Clover Provides Update on 2022 Corporate Milestones

October 9, 2022

-- Significant progress made on regulatory submissions to the China NMPA, the EMA, and the WHO for Clover's lead COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum), with completion anticipated in Q4 2022 --

-- New data demonstrating superiority as a heterologous booster compared to inactivated vaccine, robust neutralization of globally dominant Omicron BA.5 strain, and 84% reduction in transmission of SARS-CoV-2 infection to household contacts --

-- Clover poised to become a unique, integrated, vaccine-focused company with established China and global R&D, manufacturing and commercialization capabilities, and an innovative vaccine portfolio --

SHANGHAI, China, Oct. 09, 2022 (GLOBE NEWSWIRE) -- Clover Biopharmaceuticals, Ltd. (Clover; HKEX: 02197), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutics, today provided updates on its 2022 corporate milestones.

"We have made tremendous progress towards getting our lead COVID-19 vaccine candidate across the regulatory finish line, which remains our top priority, while generating important scientific evidence that paves the way to potentially make a meaningful contribution to national booster rollouts in the near term as well as annual boosting markets in the long term," **said Joshua Liang, Chief Executive Officer and Executive Director of Clover.** "Clover is poised to become a unique, integrated vaccine-focused company with established China and global R&D, manufacturing and commercialization capabilities. We look forward to continuing to build an innovative vaccine-focused pipeline with near-term value-creation opportunities."

"SCB-2019 (CpG 1018/Alum) remains the only domestic COVID-19 vaccine that has demonstrated superiority to inactivated vaccines, robust neutralization of the globally dominant BA.5 and significant reductions in household transmission of COVID-19, highlighting the potential meaningful and relevant impact that it could make on continued booster campaigns," **said Dr. Nicholas Jackson, President of Global Research and Development of Clover.** "We also remain excited about SCB-2020S, a second generation, potentially broadly protective COVID-19 vaccine candidate with clinical results expected in Q4 2022, as well as the continued utilization of our validated Trimer-Tag™ technology to develop innovative and impactful vaccines."

Clover's Lead COVID-19 Vaccine Candidate

Regulatory Submissions & Manufacturing Readiness: Significant recent momentum and progress has been made on the regulatory submissions for Clover's lead COVID-19 vaccine candidate, SCB-2019. Regulatory submissions are planned to be completed to the China National Medical Products Administration (NMPA), the European Medicines Agency (EMA), and the World Health Organization (WHO) in Q4 2022.

- China NMPA Submission (Clover's Changxing Facility): Clover's in-house manufacturing facility in Changxing has made meaningful progress towards good manufacturing practice (GMP) inspection readiness and has now completed previously identified facility remediations and improvements. Clover remains actively engaged with the China NMPA for the rolling conditional Biologics License Application (cBLA) submission for SCB-2019, and substantive submission-related interactions and processes have recently been completed or are currently ongoing. The rolling submission to the China NMPA is expected to be completed in Q4 2022.

- EMA & WHO Submissions (Clover's CDMO Facility): In September 2022, Clover's contract development and manufacturing organization (CDMO) received a European Union (EU) GMP certificate for the production of SCB-2019. The EU GMP certificate is in connection with Clover's regulatory submission to the EMA and follows a successful inspection of the CDMO site by the Ireland Health Products Regulatory Authority. It signifies that the production of SCB-2019 meets the EU's standards for quality and safety (**LINK**). Clover completed the production-related technology transfer activities for SCB-2019 at the CDMO site in Q3 2022 and expects to complete submissions to the EMA and the WHO in Q4 2022.

- Submissions in Other Countries: In Q3 2022, Clover held submission-related meetings with regulatory authorities in Brazil and Indonesia as part of Clover's ongoing pursuit of regulatory submissions and potential bilateral supply agreements strategically in certain countries.

Universal COVID-19 Booster Vaccine Data: New Phase 3 data demonstrating broad neutralization—including against the globally dominant Omicron BA.5 strain—underscores the potential role that SCB-2019 can play as a universal booster in China and other countries, regardless of previous vaccination or infection history and across age groups.

