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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 UPDATES ON BUSINESS AND
R&D PIPELINE DEVELOPMENT

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).

Commercial Highlights & Plans

Quadrivalent Seasonal Influenza Vaccine Upcoming Commercialization: In February 2023, the Company announced that it entered into an exclusive agreement with Adimmune Corporation (the “**Adimmune**”) to distribute AdimFlu-S (QIS) in mainland China, where it is the only imported seasonal quadrivalent influenza vaccine approved for use in individuals aged three years and older. The Company is currently the only Chinese company with commercial-stage quadrivalent seasonal influenza and COVID-19 booster vaccines.

- **Market Opportunity:** The market for influenza vaccine in China has been growing by approximately 30% annually and is expected to continue growing in the post-pandemic era with increasing vaccine awareness and favorable government policies. There is also increased recognition that influenza vaccination significantly decreases morbidity and mortality caused by the exacerbation of cardiovascular diseases. Moreover, demand in China continues to shift from trivalent to seasonal quadrivalent influenza vaccine options, which accounted for a majority of doses (70%) in 2022.

- **Commercialization Plans:** Commercial launch in mainland China is on track to occur in the second half of 2023. Adimmune commenced production of AdimFlu-S (QIS) in the first quarter of 2023, and importation into mainland China and subsequent batch release testing are expected to occur in the third quarter of 2023. Sales are expected to be accretive to Clover’s earnings starting in 2023 and contribute meaningful growth in 2024 and beyond.
- **Commercial Capabilities:** The Company has now completed buildup of its initial commercial team in China to support commercialization of AdimFlu-S (QIS) in 2023 as planned, and it announced in May 2023 a collaboration with Keyuan Xinhai (Beijing) Medical Products Trading Co. Ltd. (科園信海(北京)醫療用品貿易有限公司) (“**Kyuan Trade**”) to leverage Kyuan Trade’s extensive sales and distribution network to complement in-house capabilities and maximize access to AdimFlu-S (QIS).

COVID-19 Vaccine Commercialization: Due to the evolving landscape and low overall demand for COVID-19 vaccines from National Procurement in China and globally observed in 2023 to date, the Company does not expect meaningful financial contribution from COVID-19 vaccine sales in 2023. However, the Company expects that future private market sales, if and when commenced, could enable more attractive pricing and a more sustainable market opportunity, comparable to the influenza vaccine market, especially in high-risk populations such as elderly and people with underlying diseases.

- **Global (Ex-China):** In the first half of 2023, the Company completed regulatory submissions of its COVID-19 vaccine in two countries, in South East Asia and Latin America respectively. Review from the regulatory authorities is ongoing, and to date, the Company has not received any request for additional information or notification of deficiencies. Bilateral deal discussions with one country have continued and are contingent upon regulatory approval being received.
- **China:** To date, Clover’s COVID-19 vaccine has been listed in 28 provinces & municipalities in China (representing >95% population coverage), demonstrating Clover’s market access capabilities, which will be leveraged to maximize the commercial opportunities of its quadrivalent influenza vaccine.

R&D Pipeline Highlights & Plans

Building a Leading Respiratory Vaccine Franchise: The Company is focused on building a leading respiratory vaccine franchise to address unmet needs in preventing serious respiratory infectious diseases and to capture related significant cross-promotion, co-administration, and long-term lifecycle management opportunities. Prioritized respiratory vaccine products include seasonal influenza, COVID-19, Respiratory Syncytial Virus (“**RSV**”) and pneumococcal conjugated vaccine (“**PCV**”).

RSV Vaccine Candidate (SCB-1019): SCB-1019 is Clover’s RSV vaccine candidate based on prefusion-stabilized F (PreF) protein leveraging the validated Trimer-Tag platform. The Company expects to be among the first Chinese RSV PreF vaccine companies to enter human clinical trials and plans to disclose additional preclinical data and development plans in the second half of 2023.

