Clover Provides Updates on COVID-19 Vaccine Commercial Launch and Strategic Priorities in 2023

-- China commercial launch in multiple provinces and municipalities expected to begin in Q1 2023, and Clover anticipates a significant and sustained long-term annual booster market for its premium, broadly protective protein-based COVID-19 vaccines in China --

-- SCB-2019 (CpG 1018/Alum) anticipated to receive emergency use authorization (EUA) in at least one additional country and to complete multiple EUA submissions during H1 2023, with commercial value driven via bilateral supply agreements expected beginning in 2023 --

-- Expansion of Clover's mid- to late-stage pipeline expected starting in H1 2023, with a focus on (1) building a leading respiratory vaccine franchise and (2) establishing a presence in the pediatric vaccine market in China and the Asia Pacific --

SHANGHAI, China, Jan. 15, 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 the commercialization of SCB-2019 (CpG 1018/Alum) in China and strategic priorities in 2023.

"Clover transformed into a commercial-stage, vaccines-focused biotech company with proven R&D capabilities in 2022. In 2023, we are focused on launching our vaccine in multiple countries and working with health authorities in China and globally to increase booster coverage for vulnerable populations," **said Joshua Liang, Chief Executive Officer and Executive Director of Clover**. "We are also planning to expand our mid- to late-stage vaccine pipeline for near-term value creation by leveraging our established vaccine development and proven cross-border collaboration capabilities."

"Clover is well positioned to make a significant impact on the COVID-19 response with our premium and broadly protective protein-based vaccine, both in China and globally, where the need to boost protection will likely provide attractive and unique opportunities for us in 2023 and beyond," **said Dr. Nicholas Jackson, President of Global Research and Development of Clover**. "In addition, we are excited to share our development plans to build a leading respiratory vaccine franchise and establish a presence in the pediatric vaccine market in China and the Asia Pacific, which will further strengthen Clover's competitive advantages and contribution to global health."

COVID-19 Vaccine Commercialization Updates

China Commercialization: The commercial launch for SCB-2019 in China in multiple provinces and municipalities is expected to begin in Q1 2023. Given the scale and impact of the ongoing COVID-19 outbreaks across China, Clover now anticipates a significant and sustained long-term annual booster market opportunity in China for Clover's premium and broadly protective COVID-19 vaccine.

- Recent Milestones: In early December 2022, SCB-2019 was included for emergency use authorization (EUA) in China. Subsequently, the China National Health Commission formally announced its national immunization plan for a fourth dose booster campaign and recommended prioritizing specified vaccines that demonstrate broad neutralization against Omicron, including SCB-2019, for use. Additionally, the price setting process for SCB-2019 commercialized via national procurement was completed with the China National Healthcare Security Administration.

- Commercial Launch Expected to Begin in Q1 2023: Clover has started commercial launch preparation activities in multiple key provinces and municipalities, based on Clover's evaluation of market dynamics (including factors such as strategic fit, population size and competitive environment). To date, Clover has received robust interest and demand based on the premium product profile of SCB-2019 and expects the commercial launch in these strategically prioritized areas to begin in Q1 2023. Further expansion to additional provinces and municipalities is anticipated to occur throughout 2023, based on production capacity and market dynamics.

- Impact of Ongoing COVID-19 Outbreaks:

    - Near Term – Wider Window to Supply to Market: As COVID-19 continues to spread rapidly across China, the number of previously infected people is expected to increase significantly through the first half of 2023. Immunity induced by prior natural infection has been observed to wane rapidly[1], especially against Omicron[2], leading countries around the world to recommend booster vaccination at an interval range of one to six months after infection[3]. While Clover's initial commercial launch in China starting in Q1 2023 will likely be primarily comprised of boosting infection-naïve individuals, Clover expects booster vaccination of previously infected individuals to begin in Q2 2023 and to increase in proportion through the remainder of the year. Thus, Clover anticipates a more sustained, rather than short-term, rollout of booster vaccinations throughout 2023, giving Clover a wider window of time to ramp up production and maximize the impact of its premium COVID-19 vaccine.
    - Longer Term – Sustained & Robust Annual Booster Market: With the Chinese population's recent increasing awareness of the potential disease severity and impact of COVID-19, Clover believes that the level of certainty and the potential size of the future annual booster market for COVID-19 vaccines have increased significantly. Beyond

the current National Procurement phase of COVID-19 vaccine rollout, Clover anticipates 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.

Global (Ex-China) Commercialization: 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 deals starting in 2023.

