Clover Biopharmaceuticals, Ltd.
三葉草生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2197)

INSIDE INFORMATION
BUSINESS UPDATE

This announcement is made by the board (the "**Board**") of directors (the "**Directors**") of Clover Biopharmaceuticals, Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

A. SCB-2019 (CpG 1018/Alum), COVID-19 Vaccine Candidate

(i) **Regulatory Submissions:** The Company remains actively engaged with the National Medical Products Administration (國家藥品監督管理局) of China ("**NMPA**"), the European Medicines Agency ("**EMA**"), and the World Health Organization ("**WHO**") regarding the data needed to support conditional approvals for SCB-2019 (CpG 1018/Alum).

- Submission & Production Strategy: Based on the anticipated supply demands of SCB-2019 (CpG 1018/Alum) for the China market and in order to streamline supply of the vaccine to multiple markets, the Company optimized its regulatory and manufacturing strategy for 2022. In 2022, the Company's Changxing facility will be focused on seeking product approval with the China NMPA and supplying vaccine for the China market. The Company's contract development and manufacturing organization ("**CDMO**") site, which has previously received EMA and WHO approvals, will be focused on seeking product approvals from EMA and WHO with the objective of supplying our vaccine for global markets, including for the COVAX Facility (COVAX Facility refers to COVID-19 Vaccines Global Access, a global initiative aimed at equitable access to COVID-19 vaccines led by United Nations International Children's Emergency Fund, the Global Alliance for Vaccines and Immunization, the Vaccine Alliance, WHO, the Coalition for Epidemic Preparedness Innovations, and others). This plan has been communicated with and acknowledged by the relevant regulatory authorities.

- Impact of COVID-19 Outbreak in China: COVID-19 outbreaks in Shanghai and other localities across China have resulted in strict containment measures. This situation has impacted certain day-to-day operations at the Company, including the delayed delivery of certain raw materials and equipment to our manufacturing facilities, the pause in specific testing services at contract laboratories, and restrictions on travel to our manufacturing facilities. Despite the logistical impact, the Company has worked through the situation, and significant progress has been made on completing improvements to the Changxing facility and the associated chemistry, manufacturing and controls (CMC) activities. The Company now anticipates that the facility will be ready for Good Manufacturing Practices inspections in the third quarter of 2022.

- Guidance for Regulatory Submissions: The latest plans for SCB-2019 (CpG 1018/ Alum) rolling submissions and status of our Changxing and CDMO manufacturing facilities have been communicated with the regulatory authorities. Regulatory submissions are now anticipated for completion in the second half of 2022 for all three agencies, with product launch commencing thereafter upon receiving conditional approvals.

(ii) **Universal COVID-19 Booster Vaccine Development:** The Company plans to complete the development of its COVID-19 vaccine candidate as a universal COVID-19 booster vaccine in 2022, to potentially enable its use as a booster dose, regardless of the vaccine technology used for the primary vaccination or previous severe acute respiratory syndrome coronavirus 2 infection (SARS-CoV-2) history. Initial universal booster data have demonstrated that SCB-2019 (CpG 1018/Alum) can induce a significant and broadly-neutralizing immune response against variants of concern ("**VoCs**") including Omicron.

Heterologous Booster

- Boosting Coronavac™ (SinoVac Inactivated Vaccine) and Comirnaty® (Pfizer mRNA Vaccine): The Company anticipates initiating a clinical trial in the Philippines in June 2022, to evaluate SCB-2019 (CpG 1018/Alum) as a booster in individuals that previously received two doses of Coronavac™ or two doses of Comirnaty®. SCB-2019 (CpG 1018/Alum) administered as a heterologous booster will be compared head-to-head against homologous boosters of Coronavac™ and Comirnaty® respectively. Initial results from this trial are expected in the third quarter of 2022.

  (1) In this trial, the Company plans to initiate a subcohort evaluating SCB-2019 (CpG 1018/Alum) as a booster in individuals previously receiving three doses of Coronavac, which is expected to begin enrolling in the third quarter of 2022 with initial results from this trial expected in the fourth quarter of 2022.

