Clover's COVID-19 Vaccine Candidate Demonstrates 79% Efficacy Against Delta in Global Phase 2/3 SPECTRA Trial Dominated by Variants of Concern and Interest

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- Trial enrolled over 30,000 adult & elderly participants across 4 continents; 100% of SARS-CoV-2 strains observed in efficacy analysis were variants (Delta was predominant strain)
- Primary and secondary efficacy endpoints were successfully met
- 100% efficacy against severe COVID-19 & hospitalization and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA
- 79% efficacy against COVID-19 of any severity caused by the globally dominant Delta variant
- Favorable safety profile; no significant differences in systemic adverse events or severe/serious adverse events compared to placebo
- First COVID-19 vaccine to demonstrate significantly reduced risk of COVID-19 disease in previously infected individuals

CHENGDU, China, and OSLO, Norway, September 22, 2021 – Clover Biopharmaceuticals, Ltd. (Clover), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutic candidates, and CEPI, the Coalition for Epidemic Preparedness Innovations, today announced that Clover's adjuvanted protein-based COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum) achieved the primary efficacy endpoint and secondary efficacy endpoints in SPECTRA, a global pivotal Phase 2/3 clinical trial. Vaccine efficacy was successfully demonstrated in an environment where 100% of SARS-CoV-2 strains observed in the efficacy analysis were variants. SCB-2019 (CpG 1018/Alum) demonstrated 79% overall efficacy against COVID-19 of any severity caused by the globally dominant Delta variant, which currently comprises over 90% of all cases worldwide. 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.

The SPECTRA clinical trial enrolled over 30,000 adult and elderly (≥18 years of age) participants at 31 sites in five countries (Philippines, Brazil, Colombia, South Africa, Belgium) across four continents, resulting in one of the most diverse COVID-19 vaccine clinical trials conducted to-date. SPECTRA was funded by CEPI as part of a up to $328 million investment to develop and enable equitable access to SCB-2019 (CpG 1018/Alum).

“SPECTRA enrolled participants during a time when the world encountered the rapid spread of increasingly transmissible SARS-CoV-2 variants and a takeover by Delta. Amidst this backdrop, we are pleased that SCB-2019 (CpG 1018/Alum) has successfully demonstrated efficacy against the globally dominant Delta strain and other concerning variants.” stated Joshua Liang, Chief Executive Officer of Clover Biopharmaceuticals, Ltd. “Based on our pioneering data, we believe that SCB-2019 (CpG 1018/Alum) could be utilized as an important tool to combat this pandemic, and we remain dedicated to expediting the availability and equitable access of our COVID-19 vaccine candidate for global distribution.”

Dr. Ralf Clemens, Chairman of Clover's Scientific Advisory Board commented: “SCB-2019 (CpG 1018/Alum) successfully demonstrated significant vaccine efficacy against COVID-19 of any severity caused by Delta and other Variants of Concern and Interest. The safety profile of this adjuvanted protein-based vaccine candidate was favorable, with no significant differences in systemic adverse events or severe/serious adverse events compared to placebo. It is also the first COVID-19 vaccine candidate in the world to demonstrate in a randomized trial significantly reduced risk of COVID-19 disease in previously infected individuals, a growing and increasingly important population as SARS-CoV-2 continues to spread worldwide. We sincerely thank all study participants, trial staff and the national regulatory authorities and ethical review committees of the countries involved that made this landmark study possible.”

Dr. Richard Hatchett, CEO of CEPI added,“This very encouraging data demonstrates the favorable safety profile of Clover's vaccine and its efficacy against multiple variants of SARS-CoV-2 – including the predominant Delta variant – so it will be a crucial addition to our weaponry in the fight against COVID-19. CEPI's significant early investments have accelerated the clinical development and manufacturing of the vaccine and will enable equitable access to hundreds of millions of doses through COVAX. As a result of CEPI's partnership with Clover, this vaccine is poised to play a significant role in protecting those most at risk from COVID-19, wherever they are in the world.”

SPECTRA is a 1:1 randomized, double-blinded, placebo-controlled Phase 2/3 trial to evaluate the efficacy, safety and immunogenicity of SCB-2019 (CpG 1018/Alum) compared to placebo. 30,128 adult and elderly subjects (≥18 years of age) were randomized and dosed with SCB-2019 (CpG 1018/Alum) or placebo administered in a two-dose regimen (21 days apart).

