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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)

## VOLUNTARY ANNOUNCEMENT CLOVER ANNOUNCES POSITIVE PRELIMINARY PHASE I RESULTS FOR BIVALENT RSV VACCINE CANDIDATE SCB-1019 IN OLDER ADULT AND ELDERLY COHORT

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") on a voluntary basis to inform the shareholders of the Company and potential investors on the latest business development of the Group.

The Company is pleased to announce the positive preliminary immunogenicity and safety data in the older adult and elderly cohort from its Phase I trial evaluating SCB-1019 – the Company's bivalent RSV prefusion-stabilized F (PreF)-Trimer subunit vaccine candidate – which is based on Clover's Trimer-Tag vaccine technology platform. These preliminary results in the older adult and elderly cohort (aged 60-85) are consistent with the positive results in the young adult cohort (aged 18-59) announced earlier this year.

In the ongoing Phase I trial, 48 subjects were enrolled in the older adult and elderly cohort and received either SCB-1019 or saline placebo. Preliminary results for RSV neutralizing antibodies (nAbs) and safety for SCB-1019 at the selected dose-level are summarized below:

## **Immunogenicity Results**

- RSV-A nAbs: SCB-1019 induced geometric mean titers (GMTs) in RSV-A nAbs of up to 7,906 IU/mL compared to 1,078 IU/mL for placebo at Day 28.
- RSV-B nAbs: SCB-1019 induced geometric mean titers (GMTs) in RSV-B nAbs of up to 46,674 IU/mL compared to 12,185 IU/mL for placebo at Day 28.

- <u>Geometric Mean Fold Rise (GMFR)</u>: High baseline nAb titers on Day 0 (pre-vaccination), especially to RSV-B, were observed, potentially reflecting recent outbreaks near the clinical trial sites. Thus, sub-analysis in subjects with the lowest quartile baseline nAb titers was performed:
  - o GMFRs for SCB-1019 were up to 8-fold for RSV-A nAbs and 11-fold for RSV-B nAbs on Day 28 compared to Day 0 (pre-vaccination).
  - o No increases in RSV-A or RSV-B nAbs were observed for placebo on Day 28.
- The results of both RSV-A nAbs and RSV-B nAbs that SCB-1019 targets appear to be in-line or potentially favorable compared to other protein subunit RSV PreF vaccines<sup>1, 2, 3</sup> and continue to be supportive of Clover's bivalent RSV-A/B approach, given that other monovalent RSV-A vaccines have previously observed lower immune responses and/or efficacy against RSV-B<sup>1, 4, 5</sup>.
- The results further confirm that Clover's PreF antigens in SCB-1019 are in the stabilized prefusion and trimeric form, additionally supported by exploratory immunogenicity results demonstrating significant increases in Site Ø and Site V nAb-competitive titers.

## Safety & Reactogenicity Results

- SCB-1019 was generally well-tolerated. Local and systemic adverse events (AEs) were generally mild for SCB-1019 and were comparable to saline placebo.
- No serious adverse events (SAEs), adverse events of special interest (AESIs), or AEs leading to discontinuation were observed.
- The results indicate that SCB-1019 could potentially have a differentiated and favorable safety & reactogenicity profile compared to currently-approved oil-in-water adjuvanted<sup>4</sup> and/or mRNA<sup>5</sup>-based RSV vaccines.

The Phase I clinical trial in Australia is a randomized, placebo-controlled study to assess the safety, reactogenicity and immunogenicity of SCB-1019 at multiple dose levels and in different formulations in young and older adults. Full safety and immunogenicity results in the Phase I clinical trial are expected by the end of 2024 to support further development and strengthen our potentially differentiated profile for markets globally.

- <sup>1</sup> Icosavax Company Presentations (28-JUN-2022 & 22-MAY-2023) and Press Release (12-DEC-2023)
- <sup>2</sup> NIH DS-Cav1 (DOI: 10.1016/S2213-2600(21)00098-9)
- <sup>3</sup> Pfizer (DOI: 10.1093/infdis/jiab612)
- 4 GSK ACIP Presentation (21-JUN-2023)
- Moderna ACIP Presentation (29-FEB-2024)

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 18, 2024

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.