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 COVID-19 VACCINE COMMERCIAL LAUNCH AND STRATEGIC PRIORITIES IN 2023

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).

COVID-19 Vaccine Commercialization Updates

China Commercialization: The commercial launch for SCB-2019 (CpG 1018/Alum) in China in multiple provinces and municipalities is expected to begin in the first quarter of 2023. Given the scale and impact of the ongoing COVID-19 outbreaks across China, the Company now anticipates a significant and sustained long-term annual booster market opportunity in China for Clover's premium and broadly protective COVID-19 vaccine.

- Recent Milestones: In early December 2022, SCB-2019 (CpG 1018/Alum) was included for emergency use authorization ("**EUA**") in China. Subsequently, the China National Health Commission (中國國家衛生健康委員會) formally announced its national immunization plan for a fourth dose booster campaign and recommended prioritizing specified vaccines that demonstrate broad neutralization against Omicron, including SCB-2019 (CpG 1018/Alum), for use. Additionally, the price setting process for SCB-2019 (CpG 1018/Alum) commercialized via national procurement was completed with the China National Healthcare Security Administration.

- Commercial Launch Expected to Begin in the First Quarter of 2023: The Company has started commercial launch preparation activities in multiple key provinces and municipalities, based on Clover's evaluation of market dynamics (including factors such as strategic fit, population size and competitive environment). To date, the Company has received robust interest and demand based on the premium product profile of SCB-2019 (CpG 1018/Alum) and expects the commercial launch in these strategically prioritized areas to begin in the first quarter of 2023. Further expansion to additional provinces and municipalities is anticipated to occur throughout 2023, based on production capacity and market dynamics.

- Impact of Ongoing COVID-19 Outbreaks:

  - Near Term – Wider Window to Supply to Market: As COVID-19 continues to spread rapidly across China, the number of previously infected people is expected to increase significantly through the first half of 2023. According to published studies, immunity induced by prior natural infection has been observed to wane rapidly, especially against Omicron, leading countries around the world to recommend booster vaccination at an interval range of one to six months after infection. While Clover's initial commercial launch in China starting in first quarter of 2023 will likely be primarily comprised of boosting infection-naïve individuals, the Company expects booster vaccination of previously infected individuals to begin in second quarter of 2023 and to increase in proportion through the remainder of the year. Thus, the Company anticipates a more sustained, rather than short-term, rollout of booster vaccinations throughout 2023, giving the Company a wider window of time to ramp up production and maximize the impact of its premium COVID-19 vaccine.

  - Longer Term – Sustained & Robust Annual Booster Market: With the Chinese population's recent increasing awareness of the potential disease severity and impact of COVID-19, the Company believes that the level of certainty and the potential size of the future annual booster market for COVID-19 vaccines have increased significantly. Beyond the current National Procurement phase of COVID-19 vaccine rollout, the Company anticipates that a robust annual booster market for COVID-19 vaccines in a private market setting could emerge – similar to the growing seasonal influenza vaccination market – favoring premium products such as Clover's adjuvanted protein-based COVID-19 vaccine and introducing attractive product pricing dynamics.

Global (Ex-China) Commercialization: The Company expects SCB-2019 (CpG 1018/Alum) to receive an EUA in at least one additional country and to complete multiple EUA submissions during H1 2023, potentially driving revenue via bilateral deals starting in 2023.

- Bilateral EUA Submissions and Procurement Deals: The Company is now prioritizing global (ex-China) regulatory submissions directly in selected countries, primarily in Asia Pacific and Latin America, based on the potential to generate significant near-term revenue and impact via bilateral supply agreements. In addition to submitting multiple EUA applications and receiving at least one EUA for SCB-2019 (CpG 1018/Alum), the Company also expects to establish at least one bilateral supply agreement in the first half of 2023, which could begin to drive commercial value in 2023.

- Other Regulatory Submissions: Although the near-term commercial opportunity derived from regulatory approvals of SCB-2019 (CpG 1018/Alum) with the European Medicines Agency ("**EMA**") and the World Health Organization ("**WHO**") is expected to be limited compared to bilateral deals, the Company plans to complete these regulatory submissions in 2023. EMA authorization and WHO Emergency Use Listing could continue to strengthen the value of SCB-2019 (CpG 1018/Alum) in the global market and validate Clover's global development capabilities.

Commercial Manufacturing Plan: Clover's good manufacturing practice (GMP)-certified manufacturing facilities have the potential capacity to meet demand for SCB-2019 (CpG 1018/ Alum) across multiple markets. Stockpiled inventory of key raw materials to-date enables Clover to potentially produce and release over 100 million doses of SCB-2019 (CpG 1018/Alum) in 2023.

- Two GMP-Certified Commercial Facilities: The Company has the unique capability to commercially produce and supply SCB-2019 (CpG 1018/Alum) at two commercial manufacturing sites that have both passed inspections and achieved GMP-compliant status: Clover's in-house manufacturing facility in Changxing, Zhejiang Province (China GMP) and a contract development and manufacturing organization facility (European Union GMP).

