Clover Provides Updates on Business and R&D Pipeline Development

-- Clover's **leading respiratory vaccine franchise** to be strengthened from commercial launch of **quadrivalent influenza vaccine** (AdimFlu-S [QIS]) in mainland China in H2-2023 --

-- Poised to be a **leading RSV vaccine player** in China with global potential by leveraging validated Trimer-Tag platform and GMP manufacturing capabilities --

-- Resilient cash balance of approximately **RMB 1.5 billion** as of June 30, 2023 compared to RMB 1.86 billion as of December 31, 2022, with approximately 50% reduction[1] in **operating expenditures** achieved in H1-2023 compared to H1-2022; trend in **increased operating efficiencies** expected to continue over the next 12 months --

SHANGHAI, China, July 11, 2023 (GLOBE NEWSWIRE) -- 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 provided updates on business and R&D pipeline development.

"Clover has achieved significant progress on building a leading respiratory vaccine franchise since the beginning of 2023 with the addition of a commercial-stage quadrivalent flu vaccine and advancement of our RSV vaccine, which is under development utilizing the validated Trimer-Tag platform," said **Joshua Liang, Chief Executive Officer and Executive Director of Clover**. "We are also taking significant steps towards corporate financial sustainability by generating revenue from vaccine sales, improving our operating efficiency and maintaining a resilient cash position to support future success."

Commercial Highlights & Plans

Quadrivalent Seasonal Influenza Vaccine Upcoming Commercialization: In February 2023, Clover announced that it entered into an exclusive agreement with Adimmune Corporation (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. Clover 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[2] 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[3]. Moreover, demand in China continues to shift from trivalent to seasonal quadrivalent influenza vaccine options, which accounted for a majority of doses (70%) [4] in 2022.
- Commercialization Plans: Commercial launch in mainland China is on track to occur in H2-2023. Adimmune commenced production of AdimFlu-S (QIS) in Q1-2023, and importation into mainland China and subsequent batch release testing are expected to occur in Q3-2023. Sales are expected to be accretive to Clover's earnings starting in 2023 and contribute meaningful growth in 2024 and beyond.
- Commercial Capabilities: Clover 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 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, Clover does not expect meaningful financial contribution from COVID-19 vaccine sales in 2023. However, Clover 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 H1-2023, Clover 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, Clover 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: Clover 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. Clover 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 H2-2023.

- 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 : Clover 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.
    - 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[5]. To achieve the stabilized PreF, Clover is utilizing the validated Trimer-Tag platform combined with proprietary stabilizing PreF mutations in its RSV vaccine candidate (SCB-1019). To date, Clover 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.
    - 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.
    - 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.
    - 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, Clover 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 pneumococcal conjugated vaccines (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, Clover is developing an updated version of its COVID-19 vaccine including the XBB.1.5 variant. Development is planned to be completed in H2-2023.

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 Q4-2023.

Corporate & Financial Updates

- **Cash Position**: Approximately RMB 1.5Bn cash and cash equivalents as of June 30, 2023 compared to RMB 1.86Bn 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[1] in operating expenditures (R&D and G&A expenditures) was achieved in H1-2023 compared to H1-2022. 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.

About Clover Biopharmaceuticals

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.

For more information, please visit Clover's website: https://www.cloverbiopharma.com/

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, and it is not possible for us to predict all of them. Participant to the requirements of applicable laws, rules and regulations, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

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[1]Based on Unaudited Results

[2]Compound annual growth rate (CGAR) based on influenza vaccine doses released in mainland China 2016-2017 and 2020-2021 with data from the China Centers for Disease Control (CDC) and National Institutes for Food and Drug Control.

[3]Reference:

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[4]Estimate based on batch release data from the China National Institutes for Food and Drug Control.

[5]Reference:

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