Efficacy Results: SPECTRA Meets Primary and Secondary Endpoints

Accrual of COVID-19 disease cases for the final efficacy analysis occurred from April 28 through August 10, 2021 – a time when the Delta variant of SARS-CoV-2 became the dominant strain globally. A total of 207 cases of PCR-confirmed symptomatic COVID-19 of any severity occurring ≥14 days after the second dose in participants without evidence of prior SARS-CoV-2 infection ("SARS-CoV-2 naïve") were adjudicated by an independent Endpoint Adjudication Committee (EAC) and included in the primary efficacy analysis.

Strain sequencing data are available for 146 of the 207 COVID-19 cases. 100% of these sequenced strains were variants, and no cases of the original SARS-CoV-2 strain were observed. The three most prevalent strains in the study comprising 73% of all sequenced cases were Delta which was

predominant and accounted for 38% (56 cases) of all sequenced strains, Mu (37 cases) and Gamma (13 cases).

Severe COVID-19, Hospitalizations, Deaths: There were no cases of hospitalization due to COVID-19 and no cases of severe COVID-19 disease caused by any strain in the vaccine group, resulting in 100% efficacy (95% CI: 42.7,100) against hospitalization due to COVID-19 and 100% efficacy (97.86% CI: 25.3,100) against severe COVID-19, meeting predefined success criteria in the protocol. All deaths due to COVID-19 (3 cases) occurred in the placebo group (none in the vaccine group).

Moderate-to-Severe COVID-19: Efficacy against moderate-to-severe COVID-19 disease was 83.7% (97.86% CI: 55.9,95.4) against any strain and 81.7% (95% CI: 35.9,96.6) against Delta.

COVID-19 of Any Severity: Overall efficacy against COVID-19 disease of any severity caused by any strain was 67.2% (95.72% CI: 54.3,76.8), successfully achieving the primary endpoint. For the 3 most prevalent strains, efficacy was 91.8% (95% CI: 44.9,99.8) against Gamma, 78.7% (95% CI: 57.3,90.4) against Delta and 58.6% (95% CI: 13.3,81.5) against Mu. SCB-2019 (CpG 1018/Alum) is the first vaccine candidate to demonstrate significant efficacy against all three of these variants. Differences in vaccine efficacy across variant strains are driven by the unique mutation profiles of each variant, which can make some strains more transmissible and/or virulent than others and may enable immune escape.

High-Risk Populations: While enrollment of elderly participants was limited due to ongoing vaccination campaigns in countries where recruitment occurred in SPECTRA, all five cases of COVID-19 in participants 65 years of age or older occurred in the placebo group (none in the vaccine group). 18% of participants randomized in SPECTRA had co-morbidities for COVID-19 (i.e. participants at high risk for severe COVID-19), and no differences in vaccine efficacy were observed in participants with or without co-morbidities for COVID-19.

Efficacy Results: Vaccine Significantly Reduces Risk of COVID-19 Disease in Previously Infected Individuals

As SARS-CoV-2 continues to spread across the world, evaluating the efficacy and safety of COVID-19 vaccines in previously infected populations has become increasingly important.

49% of all participants randomized in SPECTRA were seropositive (evidence of prior SARS-CoV-2 infection) at baseline prior to enrollment. The baseline seropositivity rate varied by country: 65% in the Philippines, 46% in Colombia, 46% in South Africa, 30% in Brazil and 13% in Belgium. 41 cases of PCR-confirmed symptomatic COVID-19 reinfections of any severity were accrued in baseline seropositive participants, of which 17 cases were caused by Delta.

Vaccination with SCB-2019 (CpG 1018/Alum) reduced the risk of symptomatic COVID-19 reinfection caused by any strain by 64.2% (95% CI: 26.5,83.8) in previously infected participants. The risk of symptomatic COVID-19 reinfection caused by Delta was reduced by 79.1% (95% CI: 25.1,96.1).

SCB-2019 (CpG 1018/Alum) is the first COVID-19 vaccine candidate to successfully demonstrate significant incremental protection against COVID-19 in previously infected individuals in a randomized clinical trial.

Safety Results: Favorable Safety Profile and No Significant Difference in Systemic AEs Compared to Placebo

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. For all solicited systemic AEs monitored (fatigue, headache, muscle pain, joint pain, loss of appetite, nausea, chills, fever), no significant differences were observed between vaccine and placebo groups.

The independent Data & Safety Monitoring Board (DSMB) has reviewed the safety data on an ongoing basis, and no safety concerns have been identified warranting a pause or modification to the trial conduct to-date.

Additional data from the SPECTRA final analysis have been made available in a presentation that can be found on Clover's corporate website. The results will also be submitted for peer-review publication.

Clover plans to make submissions for conditional approval applications to global regulatory authorities (including China NMPA, EMA and WHO) in the fourth quarter of 2021. 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.

