Clover Announces Corporate Updates and Full Year 2022 Financial Results

March 28, 2023

-- Clover's two premium respiratory vaccines approved in China (COVID-19 and seasonal influenza) are expected to drive meaningful and diversified revenues in 2023 with continued growth thereafter --

-- Clover's COVID-19 vaccine now listed in 24 provinces and municipalities in China (representing >80% population coverage) and well-positioned to be a major player in upcoming vaccination campaigns; anticipated to receive emergency use authorization (EUA) and sign a bilateral supply agreement in at least one additional country in H1 2023 --

-- AdimFlu-S (QIS) commercial production ongoing and on-track for H2 2023 launch as the only imported quadrivalent seasonal influenza vaccine approved in mainland China in a stable and growing market --

-- On track to build a leading respiratory vaccine franchise; currently the only company in China with commercial-stage quadrivalent seasonal influenza and recommended COVID-19 vaccines, with additional catalysts anticipated in 2023 as Clover continues to expand its pipeline and commercial footprint --

SHANGHAI, China, March 29, 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 announced corporate updates and financial results for the year ended December 31, 2022.

"2022 was a pivotal year for Clover as we successfully transformed into a commercial-stage, vaccines-focused biotech following regulatory clearance for our COVID-19 vaccine in China," **said Joshua Liang, Chief Executive Officer and Executive Director of Clover**. "In 2023, we have expanded our commercial-stage portfolio and now have two premium respiratory vaccines (COVID-19 and seasonal influenza) which are expected to drive meaningful and diversified revenues this year with continued growth thereafter. We plan to leverage our validated R&D capabilities and continue expanding our pipeline, with a focus on building a leading respiratory vaccine franchise and establishing a presence in the pediatric vaccines market, for long-term value creation."

Key Commercial Highlights & Plans

COVID-19 Vaccine Commercialization: Since receiving emergency use authorization (EUA) for its adjuvanted protein-based COVID-19 vaccine, SCB-2019 (CpG 1018/Alum), in China, Clover has made significant progress in expanding market access, with SCB-2019 now commercially launched in multiple provinces and successfully listed in 24 provinces and municipalities (representing >80% population coverage).

- Comprehensive Global Vaccine Development: Clinical trial results released and published in 2022 consistently demonstrated that SCB-2019 elicited broad cross-neutralization across variants. Notably, in January 2022, Clover published the final efficacy results from its global Phase 2/3 study of SCB-2019 in *The Lancet*. Clover also announced positive data from its Phase 3 study evaluating SCB-2019 as a heterologous COVID-19 booster vaccine. Results demonstrated broad and superior cross-neutralization of all Omicron subvariants tested, including recent major subvariants such as BQ.1.1 and XBB.1.5, in participants who received SCB-2019 as a heterologous fourth dose after three doses of inactivated vaccine compared to a fourth dose of inactivated vaccine.
- EUA and Expanding Market Access in China: In December 2022, SCB-2019 was included for EUA in China and subsequently recommended as a prioritized vaccine in China's national immunization plan for a second booster dose (fourth vaccination dose) campaign targeting older adults, immunocompromised individuals and individuals with comorbidities. Since the initial launch in February 2023, Clover has commercialized its vaccine in multiple provinces and has successfully listed in 24 total provinces and municipalities (representing >80% population coverage). This broad nationwide market access positions Clover to be a major player in upcoming vaccination campaigns in 2023. With the Chinese population's recent increasing awareness of the potential disease severity and impact of COVID-19, Clover believes 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 vaccines and introducing attractive product pricing dynamics.
- Ex-China Opportunities: Clover is prioritizing global (ex-China) regulatory submissions directly in select countries, primarily in Asia Pacific and Latin America, based on the potential to generate significant near-term revenue and impact via bilateral supply agreements. Clover expects SCB-2019 to receive an EUA in at least one additional country and to complete multiple EUA submissions during H1 2023, potentially driving revenue via bilateral agreements starting in 2023. In addition, Clover expects to establish at least one bilateral supply agreement in H1 2023, which could begin to drive commercial value in 2023.
- Manufacturing Milestones: In September 2022, Clover's contract development manufacturing organization (CDMO) facility received a European Union Good Manufacturing Practice (EU GMP) certificate for the production of SCB-2019.

Subsequently, Clover's in-house manufacturing facility in Changxing, Zhejiang province was inspected and achieved commercial GMP status in China. With two commercial-ready, GMP-certified facilities, Clover can flexibly meet demand as it continues rolling out the vaccine. Stockpiled inventory of key raw materials to date enables Clover to potentially produce and release over 100 million doses of SCB-2019 in 2023.