- Heterologous Booster Data for Boosting Inactivated Vaccine in Phase 3 Study: In September 2022, Clover reported positive data from its ongoing Phase 3 study evaluating SCB-2019 as a universal COVID-19 booster. Preliminary analyses demonstrated that a third dose of SCB-2019 in participants who previously received two doses of the inactivated vaccine

elicited 5 to 6-fold higher neutralizing immune responses against the globally dominant Omicron BA.5 strain and other Omicron subvariants tested (BA.1, BA.2) and a 12-fold higher immune response against the original SARS-CoV-2 strain compared to participants receiving a third dose of the inactivated vaccine (**LINK**) (**LINK**).

    - A sub-cohort in this ongoing Phase 3 study is evaluating SCB-2019 as a fourth-dose booster in individuals who previously received three doses of the inactivated vaccine compared to a homologous fourth dose of the inactivated vaccine, with preliminary data expected in Q4 2022.

- Robust Omicron BA.5 Neutralization Responses Across Phase 2/3 Trials: The heterologous booster data for inactivated vaccine is consistent with results announced in August 2022 demonstrating robust responses against the dominant Omicron BA.5 strain when SCB-2019 was administered as a third-dose homologous booster and for vaccination in subjects with prior infection (**LINK**).

- Substantial Reduction in Household Transmission of SARS-CoV-2 Infection: In August 2022, Clover shared new results from the Phase 2/3 SPECTRA trial which demonstrated that vaccination with SCB-2019 could substantially reduce transmission of SARS-CoV-2 infection to household contacts. Compared to placebo recipients, an individual vaccinated with SCB-2019 was 84% less likely to transmit SARS-CoV-2 infection to another individual living in the same household (**LINK**). By reducing household transmission of SARS-CoV-2 infection, these results indicate that SCB-2019 can potentially help control the spread of SARS-CoV-2 within communities.

- Positive Adolescent Data in Phase 2/3 Trial: In August 2022, Clover announced that a pivotal Phase 2/3 trial evaluating SCB-2019 in adolescents (aged 12 to 17 years) successfully met its primary endpoint and demonstrated a favorable tolerability and safety profile, consistent with results previously observed in adults (**LINK**).

Commercial Preparations & Outlook for COVID-19 Vaccine: Based on anticipated potential near-term needs in China, Clover's priority target market, the company has begun conducting activities to enable a commercial launch after receiving regulatory approval and believes that it is well-positioned to continue being a key player in the future longer-term annual boosting market for COVID-19 vaccines.

- China Commercial Launch Preparations: Based on Clover's progress with the ongoing regulatory submission, positive heterologous booster results, and the potential for a fourth-dose booster campaign (**LINK**), Clover has been actively preparing for the commercial launch in China after receiving regulatory approval. Clover has conducted extensive field work strategically in certain priority provinces and will continue to engage with policymakers. Given the continued evolution of the SARS-CoV-2 virus and the initiation of new booster campaigns in countries around the world, Clover believes that, beyond the national-level procurement phase of COVID-19 vaccine rollout, an attractive annual boosting market for COVID-19 vaccines in a private market setting could emerge over time—similar to the seasonal influenza vaccination market—favoring premium products such as Clover's adjuvanted protein-based COVID-19 vaccines.

- Update on Global Commercial Plans: In September 2022, Clover and Gavi, the Vaccine Alliance, agreed to amend their Advance Purchase Agreement (APA) to remove prior restrictions on Clover supplying vaccine doses to the China market and to deploy greater pricing flexibility in China and globally through bilateral agreements. Clover had previously received US$224 million from Gavi as advance payment for purchasing non-refundable materials related to the initial order of 64 million doses of SCB-2019, which have now been converted into an option that is exercisable over an extended period of four years at Gavi's discretion but could otherwise be supplied to China or other countries. The amended APA represents Gavi's continued collaboration and support for Clover's COVID-19 vaccine technology. Clover remains committed to providing access to its premier COVID-19 vaccine candidate and continues to pursue regulatory submissions and potential bilateral supply agreements strategically in certain countries.

Business Outlook & Pipeline Strategy

Clover is poised to become an integrated, innovative vaccine-focused company with established China and global R&D, manufacturing and commercialization capabilities. Clover plans to continue utilizing its established internal capabilities and Trimer-Tag™ technology in addition to leveraging its track record of successful cross-border collaboration to build a portfolio of innovative and potential best-in-class vaccine candidates.

