Clover's Universal COVID-19 Booster Vaccine Candidate Demonstrates Superior Neutralization of Omicron BA.5 Compared to Inactivated Vaccine

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-- 5-fold higher neutralizing antibodies against dominant Omicron BA.5 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 --

-- New Phase 3 data underscores the potential role SCB-2019 can play as a heterologous booster against dominant variants in China and other countries and regions, regardless of previous vaccination or infection history --

SHANGHAI, China, Sept. 20, 2022 (GLOBE NEWSWIRE) -- Clover Biopharmaceuticals, Ltd. (Clover; HKEX: 02197), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutics, 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 data showed that SCB-2019 (CpG 1018/Alum) elicited superior levels of neutralizing antibodies against the Omicron BA.5 subvariant, the dominant SARS-CoV-2 variant circulating globally today, 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.

"Omicron BA.5 is globally dominant today, representing over 90% of circulating strains, and evidence indicates that it has some degree of immune escape," **said Dr. Nicholas Jackson, President of Global Research and Development of Clover.** "It is very encouraging to observe the consistently robust immune response against BA.5 elicited by SCB-2019 across populations, building foundational evidence for SCB-2019's potentially critical role in addressing the continuing burden of COVID-19—including in countries and regions where inactivated vaccines have been widely used to date."

A booster dose of SCB-2019 (CpG 1018/Alum) in participants who previously received two doses of the inactivated vaccine elicited superior neutralizing immune responses against Omicron BA.5 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 (CpG 1018/Alum) elicited a 6.5-fold increase in antibody titers against Omicron BA.5 relative to pre-booster levels, with geometric mean titers (GMTs) increasing from 37 (pre-booster) to 240 (14 days post-booster). This response was 5-fold higher than the response to the inactivated vaccine booster, which elicited a 1.6-fold increase in antibody titers against Omicron BA.5 (GMTs: 30 [pre-booster], 48 [14 days post-booster]).

The Omicron BA.5 heterologous booster responses are consistent with prior data from this Phase 3 study (LINK), which showed a similarly superior response against the SARS-CoV-2 prototype, Omicron BA.1 and Omicron BA.2 for SCB-2019 (CpG 1018/Alum), relative to inactivated vaccine. They are also consistent with previously released results demonstrating the strong SCB-2019 (CpG 1018/Alum)-elicited immune responses against Omicron BA.5 in other populations, including those receiving a homologous third dose of SCB-2019 (CpG 1018/Alum) and those who had a history of SARS-CoV-2 infection at baseline (LINK). Together, these results demonstrate a potentially differentiated breadth of neutralization against the globally dominant Omicron BA.5 subvariant by SCB-2019 (CpG 1018/Alum) vaccination.

These results are part of a Phase 3, double-blind, randomized and controlled study that is evaluating the safety and immunogenicity of SCB-2019 (CpG 1018/Alum) 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 (CpG 1018/Alum) 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.

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.

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: 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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