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. With this deal, Clover became the only Chinese company with commercial-stage quadrivalent seasonal influenza and recommended COVID-19 vaccines and established a presence in a rapidly growing market.

- Market Opportunity: The market for influenza vaccine in China grew by about 35% annually[1] before the pandemic and is expected to continue growing in the post-pandemic era with increasing vaccine awareness and favorable government policies. 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.[2]
- Commercialization Plans: Adimmune has already started production of AdimFlu-S (QIS) and is on track to support a commercial launch in mainland China in H2 2023. Sales are expected to be accretive to Clover's earnings starting in 2023 and contribute meaningful growth in 2024 and beyond. Further, the deal enables Clover to leverage its existing and growing commercial presence in China to commercialize both COVID-19 and influenza vaccines.
- Additional Opportunities: The agreement with Adimmune also grants Clover rights to commercialize AdimFlu-S (QIS) in Bangladesh, Brazil and the Philippines, contingent upon regulatory approvals, and to potentially collaborate with Adimmune on the development of additional vaccine candidates including next-generation influenza vaccines.

Key Research and Development (R&D) Highlights & Plans

Focused on 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. In pursuing these varied value-creation opportunities, Clover is leveraging its synergistic capabilities in R&D, manufacturing, and commercialization. Prioritized areas include respiratory syncytial virus (RSV), pneumococcus and next-generation seasonal influenza. Additionally, Clover plans to establish a presence in the pediatric vaccine market, with enterovirus A71 (EV71) and DTaP (diphtheria, tetanus, and pertussis) being two prioritized areas of interest for Clover.

- 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).
- Multivalent SARS-CoV-2 Vaccine Candidate: Clover 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 Phase 3 immunological bridging to SCB-2019 planned to support potential regulatory approvals.
- Trimer-Tagged Pre-Clinical Assets: Clover continues to leverage the validated Trimer-Tag platform technology to develop innovative protein-based vaccines with ongoing pre-clinical vaccine R&D activities.

Corporate & Financial Updates

- Cash Position: Cash and cash equivalents were RMB1,856.5 million as of December 31, 2022, compared to RMB2,835.3 million as of December 31, 2021, primarily attributable to preparations for the commercialization of SCB-2019 including a strategic procurement and stockpiling campaign for key raw material inventory and continued investment in R&D activities. Clover's cash position is expected to support and position the company for success beyond 2023.
- Operating Expenses:
  - R&D expenses were RMB1,465.3 million for 2022, compared to RMB1,826.3 million for 2021. This decrease was primarily attributable to the decrease in clinical trial expenses for late-stage clinical development of SCB-2019. The decrease was partially offset by the increase in raw materials and consumables usage and CDMO service fees mainly related to technology transfer and process validation which have been substantially completed in 2022.
  - Administrative expenses were RMB410.2 million for 2022, compared to RMB345.7 million for 2021. This increase was primarily attributable to the annualization of personnel costs in 2022 for new hires, most of whom onboarded in mid-2021. It was offset by the decrease in third-party recruitment agency costs.
  - Clover expects both R&D and G&A expenses in 2023 to decrease significantly compared to 2022, as the late-stage clinical development for SCB-2019 (including multiple global Phase 2/3 clinical trials) has been substantially completed, and the company continues to streamline corporate operations.
- Annual Loss Estimates:
  - International Financial Reporting Standards (IFRS) net loss was RMB2,451.9 million for 2022, compared to RMB6,016.3 million for 2021. The decrease was primarily attributable to the non-cash, one-time change of RMB3,807.6 million in the fair value of convertible redeemable preferred shares as required under the IFRS for

2021.

- Non-IFRS adjusted loss was RMB2,356.9 million for 2022, compared to RMB2,083.5 million for 2021. Adjusted loss for the year represents the loss for the year excluding the effect brought by share-based payment expenses and certain non-cash items and non-recurring events, namely the fair value changes of convertible redeemable preferred shares.

- Placement: In December 2022, Clover announced that it completed the placement of a total of 128,000,000 new shares, receiving net proceeds of HK$500.5 million after deducting related fees and expenses. Clover has been using the net proceeds from the placement to expand commercialization capabilities and production capacity and extend working capital needs to strengthen Clover's financial position and ensure Clover has adequate resources to support commercialization and sustained growth.

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: www.cloverbiopharma.com and follow the company on LinkedIn and Twitter.

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] 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.

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