COVID-19 Vaccine Developed by Clover Biopharmaceuticals Using Dynavax's CpG 1018 Adjuvant Meets Primary and Secondary Efficacy Endpoints in Global Phase 2/3 Trial

September 22, 2021

- Global Phase 2/3 SPECTRA Trial enrolled over 30,000 adult and elderly participants across 4 continents; 100% of SARS-CoV-2 strains observed in efficacy analysis were variants

- 100% efficacy against severe COVID-19 and hospitalizations, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2

- Favorable safety profile; no significant differences in systemic adverse events or severe/serious adverse events compared to placebo

- The impressive results in efficacy and tolerability reflect the beneficial profile of CpG 1018 as a valuable vaccine adjuvant

EMERYVILLE, Calif., Sept. 22, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing vaccines, today announced that Clover Biopharmaceuticals (Clover) reported positive data for their protein-based COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum) adjuvanted with Dynavax's CpG 1018 adjuvant, which achieved the primary and secondary efficacy endpoints in SPECTRA, a global pivotal Phase 2/3 clinical trial that enrolled over 30,000 participants. Vaccine efficacy was successfully demonstrated in an environment where 100% of SARS-CoV-2 strains observed in the efficacy analysis were variants.

Clover reported the following data from their Phase 2/3 SPECTRA trial in a press release issued September 22, 2021. SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19 and hospitalizations and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2. SCB-2019 (CpG 1018/Alum) demonstrated 79% overall efficacy against COVID-19 of any severity caused by the globally dominant Delta variant. Efficacy was 92% against the Gamma variant and 59% against the Mu variant, and collectively these three strains (Delta, Gamma and Mu) comprised 73% of all strains identified in the study. Overall efficacy was 67% against COVID-19 of any severity caused by any strain in the study, successfully meeting the primary endpoint of the trial. Clover's vaccine candidate is one of the first to demonstrate significant efficacy against Delta in a double-blind, randomized clinical trial.

SCB-2019 (CpG 1018/Alum) demonstrated a favorable safety profile. Severe and serious adverse events (AEs) were infrequent and balanced between vaccine and placebo groups. Solicited local AEs were mostly mild and transient cases of pain at the injection site and decreased in frequency after the second dose. Importantly, the frequency of solicited systemic AEs monitored (fatigue, headache, muscle pain, joint pain, loss of appetite, nausea, chills, fever), were similar between vaccine and placebo groups.

Ryan Spencer, Chief Executive Officer of Dynavax commented, "We are very pleased with the reported efficacy results demonstrated in the SPECTRA trial, especially considering that all cases were from variants. In addition to the positive efficacy results, the remarkable tolerability profile of the Clover vaccine adjuvanted with CpG 1018 could be a useful tool in overcoming vaccine hesitancy for more reactogenic platforms and for booster doses in the future. We believe these trial results demonstrate the value of our CpG 1018 adjuvant as part of the response to this pandemic and as a platform for the development of new and improved vaccines. We look forward to continuing to support Clover and the development of their COVID-19 vaccine, making it available to those in need around the world."

Additional data from the SPECTRA final analysis have been made available in a presentation that can be found on Clover's corporate website. Clover intends to submit the trial results for peer-reviewed publication.

Clover plans to submit conditional approval applications to global regulatory authorities including China's National Medical Products Administration, the European Medicines Agency, and the World Health Organization (WHO) in the fourth quarter of 2021. Contingent upon receiving a conditional approval, Clover plans to commence initial product launch of SCB-2019 (CpG 1018/Alum) potentially by the end of 2021. Subject to receiving Emergency Use Listing (EUL) from the WHO, Clover plans to supply up to 414 million doses of its COVID-19 vaccine candidate globally through the COVAX Facility as previously announced.

SPECTRA (Study Evaluating Protective-Efficacy and Safety of Clover's Trimeric Recombinant Protein-based and Adjuvanted COVID-19 Vaccine) is Clover's double-blind, randomized, placebo-controlled study of SCB-2019 (CpG 1018/Alum) administered in a two-dose regimen, 21 days apart. Global enrollment surpassed 30,000 participants aged 18 years or older in five countries across four continents resulting in one of the most ethnically diverse COVID-19 clinical trials conducted to date, including 49% of participants from Asia, 45% from Latin America and the remainder from Europe and Africa.

About CpG 1018 Adjuvant

CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 adjuvant 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 adjuvant as an advanced 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.

Forward-Looking Statements
This press release contains "forward-looking statements," including statements regarding expected results for an ongoing contractual relationship and expected business results. Forward-looking statements can generally be identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "intend," "will," "may," "plan," "project," "potential," "seek," "should," "think," "will," "would" and similar expressions, or they may use future dates. Forward-looking statements in this document include, without limitation, statements regarding our expectations as to outcomes relating to ongoing collaborations and contractual relationships, the timing of regulatory approvals and product launch, our ability to reallocate certain quantities of CpG 1018 to different programs and our expected financial performance. These forward-looking statements are subject to assumptions, risks and uncertainties that may change at any time, and readers are therefore cautioned that actual results could differ materially from those expressed in any forward-looking statements. Factors that could cause actual results to differ include, among other things: risks and uncertainties associated with actual results of clinical trials conducted by Clover as well as our other collaborators; whether and when Clover's vaccine will be approved for use and launched; whether sufficient quantities of CpG 1018 will be able to be manufactured; whether or how much Gavi or other commercial customers purchase from Clover; and other risks and uncertainties discussed in the Company's filings with the SEC, including the "Risk Factors" sections of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. The Company undertakes no obligation to update any forward-looking statements as a result of new information, future developments or otherwise, except as expressly required by law. All forward-looking statements in this document are qualified in their entirety by this cautionary statement.

Contacts:
Nicole Arndt, Investor Relations
narndt@dynavax.com
510-665-7264

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

View original content to download multimedia:https://www.prnewswire.com/news-releases/covid-19-vaccine-developed-by-clover-biopharmaceuticals-using-dynavaxs-cpg-1018-adjuvant-meets-primary-and-secondary-efficacy-endpoints-in-global-phase-23-trial-301382650.html

SOURCE Dynavax Technologies