



Clover Biopharmaceuticals Announces Publication of Phase 1 Clinical Trial Data for its Adjuvanted COVID-19 Vaccine Candidates in The Lancet

February 1, 2021

- *Adjuvanted S-Trimer COVID-19 vaccine candidates demonstrated favorable safety and tolerability profiles and strong neutralizing immune responses in a phase 1 trial*
- *Clover plans to initiate a global phase 2/3 trial in the first half of 2021 with an interim analysis for vaccine efficacy potentially in the middle of 2021*

CHENGDU, China, February 1, 2021 — [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, today announced that the data from its Phase 1 clinical trial evaluating the safety and immunogenicity of its protein-based adjuvanted S-Trimer COVID-19 vaccine candidates was published in the peer-reviewed journal, [The Lancet](#). With an accompanying editorial commentary entitled "[Next-generation COVID-19 vaccine: here comes the proteins](#)", the Lancet spoke highly of Clover's "S-Trimer" vaccine in safety, efficacy, scalability and stability in storage and transportation.

The phase 1 clinical trial was a randomized, double-blind and placebo-controlled study in 150 adult and elderly participants. Objectives were to assess the safety, reactogenicity and immunogenicity of different dose levels of Clover's protein-based S-Trimer vaccine candidates when combined with either Dynavax Technologies Corporation (Dynavax, Nasdaq: [DVAX](#)) advanced adjuvant CpG 1018 plus alum or GlaxoSmithKline plc (GSK, London Stock Exchange: GSK) pandemic adjuvant system. The candidate vaccines were given in two doses, three weeks apart.

The study found that Clover's adjuvanted S-Trimer COVID-19 vaccine candidates were well tolerated and safe. No serious adverse events related to the vaccine candidates studied were reported. Both vaccines induced high levels of neutralizing antibodies comparable to or exceeding levels in human convalescent sera as well as a strong Th1-biased cell-mediated immunity.

The S-Trimer vaccine candidates and adjuvants are expected to be stable long term at refrigerator temperatures (2-8 °C) and have demonstrated stability at room temperature for at least two months, making these constructs suitable for broad global distribution based on current results.

Dr. Ralf Clemens, Chairman of the Scientific Advisory Board for Clover's COVID-19 Vaccine Program said, "This phase 1 dose-finding and adjuvant justification study demonstrated the potential of Clover's adjuvanted vaccine candidates to bring added value to the global portfolio of COVID-19 vaccines. In both adults and elderly subjects, the vaccine candidates were safe and elicited cellular immune responses and high neutralizing antibody titers with a favorable ratio of neutralizing/binding antibodies. These findings give confidence that Clover's COVID-19 vaccine candidates are suitable for further clinical development."

Based on the preclinical data showing protection against SARS-CoV-2 challenge in two animal species, the positive Phase 1 clinical trial results and scale-up manufacturing considerations, Clover plans to initiate a global Phase 2/3 study to evaluate the safety and efficacy of S-Trimer COVID-19 vaccine candidate adjuvanted with Dynavax's advanced adjuvant CpG 1018 plus alum within the next few months. The Coalition for Epidemic Preparedness Innovations (CEPI) has committed to fund Clover's S-Trimer COVID-19 vaccine candidate through licensure with a total investment of up to \$328 million, a portion of which will support the global Phase 2/3 study.

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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, 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.

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.

About GlaxoSmithKline

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. GSK is the leading manufacturer of vaccines globally. For further information please visit www.gsk.com/en-gb/about-us/.

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).

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