- Capacity to Produce Hundreds of Millions of Doses: Across both manufacturing sites, The Company has the potential capacity to produce and supply hundreds of millions of doses annually. In 2022, the Company successfully completed a strategic procurement and stockpiling campaign for key raw material inventory to support the potential production and release of over 100 million doses of SCB-2019 (CpG 1018/Alum) in 2023.

Research and Development ("R&D") Pipeline Updates & Plans

Mid- to Late-Stage Pipeline Expansion: The Company plans to expand its mid- to late-stage pipeline (Phase 2, Phase 3, Commercial) beginning in the first half of 2023, with a focus on (1) building a leading respiratory vaccine franchise and (2) establishing a presence in the pediatric vaccine market in China and Asia Pacific region. The Company is currently pursuing multiple business development opportunities in these areas.

- At least One In-Licensing Deal in the First Half of 2023: At least one mid- to late-stage vaccine in-licensing deal announcement is expected in the first half of 2023. Potentially differentiated (first/best-in-class) assets that could generate near-term catalysts and value creation are being prioritized. Following deal execution, Clover plans to utilize its proven R&D capabilities to achieve near-term catalysts that can continue to drive value.

- Building a Leading Respiratory Vaccine Franchise: The expected seasonal nature of respiratory virus outbreaks creates a potential market opportunity for co-promoting and co-administering multiple respiratory vaccines. Seizing longer-term lifecycle management opportunities to develop co-formulated product(s) could further benefit Clover and people seeking to protect themselves and their families from multiple seasonal diseases. In pursuing these varied value-creation opportunities, the Company will leverage its synergistic capabilities in R&D, manufacturing, and commercialization to potentially be a leading company in respiratory vaccines. Prioritized areas include respiratory syncytial virus and seasonal influenza.

- Establishing a Presence in the Pediatric Vaccine Market: The pediatric vaccine market in China is stable and commercially attractive. the Company believes that having a presence in the pediatric market creates a potential cross-selling opportunity, not only within pediatrics but also across generations, such that older adults could be offered respiratory virus vaccines when bringing children and grandchildren to be vaccinated. Enterovirus A71, the leading pathogenic cause of severe cases and deaths due to hand-foot-mouth disease in children, and DTaP (diphtheria, tetanus, and pertussis) are two prioritized areas of interest for Clover.

COVID-19 R&D Pipeline:

- SCB-2019 (CpG 1018/Alum): Concurrent with its commercial launch in China, the Company plans to conduct real-world effectiveness studies, with data potentially available in the second quarter of 2023. These studies could provide valuable insight into the prevention of severe disease, hospitalization and death due to COVID-19 caused by newly circulating Omicron variants in at-risk populations, and this data has the potential to strengthen SCB-2019 (CpG 1018/Alum)'s commercial value and competitive positioning.

- Multivalent SARS-CoV-2 Vaccine Candidate: The Company is conducting research to develop a multivalent SARS-CoV-2 vaccine leveraging the Trimer-Tag™ technology platform and designed to be broadly protective against currently circulating and potential future strains of the virus. Clinical development is planned to begin in 2023, with immunological bridging to SCB-2019 (CpG 1018/Alum) planned to support potential regulatory approvals.

- SCB-2020S COVID-19 Vaccine Candidate (chimeric beta and original strain): SCB-2020S is a second generation and potentially broadly protective COVID-19 vaccine candidate that is being evaluated with CAS-1, the Company's in-house adjuvant system. In an ongoing Phase 1 study in South Africa, initial immunogenicity results indicated a robust immune response and broad neutralization against multiple Omicron strains elicited by SCB-2020S (CAS-1) that were in line with data for SCB-2019 (CpG 1018/Alum). A favorable safety and tolerability profile for SCB-2020S and CAS-1 was also observed. The results demonstrated clinical proof-of-concept for (1) antigen strain-change utilizing the Trimer-Tag™ technology platform and (2) the immunogenicity and safety of the Company's in-house CAS-1 adjuvant. The Company expects the study data to support the further development of the Company's planned multivalent SARS-CoV-2 vaccine candidate, as well as the planned use of CAS-1 adjuvant in other new vaccines internally and via partnerships.

Corporate & Financial Updates

- Cash Position: As of December 31, 2022, Clover's unaudited cash and cash equivalents was approximately US$270 million (RMB1.9 billion), supporting and positioning the Company for success beyond 2023. The Company has already stockpiled key raw materials (supporting potential production of over 100 million doses of SCB-2019 (CpG 1018/Alum)) and expects to begin converting its inventory into revenue and cash with the commercial launch in the first quarter of 2023.

- R&D and General and Administrative ("**G&A**") Expenditures in 2023: The Company expects both R&D and G&A expenditures in 2023 to decrease significantly compared to 2022 and 2021, as the late-stage clinical development for SCB-2019 (CpG 1018/Alum) (including multiple global Phase 2/3 clinical trials) has been substantially 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.

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, January 16, 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.