Clover Biopharmaceuticals Announces Positive Preclinical Data and Updates on Phase 1 Study for its Adjuvanted S-Trimer COVID-19 Vaccine Candidate

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- Preclinical data show Clover's protein-based adjuvanted COVID-19 vaccine candidate, S-Trimer, induces a strong neutralizing immune response in animalsand protects nonhuman primates from SARS-CoV-2 challenge

- Strong immune response and protection observed with adjuvant systems from GSK and Dynavax led to inclusion of both adjuvants separately into Clover's ongoing Phase 1 clinical trial of S-Trimer

- Clover's ongoing Phase 1 trial of S-Trimer COVID-19 vaccine candidate completed enrollment of 150 adult and elderly participants in dose escalation, with 200 additional subjects planned for enrollment in dose expansion

- A global Phase 2/3 efficacy clinical study of the COVID-19 S-Trimer program is planned before the end of 2020

CHENGDU, China -- (BUSINESS WIRE) -- Clover Biopharmaceuticals, a global clinical-stage biotechnology company focused on discovering and developing transformative biologic therapies and vaccines, today announced positive preclinical data demonstrating that its protein-based COVID-19 S-Trimer vaccine candidate in combination with adjuvants from either GSK (London Stock Exchange: GSK) or Dynavax (Nasdaq: DVAX) induces a strong immune response and protection against SARS-CoV-2 in animal models. The manuscript describing the results titled "S-Trimer, a COVID-19 subunit vaccine candidate, induces protective immunity in nonhuman primates" has been submitted for peer review and can be accessed on an online preprint server at bioRxiv.

Joshua Liang, Chief Executive Officer of Clover Biopharmaceuticals, said, "We are excited to share these important preclinical results showing that our S-Trimer COVID-19 vaccine candidate induces immune protection against SARS-CoV-2, and we are also pleased with the progress and preliminary data of our Phase 1 clinical trial evaluating S-Trimer. More than ever, we remain committed to developing a safe, effective and accessible COVID-19 vaccine at a scale that could contribute to the control of the pandemic globally."

Thomas Breuer, Chief Medical Officer of GSK Vaccines, commented, "We are pleased with the preclinical results that, together with the preliminary insights from the Phase 1 clinical data, underline expectations that the GSK pandemic adjuvant system combined with Clover's antigen leads to a substantial strengthening of the immune response with the promise of higher efficacy and dose sparing capabilities. Adjuvants are powerful tools in the global fight against the COVID-19 pandemic, and we are looking forward to seeing the progress of the vaccine candidate using GSK's pandemic adjuvant technology."

Rob Janssen, Chief Medical Officer of Dynavax, commented, "We are pleased with the strong preclinical results observed when Dynavax's advanced adjuvant CpG 1018 plus alum was combined with Clover's S-Trimer antigen. We are especially encouraged by the absence of measurable viral load in lung tissue as well as other clinical measures in non-human primates challenged with SARS-CoV-2, and by the Th1-polarized T cell response in rodents. These data demonstrate CpG 1018's potential to significantly increase efficacy by rapidly controlling infection. We are proud to be collaborating with Clover on the development of this vaccine for COVID-19, and are committed to supporting Clover in making the vaccine available globally."

Dr. Peng Liang, Founder and Chairman of Clover and inventor of Trimer-Tag© technology, added, "Together with an accompanying manuscript entitled 'Cryo-EM structure of S-Trimer, a subunit vaccine candidate for COVID-19' which discloses that our S-Trimer resembles the native SARS-CoV-2 spike antigen in atomic resolution, our complete preclinical studies validate Trimer-Tag© as a potential platform technology for subunit vaccine development against current and future enveloped RNA viruses."

Clover's COVID-19 S-Trimer vaccine was developed by combining the trimeric SARS-CoV-2 spike (S)-protein with the company's proprietary Trimer-Tag© technology. In preclinical studies, adjuvanted S-Trimer induced strong humoral and Th1-biased cell-mediated immune responses in mice, rats and monkeys, with levels of neutralizing antibodies at or higher than levels observed in human convalescent sera. Rhesus macaques that received the vaccine and were subsequently challenged with SARS-CoV-2 virus were protected against infection, as demonstrated by clinical observations (protection from body weight loss and increases in body temperature) and significant reduction in viral loads in lung tissues and swabs, with no signs of disease enhancement. Strong immune responses and protection were observed when the S-Trimer was administered with either GSK's pandemic adjuvant system or Dynavax's CpG 1018 adjuvant plus alum. These positive preclinical data supported the decision to progress adjuvanted vaccine candidates using both adjuvants into Clover's ongoing Phase 1 clinical study of S-Trimer in healthy adult and elderly participants.

In June 2020, Clover announced the start of a Phase 1 clinical trial. The trial is a randomized, observer-blind, placebo-controlled study to assess the safety, reactogenicity and immunogenicity of the adjuvanted COVID-19 S-Trimer vaccine at multiple dose levels. The study has completed enrollment of 150 adult and elderly participants. Preliminary results show that the vaccine is likely to be safe and well-tolerated, with high levels of neutralizing antibodies observed. Based on these preliminary results, an additional 200 participants will be enrolled in a Phase 1 dose-expansion study at the selected S-Trimer dose-level and adjuvanted with either GSK's pandemic adjuvant or Dynavax's advanced adjuvant CpG 1018 plus alum. Clover intends to initiate a global Phase 2/3 vaccine efficacy study before the end of 2020. Detailed Phase 1 data will be made available in a peer-reviewed publication in the near future. The clinical trials and Clover's COVID-19 vaccine program are being supported by funding and collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI).

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 $200 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 to support large-scale production of its biologic therapies. For more information, please visit our website: www.cloverbiopharma.com.

About COVID-19 S-Trimer Vaccine

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.

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.

Contacts

Clover Biopharmaceuticals:
Cindy Min
Vice President, Public Affairs
cindy.min@cloverbiopharma.com
+86 010-82022601

Media:
Alison Chen
LifeSci Communications
achen@lifescicomms.com
646-876-4932