Clover's COVID-19 Vaccine Candidate Demonstrates Superior Booster Responses Compared to Inactivated Vaccine

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-- Up to 12-fold higher neutralizing antibody titers observed in participants who received SCB-2019 (CpG 1018/Alum) as a heterologous third dose after two doses of inactivated vaccine compared to a third dose of inactivated vaccine --

-- Superior immune responses observed for SCB-2019 versus the inactivated vaccine booster against the original strain and Omicron subvariants --

-- Positive heterologous booster responses consistent with prior observations for homologous booster and in subjects with prior infection, underscoring the potential of SCB-2019 as a universal COVID-19 booster vaccine --

SHANGHAI, China, Sept. 06, 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 its ongoing Phase 3 study evaluating Clover's SCB-2019 (CpG 1018/Alum) as a universal COVID-19 booster vaccine candidate. The preliminary data showed that SCB-2019 elicited superior levels of neutralizing antibodies against the original strain of SARS-CoV-2 and Omicron subvariants BA.1 and BA.2 when administered as a heterologous third dose in participants who previously received two doses of an inactivated vaccine compared to a third dose of the inactivated vaccine.

"The positive booster data against Omicron subvariants from this landmark Phase 3 heterologous booster study represents a pivotal step in our efforts to develop our lead COVID-19 vaccine candidate as a universal booster," **said Dr. Nicholas Jackson, President of Global R&D of Clover.** "These results further validate our confidence in SCB-2019 as a valuable COVID-19 prevention option, especially in China and other countries and regions where inactivated vaccines have played an important role in primary vaccination campaigns."

A booster dose of SCB-2019 in participants who previously received two doses of the inactivated vaccine elicited superior neutralizing immune responses against the original strain and Omicron BA.1 and BA.2 compared to responses in participants receiving a third dose of the inactivated vaccine. Preliminary analyses in subjects with low pre-booster neutralizing antibody levels (defined as baseline pre-booster neutralizing antibody titers ≤100 using validated live SARS-CoV-2 neutralization assays) showed that SCB-2019 elicited a 17-fold increase in neutralizing antibodies against the original strain, with geometric mean titers (GMT) of antibodies increasing from 44 at baseline (pre-booster) to 733 (14 days post-booster). This response was 12-fold higher than the response to the inactivated vaccine, which elicited a 2-fold increase (GMTs: 33 [baseline], 61 [post-booster]) in neutralizing antibodies against the original strain. In the same population, SCB-2019 elicited a 6-fold increase (GMTs: 33 [baseline], 193 [post-booster]) in neutralizing antibodies against Omicron BA.1 and an 8-fold increase (GMTs: 51 [baseline], 410 [post-booster]) in neutralizing antibodies against Omicron BA.2. This response was 5 and 6-fold higher, respectively, than the response to the inactivated vaccine, which elicited a 1-fold increase (GMTs: 30 [baseline], 42 [post-booster]) against Omicron BA.1 and a 1-fold increase (GMTs: 47 [baseline], 67 [post-booster]) against Omicron BA.2. Additional results against Omicron BA.5 in these participants are expected in the near future.

These heterologous booster responses are consistent with prior observations for SCB-2019 (CpG 1018/Alum) as a homologous booster against Omicron BA.1 (LINK) and BA.2 (LINK) and in subjects with prior infection against Omicron BA.5 (LINK) and the original strain and all other Variants of Concern (LINK).

These results are part of a Phase 3, double-blind, randomized and controlled study that is evaluating the safety and immunogenicity of SCB-2019 administered as a booster dose in individuals who received two doses of inactivated vaccine compared to third, homologous booster dose of the inactivated vaccine. Clover is also currently enrolling a subcohort evaluating SCB-2019 as a fourth dose booster in individuals previously receiving three doses of the inactivated vaccine compared to a fourth, homologous booster dose of the inactivated vaccine. The study has enrolled over 1,500 adult and elderly participants in the Philippines to date.

This new study data adds to the growing body of evidence evaluating SCB-2019 as a potential universal COVID-19 booster candidate. 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 in the second half of 2022, while concurrently preparing for its commercialization in China and globally.

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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