Dynavax and Clover Biopharmaceuticals Announce Research Collaboration to Evaluate Coronavirus (COVID-19) Vaccine Candidate with CpG 1018 Adjuvant

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- Dynavax is providing CpG 1018, the adjuvant contained in U.S. FDA-approved HEPLISAV-B vaccine, to support the rapid development of Clover's COVID-19 vaccine
- Clover advancing evaluation of its protein-based coronavirus vaccine candidate (COVID-19 S-Trimer)

EMERYVILLE, Calif. and CHENGDU, China, March 24, 2020 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, and Clover Biopharmaceuticals, a China-based global clinical-stage biotechnology company focused on developing novel and transformative biologic therapies, today announced that they have entered into a research collaboration to develop a vaccine candidate to prevent COVID-19. Clover is advancing evaluation of its protein-based coronavirus vaccine candidate (COVID-19 S-Trimer) in preclinical studies. Dynavax is providing technical expertise and the company's proprietary toll-like receptor 9 (TLR9) agonist adjuvant, CpG 1018, to support this initiative.

In late-January 2020, upon knowing the genomic DNA sequence of the newly identified SARS-CoV-2 virus, which causes a disease named COVID-19, Clover scientists started designing the viral spike (S)-protein construct and completed its gene synthesis. Utilizing its patented Trimer-Tag® technology, Clover has produced a COVID-19 S-Trimer subunit vaccine candidate that resembles the native trimeric viral spike via a rapid mammalian cell-culture based expression system. Having one of the largest in-house, commercial-scale cGMP biomanufacturing capabilities in China, Clover could potentially rapidly scale-up and produce large-quantities of a new coronavirus vaccine.

“At Clover, we are eager to begin evaluating the combination of our S-Trimer vaccine candidate and Dynavax’s CpG 1018 adjuvant, as we believe adjuvants could play an important role in developing a successful and widely-available vaccine for this pandemic,” said Joshua Liang, Chief Strategy Officer at Clover and co-inventor of COVID-19 S-Trimer vaccine. “Leveraging our proprietary Trimer-Tag technology, S-Trimer is being rapidly developed to support global efforts in combating the current and any future coronavirus outbreaks.”

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, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine.

“Successfully responding to this public health emergency will require a collaborative approach, combining technologies and sharing data, to rapidly develop a vaccine to prevent COVID-19,” commented Ryan Spencer, Chief Executive Officer of Dynavax. “We are proud to contribute to this global effort with the goal of supporting rapid development and enabling large-scale manufacturing through the utilization of CpG 1018 which has already been successfully implemented in an approved, marketed vaccine in the U.S.”

About the Novel Coronavirus SARS-CoV-2 (and COVID-19 Disease)
SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of respiratory system. The virus, which causes a disease named COVID-19, has never before been found in humans. Since this outbreak was first reported in late-2019, the virus has infected over 334,000 people and has caused over 14,600 reported deaths (as of 23 March 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® 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$ 100 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 cGMP biomanufacturing capabilities to develop select biosimilars. For more information, please visit our website: www.cloverbiopharma.com.

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 advancing CpG 1018 as an advanced vaccine adjuvant through research collaborations and partnerships. 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 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, the results of clinical trials, and whether and when the vaccine will be approved for use, 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.

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