Clover's COVID-19 Booster Vaccine Candidate Demonstrates Robust Neutralization of Dominant Omicron BA.5

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-- 12 to 61-fold increase in neutralizing antibodies against BA.5 among participants receiving SCB-2019 (CpG 1018/Alum) as a homologous third dose or with a history of prior SARS-CoV-2 infection --

-- BA.5 neutralizing antibody levels were approximately two to four-fold higher than BA.1 neutralizing antibody levels, demonstrating a potentially differentiated breadth of neutralization against the globally dominant BA.5 subvariant by SCB-2019 (CpG 1018/Alum) vaccination --

-- New positive data adds to the growing body of evidence supporting both the potential use of SCB-2019 (CpG 1018/Alum) as a universal booster against COVID-19 and its ability to potently cross-neutralize Omicron subvariants --

SHANGHAI, China, Aug. 30, 2022 (GLOBE NEWSWIRE) -- Clover Biopharmaceuticals, Ltd. (Clover; HKEX: 02197), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutics, today announced positive Phase 2/3 clinical trial data demonstrating that its lead COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum), elicited a robust immune response to Omicron BA.5 subvariant, the dominant SARS-CoV-2 variant circulating globally today, building upon previously announced results for neutralization against Omicron BA.2 [LINK] and BA.1 [LINK]. This new positive data adds to the growing body of consistent evidence supporting the potential use of SCB-2019 (CpG 1018/Alum) as a universal COVID-19 booster vaccine to address the variant of SARS-CoV-2 most relevant today.

"This new data makes clear the immediate potential for SCB-2019 (CpG 1018/Alum) to neutralize the Omicron BA.5 subvariant, the current major public health threat from COVID-19 globally," **said Dr. Nicholas Jackson, President of Global Research and Development of Clover.** "It builds upon the full breadth of our development of SCB-2019 (CpG 1018/Alum) as a universal booster demonstrating broad neutralization against the most current Omicron lineages and all Variants of Concern to date."

In this Phase 2/3 trial, a homologous booster dose of SCB-2019 (CpG 1018/Alum) in individuals who previously received two doses of SCB-2019 (CpG 1018/Alum) induced a robust and rapid neutralizing antibody immune response (using validated live SARS-CoV-2 virus neutralization assays). A cohort comprised of individuals who were baseline seronegative (individuals with no evidence of natural infection using anti-N antibody testing and observed waning neutralizing antibody levels after the second dose and prior to the booster dose) demonstrated a robust 12-fold increase against the Omicron BA.5 subvariant, with geometric mean titers (GMTs) of neutralizing antibodies increasing from 35 (pre-booster) to 408 (14 days post-booster). We previously released results from this study demonstrating that, relative to pre-booster levels, a third dose of SCB-2019 (CpG 1018/Alum) exhibited a 19-fold boost in neutralizing antibodies against the Omicron BA.2 subvariant (GMTs: 25 [pre-booster], 469 [post-booster]) and a 12-fold boost in neutralizing antibodies against Omicron BA.1 (GMTs: 18 [pre-booster], 211 [post-booster]) [LINK]. Together, this data supports the potential of SCB-2019 (CpG 1018/Alum) as a broadly neutralizing vaccine against divergent lineages of the Omicron variant.

Among participants with evidence of prior SARS-CoV-2 infection in the Phase 2/3 trial, two doses of SCB-2019 (CpG 1018/Alum), administered three weeks apart, elicited a 61-fold increase in neutralizing antibodies against BA.5, with GMTs increasing from 16 (baseline) to 984 (14 days after second dose). In the same participants, SCB-2019 (CpG 1018/Alum) vaccination exhibited a 37-fold boost in neutralizing antibodies against the Omicron BA.2 subvariant (GMTs: 12 [baseline], 442 [after second dose]) and a 20-fold boost in neutralizing antibodies against Omicron BA.1 (GMTs: 10 [baseline], 208 [after second dose]). We previously found that vaccination with SCB-2019 (CpG 1018/Alum) in this population significantly increased protection against COVID-19 [LINK].

These results indicate that Omicron BA.5 neutralizing antibody levels were approximately two to four-fold higher than Omicron BA.1 neutralizing antibody levels induced by SCB-2019 (CpG 1018/Alum), demonstrating a potentially differentiated breadth of neutralization elicited by SCB-2019 (CpG 1018/Alum) against the globally dominant BA.5 subvariant.

These results come from two study cohorts of the global, double-blind, randomized, controlled Phase 2/3 SPECTRA trial. In the subgroup receiving SCB-2019 (CpG 1018/Alum) as a homologous third dose, 3,755 total participants were enrolled in Brazil, Colombia, and the Philippines. In the subgroup with evidence of prior SARS-CoV-2 infection, 14,692 total participants were enrolled in Belgium, Brazil, Colombia, the Philippines, and South Africa.

Clover remains focused on completing regulatory submissions to the China National Medical Products Administration, the European Medicines Agency, and the World Health Organization 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 therapeutics. 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: http://www.cloverbiopharma.com and follow the company on LinkedIn and Twitter.

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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