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
CLOVER PROVIDES UPDATE ON 2022 CORPORATE MILESTONES

This announcement is made by the board (the "**Board**") of directors (the "**Directors**") of Clover Biopharmaceuticals, Ltd. (the "**Company**" or "**Clover**", 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).

The Company's Lead COVID-19 Vaccine Candidate

Regulatory Submissions & Manufacturing Readiness: Significant recent momentum and progress has been made on the regulatory submissions for the Company's lead COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum). Regulatory submissions are planned to be completed to the China National Medical Products Administration (國家藥品監督管理局) ("**NMPA**"), the European Medicines Agency ("**EMA**"), and the World Health Organization ("**WHO**") in the fourth quarter of 2022.

- China NMPA Submission (the Company's Changxing Facility): The Company's in-house manufacturing facility in Changxing has made meaningful progress towards good manufacturing practice ("**GMP**") inspection readiness and has now completed previously identified facility remediations and improvements. The Company remains actively engaged with the China NMPA for the rolling conditional Biologics License Application (cBLA) submission for SCB-2019 (CpG 1018/Alum), and substantive submission-related interactions and processes have recently been completed or are currently ongoing. The rolling submission to the China NMPA is expected to be completed in the fourth quarter of 2022.

- EMA & WHO Submissions (The Company's CDMO Facility): In September 2022, The Company's contract development and manufacturing organization ("**CDMO**") received a European Union ("**EU**") GMP certificate for the production of SCB-2019 (CpG 1018/Alum). The EU GMP certificate is in connection with the Company's regulatory submission to the EMA and follows a successful inspection of the CDMO site by the Ireland Health Products Regulatory Authority. It signifies that the production of SCB-2019 (CpG 1018/Alum) meets the EU's standards for quality and safety. The Company completed the production-related technology transfer activities for SCB-2019 (CpG 1018/Alum) at the CDMO site in the third quarter of 2022 and expects to complete submissions to the EMA and the WHO in the fourth quarter of 2022.

- Submissions in Other Countries: In the third quarter of 2022, the Company held submission-related meetings with regulatory authorities in Brazil and Indonesia as part of the Company's ongoing pursuit of regulatory submissions and potential bilateral supply agreements strategically in certain countries.

Universal COVID-19 Booster Vaccine Data: New Phase 3 data demonstrating broad neutralization – including against the globally dominant Omicron BA.5 strain – underscores the potential role that SCB-2019 (CpG 1018/Alum) can play as a universal booster in China and other countries, regardless of previous vaccination or infection history and across age groups.

- Heterologous Booster Data for Boosting Inactivated Vaccine in Phase 3 Study: In September 2022, the Company reported positive data from its ongoing Phase 3 study evaluating SCB-2019 (CpG 1018/Alum) as a universal COVID-19 booster. Preliminary analysis demonstrated that a third dose of SCB-2019 (CpG 1018/Alum) in participants who previously received two doses of the inactivated vaccine elicited 5 to 6-fold higher neutralizing immune responses against the globally dominant Omicron BA.5 strain and other Omicron subvariants tested (BA.1, BA.2) and a 12-fold higher immune response against the original SARS-CoV-2 strain compared to participants receiving a third dose of the inactivated vaccine.

    - A sub-cohort in this ongoing Phase 3 study is evaluating SCB-2019 (CpG 1018/Alum) as a fourth-dose booster in individuals who previously received three doses of the inactivated vaccine compared to a homologous fourth dose of the inactivated vaccine, with preliminary data expected in the fourth quarter of 2022.

- Robust Omicron BA.5 Neutralization Responses Across Phase 2/3 Trials: The heterologous booster data for inactivated vaccine is consistent with results announced in August 2022 demonstrating robust responses against the dominant Omicron BA.5 strain when SCB-2019 (CpG 1018/Alum) was administered as a third-dose homologous booster and for vaccination in subjects with prior infection.

- Substantial Reduction in Household Transmission of SARS-CoV-2 Infection: In August 2022, the Company shared new results from the Phase 2/3 SPECTRA trial which demonstrated that vaccination with SCB-2019 (CpG 1018/Alum) could substantially reduce transmission of SARS-CoV-2 infection to household contacts. Compared to placebo recipients, an individual vaccinated with SCB-2019 (CpG 1018/Alum) was 84% less likely to transmit SARS-CoV-2 infection to another individual living in the same household. By reducing household transmission of SARS-CoV-2 infection, these results indicate that SCB-2019 (CpG 1018/Alum) can potentially help to control the spread of SARS-CoV-2 within communities.

- Positive Adolescent Data in Phase 2/3 Trial: In August 2022, the Company announced that a pivotal Phase 2/3 trial evaluating SCB-2019 (CpG 1018/Alum) in adolescents (aged 12 to 17 years) successfully met its primary endpoint and demonstrated a favorable tolerability and safety profile, consistent with results previously observed in adults.

Commercial Preparations & Outlook for COVID-19 Vaccine: Based on anticipated potential near-term needs in China, the Company's priority target market, the Company has begun conducting activities to enable a commercial launch after receiving regulatory approval and believes that it is well-positioned to continue being a key player in the future longer-term annual boosting market for COVID-19 vaccines.