Continued Development of Trimer-Tagged Vaccines: Clover continues to leverage the validated Trimer-Tag™ platform technology to develop innovative protein-based vaccines.

- SCB-2020S (chimeric beta and original strain COVID-19 vaccine candidate): SCB-2020S, a second generation and potentially broadly protective COVID-19 vaccine candidate, is being evaluated in a Phase 1 study in South Africa. The study is evaluating SCB-2020S with CAS-1, Clover's in-house adjuvant system. Safety and immunogenicity data for SCB-2020S is expected in Q4 2022. SCB-2020S represents a potential additional option for continued booster campaigns that could be complementary to SCB-2019.

- Pan SARS-CoV-2 Vaccine: Clover is conducting research to develop a multi-valent SARS-CoV-2 vaccine designed to be

broadly protective against all current and potential strains of the virus which may emerge in the future. A candidate selection for further development is planned in Q4 2022.

- SCB-1001 (Rabies G-Trimer Vaccine): Clover's rabies vaccine candidate utilizing Trimer-Tag ™ is planned to be developed with its in-house CAS-1 adjuvant. Additional preclinical results and an update on development plans for this candidate are expected in Q4 2022.

Business Development for Mid- to Late-Stage Vaccine Assets: Based on Clover's established and integrated vaccine R&D and manufacturing capabilities as well as its track record of successful cross-border collaboration, Clover is currently actively evaluating business development opportunities for mid- to late-stage innovative vaccine assets which could be synergistic with its internal Trimer-Tagged vaccine portfolio and potentially create significant near-term value.

Corporate Updates

Cash Position & Business Focus:

- Cash Position: As of June 30, 2022, Clover had cash and cash equivalents of approximately US$336 million (RMB2,256 million), which Clover believes is sufficient to sustain the company through the commercial launch of its COVID-19 vaccine and positions the company for continued success. A credit agreement with China Merchants Bank for up to US$300 million is in place and could be accessed to support potential working capital needs during commercial launch if needed. The company has no immediate plan to access this credit facility at this time.

- Business Focus: To navigate the challenges of the current macroeconomic environment, Clover has taken significant additional steps to (1) heighten focus on its core strengths and capabilities in vaccine development and (2) prudently evaluate its expenses and streamline the organization to increase efficiency and improve effectiveness. Non-core activities (including monoclonal antibody platform development) have been terminated, and headcount reductions in non-critical positions, primarily in general and administrative functions and non-core R&D roles, have occurred. Clover will continue to focus resources on achieving the company's top priorities while continuing to build an innovative vaccine-focused portfolio that can potentially generate significant near-term value-creation opportunities**.**

SCB-2019 (CpG 1018/Alum)
Clover developed the SCB-2019 antigen, a stabilized trimeric form of the S-protein based on the original strain of the SARS-CoV-2 virus, and combined it with Dynavax's (Nasdaq: DVAX) CpG 1018 advanced adjuvant and aluminum hydroxide (alum). Phase 2/3 data from 30,000+ participants across five countries showed that SCB-2019 (CpG 1018/Alum) achieved 100% efficacy against severe COVID-19 and hospitalization caused by all strains of SARS-CoV-2 circulating during the trial, and a potentially best-in-field safety profile. Clover is developing SCB-2019 (CpG 1018/Alum) as a universal booster candidate for potential use regardless of previous vaccination technology or infection history. To date, these trials have shown that SCB-2019 (CpG 1018/Alum) elicited a robust neutralization of variants including Omicron. Clover is pursuing regulatory approval of SCB-2019 (CpG 1018/Alum) with the China National Medical Products Administration, the European Medicines Agency, and the World Health Organization.

About Clover Biopharmaceuticals
Clover Biopharmaceuticals is a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutics. The Trimer-Tag™ technology platform is a product development platform for the creation of novel vaccines and biologic therapies. Clover leveraged the Trimer-Tag™ technology platform to become a COVID-19 vaccine developer and created SCB-2019 (CpG 1018/Alum) to address the COVID-19 pandemic caused by SARS-CoV-2.

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.

Clover Biopharmaceuticals:
Albert Liao
Executive Director, Corporate Communications
media@cloverbiopharma.com

Elaine Qiu

Director, Investor Relations
investors@cloverbipharma.com