- **Market Opportunity:** With RSV being a leading cause of acute respiratory infection, disease and death in the elderly and infants, the market for RSV vaccines is expected to potentially reach over US\$10 billion in peak annual sales globally, which would make it comparable to the market size for pneumococcal vaccines. The market for RSV vaccines in China could be particularly attractive, as China has (1) the largest population of older adults and elderly globally with approximately 270 million people aged 60 years and older and (2) has a robust and growing private market for other respiratory vaccines (pneumococcal and influenza vaccines).
- **Clover’s Differentiation & Advantages:** The Company believes it can uniquely address the high technical hurdles for RSV vaccine development, enabling it to be a leading RSV vaccine developer in China with differentiation to compete in global markets.
 - o **Stabilized PreF Antigen:** Stabilization of the RSV fusion (F) antigen in its native prefusion and trimeric conformation (“**PreF**”) is critical to conferring protective efficacy by preserving the most potent neutralizing antibody epitopes, but production of PreF has historically been challenging due to the tendency of the F antigen to adopt the postfusion conformation (“**PostF**”). PostF lacks multiple neutralizing antibody epitopes and has failed to demonstrate efficacy in previous clinical trials. To achieve the stabilized PreF, the Company is utilizing the validated Trimer-Tag platform combined with proprietary stabilizing PreF mutations in its RSV vaccine candidate (SCB-1019). To date, the Company has confirmed that SCB-1019 preserves all of the most prominent neutralizing antibody epitopes (sites Ø, V, IV, III, II, I) and importantly does not bind to postfusion-specific monoclonal antibody, which may enable SCB-1019 to potentially achieve a top-tier protective efficacy profile.
 - o **Immunological Breadth:** Most RSV vaccines in development to date are based on a monovalent RSV A F antigen. However, outbreaks of the two main RSV groups (RSV A and RSV B) typically alternate in prevalence between seasons. Amino acid sequence differences on the F antigens for RSV A and RSV B result in different antibody binding epitopes including at the most potent neutralization sites on PreF (such as site Ø and site V). SCB-1019 is designed to induce neutralization across both RSV A and RSV B which is important to conferring broad and durable protection against RSV across different regions and seasons.

- o **Safety & Tolerability:** The safety and tolerability profile of vaccines is important to maximizing uptake and differentiating against competition. Oil-in-water emulsion adjuvanted protein-based vaccines and mRNA vaccines have observed higher rates of adverse events than other protein-based vaccines. Based on preclinical studies to date, SCB-1019 is planned to be developed without the use of an oil-in-water emulsion adjuvant and is thus expected to potentially have a best-in-field safety and tolerability profile, which may also enable it to be developed for the infant population.
- o **Commercial Manufacturing Readiness:** SCB-1019 is produced utilizing the same Trimer-Tag platform used in Clover's COVID-19 vaccine, and commercial production is planned at Clover's Changxing facility which has passed multiple GMP inspections and has also received a vaccine Drug Manufacturing License (DML) from China NMPA, representing potential advantages compared to other domestic manufacturers utilizing new manufacturing sites.

Mid- to Late-Stage Pipeline Expansion: In addition to the Adimmune quadrivalent seasonal influenza deal, the Company further anticipates at least one additional in-licensing deal in 2023 to expand its mid- to late-stage pipeline (Phase 2, Phase 3, Commercial). Prioritized areas include PCV and pediatric vaccines (such as enterovirus A71 [EV71] and pediatric combination vaccines).

XBB-Adapted COVID-19 Vaccine Candidate: To prepare for potential future private market opportunities, the Company is developing an updated version of its COVID-19 vaccine including the XBB.1.5 variant. Development is planned to be completed in the second half of 2023.

SCB-219M (Chemo-Induced Thrombocytopenia): SCB-219M is a fusion protein (TPO-mimetic bispecific-Fc) targeted to treat chemo-induced thrombocytopenia (CIT). Compared to native TPO-based therapy which is commercially available in China, SCB-219M could potentially overcome reduced efficacy due to anti-drug antibodies (ADA) and achieve a more convenient dosing regimen attributed to its longer half-life. Interim Phase 1 clinical trial data is anticipated in the fourth quarter of 2023.

Corporate & Financial Updates

- **Cash Position:** Approximately RMB1.5 billion cash and cash equivalents as of June 30, 2023 compared to RMB1.86 billion as of December 31, 2022. Cash position is expected to support the company at least through 2024 and can potentially be sustainable if influenza commercialization and operating efficiency targets are achieved.
- **R&D and G&A Expenditures:** Approximately 50% reduction in operating expenditures (R&D and G&A expenditures) was achieved in the first half of 2023 compared to the first half of 2022. This trend in increased operating efficiency and cost reduction is expected to continue over the next 12 months, as COVID-19 vaccine-related R&D (clinical, CMC and regulatory) activities are completed and the company continues to streamline corporate operations.

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.

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, July 11, 2023

As of the date of this announcement, the Board comprises Dr. Peng LIANG and Mr. Joshua G LIANG as executive Directors; Dr. Xiaodong WANG, 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.