



Clover Announces Positive Phase 2/3 Results in Adolescents for its COVID-19 Vaccine

August 25, 2022

-- SCB-2019 (CpG 1018/Alum) elicited approximately 2-fold higher neutralizing antibody titers in adolescents (aged 12 to 17 years) compared to young adults (aged 18 to 25 years) --

-- Favorable tolerability and safety profile in adolescents, consistent with results previously observed in adults --

-- Clover plans to submit adolescent data to global regulatory authorities, in addition to its ongoing submissions for use in adults and elderly, to broaden potential use of SCB-2019 (CpG 1018/Alum) across age groups and as a universal COVID-19 booster vaccine --

SHANGHAI, China, Aug. 25, 2022 (GLOBE NEWSWIRE) -- [Clover Biopharmaceuticals, Ltd.](#) (Clover; HKEX: 02197), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutic candidates, today announced positive data from a global Phase 2/3 trial evaluating Clover's COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum), in adolescents (aged 12 to 17 years). The study successfully met the primary endpoint and demonstrated that vaccination with SCB-2019 (CpG 1018/Alum) elicited approximately 2-fold higher neutralizing antibody titers in adolescents compared to young adults (aged 18 to 25 years), a population where SCB-2019 (CpG 1018/Alum) had previously been demonstrated to be highly protective against COVID-19. Clover plans to submit the data and seek licensure in adolescents from global regulatory authorities, in addition to its ongoing submissions to the China National Medical Products Administration (NMPA), the European Medicines Agency (EMA), and the World Health Organization (WHO) for use in adults and elderly, to broaden the potential use of SCB-2019 (CpG 1018/Alum) across age groups and as a universal COVID-19 booster vaccine.

"We are highly encouraged by these positive pivotal Phase 2/3 trial data in adolescents. This new data shows that SCB-2019 (CpG 1018/Alum) elicits a robust immune response combined with a favorable safety and reactogenicity profile in younger populations, where tolerability is critically important," **said Dr. Nicholas Jackson, President of Global Research and Development of Clover.** "These latest findings support our COVID-19 vaccine candidate's pathway to licensure across age groups and its potential integral role in the long-term protection against SARS-CoV-2 in China and globally."

The Phase 2/3 trial in adolescents enrolled 1,278 participants and evaluated the immunogenicity, safety, and efficacy of SCB-2019 (CpG 1018/Alum) vaccine, administered as 2 doses given 21 days apart. The double-blind, randomized study met the primary endpoint and demonstrated a superior, approximately 2-fold higher neutralizing immune response in adolescents (aged 12 to 17 years) compared to young adults (aged 18 to 25 years). In the adult population (≥ 18 years of age), SCB-2019 (CpG 1018/Alum) ([LINK](#)) had previously demonstrated 100% efficacy in preventing severe COVID-19 and 95% efficacy against hospitalizations associated with COVID-19 caused by any SARS-CoV-2 strain at 5 months after vaccination.

SCB-2019 (CpG 1018/Alum) demonstrated a favorable safety and reactogenicity profile. Adverse events were mostly mild and transient, were balanced between vaccine and placebo (saline) groups, and comparable to results observed in the adult population.

These study results will contribute to the SCB-2019 (CpG 1018/Alum) data package and the licensure pathway for Clover's COVID-19 vaccine candidate in adolescents. Clover remains focused on completing regulatory submissions to China NMPA, the EMA, and the WHO for SCB-2019 (CpG 1018/Alum) in the second half of 2022, while concurrently preparing for its commercialization in China and globally.

The development of SCB-2019 (CpG 1018/Alum) is funded by the Coalition for Epidemic Preparedness Innovations (CEPI), which has awarded Clover up to US\$397.4 million in funding to enable equitable access to Clover's vaccine candidate.

About SCB-2019 (CpG 1018/Alum)

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. Clover created its 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. Clover 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 Clover's website: www.cloverbiopharma.com and follow the company on [Twitter](#) and [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, 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.

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