

# DYNAVAX

## Clover and Dynavax Announce Planned Global Phase 2/3 Efficacy Trial of Adjuvanted COVID-19 Vaccine Candidate

February 1, 2021

- Clover plans to initiate a global Phase 2/3 efficacy trial of its protein-based S-Trimer COVID-19 vaccine candidate adjuvanted with Dynavax's CpG 1018 plus alum in the first half of 2021 with an interim analysis for vaccine efficacy potentially in the middle of 2021.
- The Coalition for Epidemic Preparedness Innovations (CEPI) continues to support Clover's COVID-19 vaccine candidate and will fund its development through licensure.

EMERYVILLE, Calif. and CHENGDU, China, Feb. 1, 2021 /PRNewswire/ -- [Clover Biopharmaceuticals](#) (Clover), a global clinical-stage biotechnology company committed to developing transformative biologics as vaccines and therapeutics for the world's most debilitating diseases, and [Dynavax Technologies Corporation](#) (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing vaccines, today announced the plan to initiate a global Phase 2/3 efficacy trial with the S-Trimer COVID-19 vaccine candidate adjuvanted with CpG 1018 plus alum in the first half of 2021 with an interim analysis for vaccine efficacy potentially in the middle of 2021. The Coalition for Epidemic Preparedness Innovations (CEPI) will continue to support the development of Clover's COVID-19 vaccine candidate and will fund the development, including the Phase 2/3 trial, through licensure.



In its Phase 1 clinical trial, Clover's protein-based COVID-19 S-Trimer vaccine candidates in combination with adjuvants from either Dynavax or GlaxoSmithKline plc both performed well and induced high levels of neutralizing antibodies while demonstrating favorable safety and tolerability profiles. Clover expects to produce hundreds of millions of vaccine doses in 2021 and up to 1 billion vaccine doses in peak annual production as required by global demand.

Joshua Liang, Chief Executive Officer of Clover Biopharmaceuticals, said, "Given the encouraging results of our adjuvanted S-Trimer COVID-19 vaccine candidate to-date, we are enthusiastic about progressing to a global Phase 2/3 efficacy study utilizing Dynavax's advanced adjuvant CpG 1018 plus alum. We believe this vaccine candidate could be efficacious while potentially having a differentiated, beneficial reactogenicity and safety profile which could make it attractive for a broad population of peoples. We will continue to work closely with our collaborators and regulatory authorities worldwide to help make our vaccine accessible to those most in need as quickly as possible."

Ryan Spencer, Chief Executive Officer of Dynavax, commented, "We are excited to be rapidly progressing to an efficacy trial to support filing for emergency use and approval. Clover's S-Trimer antigen adjuvanted with CpG 1018 plus alum demonstrated low reactogenicity while providing high levels of neutralizing antibodies and a strong Th1-biased cell-mediated immune response. 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."

Dr. Richard Hatchett, Chief Executive Officer of CEPI, commented: "To end the acute phase of this pandemic, and to control the virus in the longer term, the world needs multiple safe and effective vaccines which can be deployed in a range of populations and countries. Clover's vaccine candidate has the potential to be manufactured at scale and stored in a regular refrigerator which makes it suitable for use around the globe, including in low-resource settings. Through this partnership we hope to make hundreds of millions of doses of this vaccine globally accessible through COVAX, if it is proven to be safe and effective."

Clover and GSK also decided to discontinue their partnership to evaluate the S-Trimer COVID-19 vaccine candidate with GSK's pandemic adjuvant system. The companies all remain united in their missions to maximize their contributions to ending the current pandemic. All parties remain confident that their respective strategies and collaborations for COVID-19 vaccine development will be able to maximize their respective and overall impacts against the COVID-19 pandemic.

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

Utilizing Clover's proprietary 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. S-Trimer is intended to be adjuvanted.

### About Trimer-Tag<sup>®</sup> Technology

Trimer-Tag<sup>®</sup> 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<sup>®</sup> 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, 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 USD \$350 million in total capital since 2016, Clover is utilizing its proprietary Trimer-Tag® technology platform to develop novel biologics targeting trimerization-dependent pathways. Additionally, Clover is leveraging its in-house GMP biomanufacturing capabilities which is certificated by Qualified Person(QP) within the European Union(EU) to support large-scale production of its biologic therapies. For more information, please visit our website: [www.cloverbiopharma.com](http://www.cloverbiopharma.com).

### **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, to support the rapid 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 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](http://www.dynavax.com) and follow the company on [LinkedIn](#).

### **About CEPI**

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, 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, 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](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

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