About SPECTRA

SPECTRA (Study Evaluating Protective-Efficacy and Safety of Clover’s Trimeric Recombinant Protein-based and Adjuvanted COVID-19 Vaccine) is a 1:1 randomized, placebo-controlled, double-blinded study to evaluate the efficacy, safety and immunogenicity of SCB-2019 (CpG 1018/Alum) compared to placebo in over 30,000 participants 18 years of age and older in 31 study sites in the Philippines, Brazil, Colombia, South Africa and Belgium. Participants received SCB-2019 (CpG 1018/Alum) administered in a two-dose regimen, 21 days apart, or placebo. Efficacy and safety result are reviewed by the independent Data and Safety Monitoring Board (DSMB), and all COVID-19 cases included in the efficacy analysis were adjudicated by an independent Endpoint Adjudication Committee (EAC). The SPECTRA study is sponsored by Clover and is funded by CEPI.

About Study Endpoints

The primary endpoint for SPECTRA was prevention of PCR-confirmed symptomatic COVID-19 of any severity (mild, moderate or severe) with onset ≥14 days after the second dose in adult and elderly participants (≥18 years of age) without evidence of prior SARS-CoV-2 infection (seronegative) at baseline. The statistical success criterion was lower bound 95.72% CI >30%.

Predefined key secondary endpoints with available results included prevention of PCR-confirmed moderate-to-severe COVID-19 and severe COVID-19 with onset ≥14 days after the second dose in adult and elderly participants (≥18 years of age) without evidence of prior SARS-CoV-2 infection (seronegative) at baseline. The statistical success criterion was lower bound 97.86% CI >0%.

About SCB-2019 (CpG 1018/Alum)

SCB-2019 (CpG 1018/Alum), our COVID-19 vaccine candidate, is anticipated to potentially be one of the first protein-based COVID-19 vaccines commercialized globally through the COVAX Facility. Employing the Trimer-Tag™ technology platform, Clover developed the SCB-2019 antigen, a stabilized trimeric form of the S-protein (referred to as S-Trimer™) based on the original strain of the SARS-CoV-2 virus. We created our COVID-19 vaccine candidate by combining SCB-2019 with Dynavax's (Nasdaq: DVAX) CpG 1018 advanced adjuvant and aluminum hydroxide (alum).

About Clover Biopharmaceuticals

Clover Biopharmaceuticals is a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates. The Trimer-Tag™ technology platform is a product development platform for the creation of novel vaccines and biologic therapies. We have leveraged the Trimer-Tag™ technology platform to become a COVID-19 vaccine developer and created SCB-2019 (CpG 1018/Alum) to address the COVID-19 pandemic caused by SARS-CoV-2.

For more information, please visit our website: www.cloverbiopharma.com and follow the company on LinkedIn.

Clover Forward-looking Statements

This press release contains certain forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this [document], the words "aim," "anticipate," "believe," "could," "estimate," "expect," "going forward," "intend," "may," "might," "ought to," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. We give no assurance that these expectations and assumptions will prove to have been correct. Because forward-looking statements relate to the future, they are participant to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. We caution you therefore against placing undue reliance on any of these forward-looking statements. Any forward-looking statement made by us in this document speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. Participant to the requirements of applicable laws, rules and regulations, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines against future epidemics. Prior to COVID-19 CEPI's work focused on developing vaccines against Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus - it has over 20 vaccine candidates against these pathogens in development. CEPI has also invested in new platform technologies for rapid vaccine development against unknown pathogens (Disease X).

During the current pandemic, CEPI initiated multiple programmes to develop vaccines against SARS-CoV-2 and its variants with a focus on speed, scale, and access. These programmes leverage the rapid response platforms previously developed by CEPI's partners prior to the emergence of COVID-19 as well as new collaborations. The aim is to advance clinical development of a diverse portfolio of safe and effective COVID-19 candidates and to enable fair allocation to these vaccines worldwide through COVAX.

CEPI's 5-year plan lays out a $3.5 billion roadmap to compress vaccine development timelines to 100 days, develop a universal vaccine against COVID-19 and other Betacoronaviruses, and create a "library" of vaccine candidates for use against known and unknown pathogens. The plan is available at endpandemics.cepi.net.

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About COVAX
COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is co-convened by CEPI, Gavi, the Vaccine Alliance and the World Health Organization (WHO) – working in partnership with UNICEF as key implementing partner, developed and developing country vaccine manufacturers, the World Bank, and others. It is the only global initiative that is working with governments and manufacturers to ensure COVID-19 vaccines are available worldwide to both higher-income and lower-income countries.