation) as well as enveloped RNA virus antigens responsible for entry into host cells. Clover is using its Trimer-Tag[®] technology with global IP position to develop recombinant trimerized fusion proteins that are able to effectively target these previously undruggable pathways.

About Clover Biopharmaceuticals

Clover Biopharmaceuticals is a global clinical-stage biotechnology company developing transformative biologics as vaccines and therapeutics for the

world's most debilitating diseases. By leveraging its proprietary Trimer-Tag® platform, Clover has developed a protein-based COVID-19 vaccine candidate. Clover expects to utilize its in-house cGMP biomanufacturing capabilities to potentially produce and broadly distribute hundreds of millions of COVID-19 vaccine doses annually to those who need it most around the globe. Clover's lead oncology asset, SCB-313, is in multiple ongoing Phase I clinical trials in Australia and China. Clover expects to advance multiple new pipeline products to the clinic and continues to discover, develop and deliver innovative and affordable medical solutions to improve the quality of life and wellbeing of patients around the world. Clover has corporate offices in Chengdu, Changxing, Shanghai and Beijing in China and expects to open a U.S. headquarters in Boston in the first half of 2021. Since 2020, Clover has raised more than USD \$400 million and has built strong partnerships with internationally renowned healthcare organizations. For more information, please visit our website: www.cloverbiopharma.com and follow the company on [LinkedIn](#).

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) and the European Commission. 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. and Europe 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](#).

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics. CEPI has moved with great urgency and in coordination with WHO in response to the emergence of COVID-19. CEPI has initiated 11 partnerships to develop vaccines against the novel coronavirus. The programmes are leveraging rapid response platforms already supported by CEPI as well as new partnerships.

Before the emergence of COVID-19, CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).

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 initiating clinical trials and completing development, whether CpG 1018 plus aluminum combined with Clover's protein subunit vaccine will prove to be beneficial in clinical trials, whether and when the vaccine will be approved for use, whether CEPI will continue to fund the Clover program through development and licensure, and whether sufficient quantities of CpG 1018 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, 2020, 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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