  (2) Separately, the Company recently received an update from investigators in an ongoing investigator-initiated study in Brazil evaluating SCB-2019 (CpG 1018/Alum) used as a booster in individuals previously receiving two doses of Coronavac™. Since the Coronavac™ booster study group had met significant challenges with enrollment due to a preference for other licensed vaccines, the investigators and study funders have decided to terminate the study.

Homologous Booster

- Boosting SCB-2019 (CpG 1018/Alum): A homologous booster dose of SCB-2019 (CpG 1018/Alum) in individuals previously receiving two doses of SCB-2019 (CpG 1018/Alum) induced a robust and rapid neutralizing antibody immune response that exceed levels after the primary immunization series by approximately 5-fold. The safety and reactogenicity profile of the homologous booster dose was consistent with the primary immunization series. The study evaluated SCB-2019 (CpG 1018/Alum) in 3,755 participants in Brazil, the Philippines and Columbia.

  Additional data from this trial including Omicron neutralization results and a cohort boosted with a half-dose of SCB-2019 (CpG 1018/Alum) are expected to be available in the middle of 2022.

B. Promising Next-Generation COVID-19 Vaccine Candidates

(i) SCB-2020S (prototype and beta-variant chimeric vaccine candidate): The Company initiated a Phase 1 clinical trial in South Africa evaluating SCB-2020S in May 2022, with preliminary results expected in the fourth quarter of 2022. The results will provide further proof-of-concept for variant strain change utilizing the Trimer-Tag™ platform and will also generate first-in-human data for CAS-1 (an in-house oil-in-water emulsion adjuvant).

(ii) Bivalent Vaccine (prototype and omicron-variant combined formulation vaccine candidate): The Company has nominated a bivalent candidate vaccine into its development portfolio based on promising preclinical data against VOCs. The manuscript ***"Cross-Protection to VOCs by Bivalent S-Trimer COVID-19 Vaccine"*** is available for pre-print on bioRxiv and has been accepted by a peer-reviewed scientific journal.

C. Other Business Updates: After completing internal scientific, financial, and strategic assessments, the Company will prioritize resources on the development of COVID-19 assets and certain early-stage programs/platforms while limiting investments in non-COVID-19 mid/late-stage programs and new infrastructure. In navigating the current macroeconomic environment, the Company continues to prudently evaluate its expenses and explore opportunistic financing options to extend its cash runway.

(i) Focused on Near-term Value Drivers: Regulatory submissions for SCB-2019 (CpG 1018/Alum) remains the Company's highest priority. The Company is also maximizing its impact on COVID-19 by completing universal booster development for SCB-2019 (CpG 1018/Alum) and advancing additional COVID-19 vaccine candidates including SCB-2020S and a bivalent COVID-19 vaccine candidate. SCB-219M will also advance into a Phase 1 clinical trial in the near-term. Additional investments in SCB-313 (TRAIL-Trimer for oncology), SCB-808 and SCB-420 (Fc-Fusion protein programs) have been paused for the time being.

(ii) Up to US$300 Million Credit Agreement Approved: China Merchants Bank has approved a one-year credit agreement for up to US$300 million to support potential working capital needs during commercial launch. Drawdown on this agreement is subject to a review of the Company's business condition and changes in the Company's condition may result in early repayment. Additional terms including the repayment date and interest rate will be fixed at the time of drawdown approval.

This announcement may contain forward-looking statements that involve risks and uncertainties. The Company's shareholders and potential investors should not place undue reliance on these forward-looking statements, which reflect our belief only as of the date of these statements. These forward-looking statements are based on the Group's own information and information from other sources we believe to be reliable. The Group's actual results may be materially less favorable than those expressed or implied by these forward-looking statements, which could depress the market price of the Company's shares.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will be able to ultimately commercialize SCB-2019 (CpG 1018/Alum) successfully.

Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Clover Biopharmaceuticals, Ltd.
Dr. Peng LIANG
Chairman of the Board

Shanghai, PRC, June 5, 2022

As of the date of this announcement, the Board comprises Dr. Peng LIANG and Mr. Joshua G LIANG as executive Directors; Dr. Xiaodong WANG and Mr. Dong LYU as non-executive Directors; and Dr. Xiaobin WU, Mr. Xiang LIAO, Mr. Jeffrey FARROW and Mr. Thomas LEGGETT as independent non-executive Directors.