



Clover's Bivalent COVID-19 Vaccine Candidate Demonstrates Broad Neutralization Against Omicron and Other Variants of Concern

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-- Bivalent candidate (Prototype + Omicron) demonstrates broad neutralization against Omicron and all VoCs in both primary vaccination and booster settings in preclinical study --

-- Potential to pursue licensure pathway based on immuno-bridging to prototype vaccine candidate SCB-2019 (CpG 1018/Alum) which utilizes the validated Trimer-Tag™ technology platform --

SHANGHAI, China, May 05, 2022 (GLOBE NEWSWIRE) -- [Clover Biopharmaceuticals, Ltd.](#) (Clover; HKEX: 02197), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutic candidates, today announced new promising data from a preclinical study on Clover's bivalent vaccine candidate, which combines the trimeric spike antigens from the original SARS-CoV-2 strain and the Omicron variant. The bivalent vaccine candidate elicited broad neutralization against all Variants of Concern (VoC), including Omicron, in both primary vaccination and booster settings in a preclinical study. The manuscript "**Cross-Protection to VOCs by Bivalent S-Trimer COVID19 Vaccine**" [is available for pre-print on bioRxiv](#) and will be submitted for peer-review publication in a scientific journal.

"Given the SARS-CoV-2 virus is expected to continue changing, development of a broadly protective COVID-19 vaccine that can potentially neutralize existing and potential future variants is critical to preparing for the next chapter of COVID-19. We are excited by the emerging data demonstrating broad neutralization for our new bivalent COVID-19 vaccine candidate, and we believe the breadth observed is a result of combining spike proteins from two strains at diverse ends of the mutation universe, namely the original strain and the Omicron variant," **said Dr. Nicholas Jackson, President of Global Research and Development of Clover.** "Importantly, our bivalent candidate also utilizes the same Trimer-Tag™ platform as our prototype COVID-19 vaccine, SCB-2019 (CpG 1018/Alum), which has previously demonstrated a favorable safety profile and significant field efficacy against COVID-19 in a global Phase 2/3 trial. Thus, we believe there is a potential licensure pathway for the bivalent candidate based on clinical immuno-bridging to SCB-2019 (CpG 1018/Alum). We look forward to continued development of this exciting new candidate and providing a new tool for the world in this ongoing fight against COVID-19."

In the pre-clinical study, the bivalent COVID-19 vaccine candidate was comprised of the trimeric spike proteins from the original strain (SCB-2019) and the Omicron variant (SCB-2022B). In mice immunized in both the primary vaccination setting and the booster setting (previously vaccinated with two doses of prototype vaccine), the bivalent COVID-19 vaccine candidate demonstrated potent neutralization of all VoCs including the Omicron variant. Importantly, compared to the monovalent Omicron variant vaccine (SCB-2022B) alone, the bivalent COVID-19 vaccine demonstrated higher levels of neutralization against most of the variants tested and comparable levels against Omicron.

Based on these findings, Clover intends to advance development of the bivalent COVID-19 vaccine candidate into clinical development. Clover also expects to initiate a Phase 1 trial in the second quarter of this year evaluating SCB-2020S (a prototype and beta-variant chimeric vaccine candidate) to demonstrate proof-of-concept for variant strain change utilizing the Trimer-Tag™ platform. Clover remains focused on completing regulatory submissions to the NMPA, the EMA, and the WHO for SCB-2019 (CpG 1018/Alum) as well as preparing for commercialization in China and around the world as the highest priorities, given that the clinical results to-date suggest that SCB-2019 (CpG 1018/Alum) as a booster vaccine can significantly increase immune responses against Omicron.

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 Bivalent Candidate

Employing the Trimer-Tag™ technology platform, Clover has developed a bivalent vaccine candidate based upon the prototype vaccine candidate SCB-2019 (CpG 1018/Alum) and SCB-2022B antigen, a stabilized trimeric form of the S-protein (referred to as S-Trimer™) based on the Omicron strain of the SARS-CoV-2 virus. Clover has developed the Bivalent candidate by combining SCB-2019, SCB-2020B, and 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 [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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