Clover Announces Positive Preliminary Phase I Results for Bivalent RSV Vaccine Candidate SCB-1019 in Older Adults

-- Bivalent SCB-1019 significantly boosted RSV-A and RSV-B neutralizing antibody titers in older adults up to approximately 7,900 IU/mL (up to 8-fold increase) and approximately 46,700 IU/mL (up to 11-fold increase), respectively --

-- Favorable safety & reactogenicity profile comparable to saline placebo --

-- Full Phase I data readout is planned by year-end 2024 --

SHANGHAI, June 18, 2024 /PRNewswire/ -- Clover Biopharmaceuticals, Ltd. (Clover; HKEX: 02197), a global commercial-stage biotechnology company committed to unleashing the power of innovative vaccines to save lives and improve health around the world, today announced positive preliminary immunogenicity and safety data in the older adult & 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 older adults & elderly cohort (aged 60-85) are consistent with the positive results in younger adults (aged 18-59) announced earlier this year.

"As the first RSV PreF vaccine candidate developed in China to enter the clinical trial stage and generate clinical data, SCB-1019 Phase I results in older adults demonstrate broad and significant neutralizing antibody responses against both RSV-A and RSV-B as well as a favorable tolerability profile," said **Joshua Liang, Chief Executive Officer & Board Director of Clover**. "We look forward to the full Phase I clinical readout by the end of 2024 to support further development and strengthen our potentially differentiated profile for markets globally."

In the ongoing Phase I trial, 48 subjects were enrolled in the older adult & 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 neutralizing antibody titers (nAbs) of up to 46,674 IU/mL compared to 12,185 IU/mL for placebo at Day 28.
- Geometric Mean Fold Rise (GMFR): High baseline nAb titers at 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:
  - GMFRs for SCB-1019 were up to 8-fold for RSV-A nAbs and 11-fold for RSV-B nAbs at Day 28 compared to Day 0 (pre-vaccination).
  - No increases in RSV-A or RSV-B nAbs were observed for placebo at Day 28.
- nAb results across both RSV-A and RSV-B appear to be in-line or potentially favorable compared to other protein subunit RSV PreF vaccines[1, 2, 3] 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 [1, 4, 5].
- 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.
- Results indicate that SCB-1019 could potentially have a differentiated and favorable safety & reactogenicity profile compared to currently-approved oil-in-water adjuvanted[4] and/or mRNA[5]-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.

[1] Icosavax Company Presentations (28-JUN-2022 & 22-MAY-2023) and Press Release (12-DEC-2023)

[2] NIH DS-Cav1 (DOI: 10.1016/S2213-2600(21)00098-9)

[3] Pfizer (DOI: 10.1093/infdis/jiab612)

[4] GSK ACIP Presentation (21-JUN-2023)

[5] Moderna ACIP Presentation (29-FEB-2024)

About Clover

Clover Biopharmaceuticals is a global commercial-stage biotechnology company committed to unleashing the power of innovative vaccines to save lives and improve health around the world. With integrated research and development, manufacturing and commercial capabilities as well as strong partnerships with organizations globally, Clover has a diverse pipeline of candidates that have the potential to meaningfully reduce the burden of vaccine-preventable diseases—and to make more diseases preventable.

Clover Forward-looking Statements

This press release contains certain forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used, the words "aim," "anticipate," "believe," "could," "estimate," "expect," "going forward," "intend," "may," "might," "ought to," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. We give no assurance that these expectations and assumptions will prove to have been correct. Because forward-looking statements relate to the future, they are participant to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. We caution you therefore against placing undue reliance on any of these forward-looking statements. Any forward-looking statement made by us in this document speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time.

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