- China Commercial Launch Preparations: Based on the Company's progress with the ongoing regulatory submission, positive heterologous booster results, and the potential for a fourth-dose booster campaign, the Company has been actively preparing for the commercial launch in China after receiving regulatory approval. the Company has conducted extensive field work strategically in certain priority provinces and will continue to engage with policymakers. Given the continued evolution of the SARS-CoV-2 virus and the initiation of new booster campaigns in countries around the world, the Company believes that, beyond the national-level procurement phase of COVID-19 vaccine rollout, an attractive annual boosting market for COVID-19 vaccines in a private market setting could emerge over time – similar to the seasonal influenza vaccination market – favoring premium products such as the Company's adjuvanted protein-based COVID-19 vaccines.

- Update on Global Commercial Plans: In September 2022, the Company and Gavi, the Vaccine Alliance, agreed to amend their Advance Purchase Agreement ("**APA**") to remove prior restrictions on the Company supplying vaccine doses to the China market and to deploy greater pricing flexibility in China and globally through bilateral agreements. The Company had previously received US$224 million from Gavi as advance payment for purchasing non-refundable materials related to the initial order of 64 million doses of SCB-2019 (CpG 1018/Alum), which have now been converted into an option that is exercisable over an extended period of four years at Gavi's discretion but could otherwise be supplied to China or other countries. The amended APA represents Gavi's continued collaboration and support for the Company's COVID-19 vaccine technology. The Company remains committed to providing access to its premier COVID-19 vaccine candidate and continues to pursue regulatory submissions and potential bilateral supply agreements strategically in certain countries.

Business Outlook & Pipeline Strategy

The Company is poised to become an integrated, innovative vaccine-focused company with established China and global R&D, manufacturing and commercialization capabilities. The Company plans to continue utilizing its established internal capabilities and Trimer-Tag™ technology in addition to leveraging its track record of successful cross-border collaboration to build a portfolio of innovative and potential best-in-class vaccine candidates.

Continued Development of Trimer-Tagged Vaccines: The Company continues to leverage the validated Trimer-Tag™ platform technology to develop innovative protein-based vaccines.

- SCB-2020S (chimeric beta and original strain COVID-19 vaccine candidate): SCB-2020S, a second generation and potentially broadly protective COVID-19 vaccine candidate, is being evaluated in a Phase 1 study in South Africa. The study is evaluating SCB-2020S with CAS-1, the Company's in-house adjuvant system. Safety and immunogenicity data for SCB-2020S is expected in the fourth quarter of 2022. SCB-2020S represents a potential additional option for continued booster campaigns that could be complementary to SCB-2019 (CpG 1018/Alum).

- Pan SARS-CoV-2 Vaccine: The Company is conducting research to develop a multi-valent SARS-CoV-2 vaccine designed to be broadly protective against all current and potential strains of the virus which may emerge in the future. A candidate selection for further development is planned in the fourth quarter of 2022.

- SCB-1001 (Rabies G-Trimer Vaccine): The Company's rabies vaccine candidate utilizing Trimer-Tag™ is planned to be developed with its in-house CAS-1 adjuvant. Additional preclinical results and an update on development plans for this candidate are expected in the fourth quarter of 2022.

Business Development for Mid– to Late-Stage Vaccine Assets: Based on the Company's established and integrated vaccine R&D and manufacturing capabilities as well as its track record of successful cross-border collaboration, the Company is currently actively evaluating business development opportunities for mid- to late-stage innovative vaccine assets which could be synergistic with its internal Trimer-Tagged vaccine portfolio and potentially create significant near-term value.

Corporate Updates

Cash Position & Business Focus:

- Cash Position: As of June 30, 2022, the Company had cash and cash equivalents of approximately US$336 million (RMB2,256 million), which the Company believes is sufficient to sustain the Company through the commercial launch of its COVID-19 vaccine and positions the Company for continued success. A credit agreement with China Merchants Bank for up to US$300 million is in place and could be accessed to support potential working capital needs during commercial launch if needed. The Company has no immediate plan to access this credit facility at this time.

- Business Focus: To navigate the challenges of the current macroeconomic environment, the Company has taken significant additional steps to (1) heighten focus on its core strengths and capabilities in vaccine development and (2) prudently evaluate its expenses and streamline the organization to increase efficiency and improve effectiveness. Non-core activities (including monoclonal antibody platform development) have been terminated, and headcount reductions in non-critical positions, primarily in general and administrative functions and non-core R&D roles, have occurred. The Company will continue to focus resources on achieving the Company's top priorities while continuing to build an innovative vaccine-focused portfolio that can potentially generate significant near-term value-creation opportunities.

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, October 9, 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, Mr. Dong LYU, Dr. Donna Marie AMBROSINO and Dr. Ralf Leo CLEMENS as non-executive Directors; and Dr. Xiaobin WU, Mr. Xiang LIAO, Mr. Jeffrey FARROW and Mr. Thomas LEGGETT as independent non-executive Directors.