- Bilateral EUA Submissions and Procurement Deals: Clover is now 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. In addition to submitting multiple EUA applications and receiving at least one EUA for SCB-2019, Clover also expects to establish at least one bilateral supply agreement in H1 2023, which could begin to drive commercial value in 2023.

- Other Regulatory Submissions: Although the near-term commercial opportunity derived from regulatory approvals of SCB-2019 with the European Medicines Agency (EMA) and the World Health Organization (WHO) is expected to be limited compared to bilateral deals, Clover plans to complete these regulatory submissions in 2023. EMA authorization and WHO Emergency Use Listing could continue to strengthen the value of SCB-2019 in the global market and validate Clover's global development capabilities.

Commercial Manufacturing Plan: Clover's good manufacturing practice (GMP)-certified manufacturing facilities have the potential capacity to meet demand for SCB-2019 across multiple markets. Stockpiled inventory of key raw materials to-date enables Clover to potentially produce and release over 100 million doses of SCB-2019 in 2023.

- Two GMP-Certified Commercial Facilities: Clover has the unique capability to commercially produce and supply SCB-2019 at two commercial manufacturing sites that have both passed inspections and achieved GMP-compliant status: Clover's in-house manufacturing facility in Changxing, Zhejiang Province (China GMP) and a contract development and manufacturing organization facility (European Union GMP).

- Capacity to Produce Hundreds of Millions of Doses: Across both manufacturing sites, Clover has the potential capacity to produce and supply hundreds of millions of doses annually. In 2022, Clover successfully completed a strategic procurement and stockpiling campaign for key raw material inventory to support the potential production and release of over 100 million doses of SCB-2019 in 2023.

R&D Pipeline Updates & Plans

Mid- to Late-Stage Pipeline Expansion: Clover plans to expand its mid- to late-stage pipeline (Phase 2, Phase 3, Commercial) beginning in H1 2023, with a focus on (1) building a leading respiratory vaccine franchise and (2) establishing a presence in the pediatric vaccine market in the China and Asia Pacific region. Clover is currently pursuing multiple business development opportunities in these areas.

- At Least One In-Licensing Deal in H1 2023: At least one mid- to late-stage vaccine in-licensing deal announcement is expected in H1 2023. Potentially differentiated (first/best-in-class) assets that could generate near-term catalysts and value creation are being prioritized. Following deal execution, Clover plans to utilize its proven R&D capabilities to achieve near-term catalysts that can continue to drive value.

- Building a Leading Respiratory Vaccine Franchise: The expected seasonal nature of respiratory virus outbreaks creates a potential market opportunity for co-promoting and co-administering multiple respiratory vaccines. Seizing longer-term lifecycle management opportunities to develop co-formulated product(s) could further benefit Clover and people seeking to protect themselves and their families from multiple seasonal diseases. In pursuing these varied value-creation opportunities, Clover will leverage its synergistic capabilities in R&D, manufacturing, and commercialization to potentially be a leading company in respiratory vaccines. Prioritized areas include respiratory syncytial virus (RSV) and seasonal influenza.

- Establishing a Presence in the Pediatric Vaccine Market: The pediatric vaccine market in China is stable and commercially attractive. Clover believes that having a presence in the pediatric market creates a potential cross-selling opportunity, not only within pediatrics but also across generations, such that older adults could be offered respiratory virus vaccines when bringing children and grandchildren to be vaccinated. Enterovirus A71 (EV71), the leading pathogenic cause of severe cases and deaths due to Hand, Foot and Mouth disease in children, and DTaP (diphtheria, tetanus, and pertussis) are two prioritized areas of interest for Clover.

COVID-19 R&D Pipeline:

- SCB-2019: Concurrent with its commercial launch in China, Clover plans to conduct real-world effectiveness studies, with data potentially available in H2 2023. These studies could provide valuable insight into the prevention of severe disease, hospitalization and death due to COVID-19 caused by newly circulating Omicron variants in at-risk populations, and this

data has the potential to strengthen SCB-2019's commercial value and competitive positioning.

- 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 immunological bridging to SCB-2019 planned to support potential regulatory approvals.

- SCB-2020S COVID-19 Vaccine Candidate (chimeric beta and original strain): SCB-2020S is a second generation and potentially broadly protective COVID-19 vaccine candidate that is being evaluated with CAS-1, Clover's in-house adjuvant system. In an ongoing Phase 1 study in South Africa, initial immunogenicity results indicated a robust immune response and broad neutralization against multiple Omicron strains elicited by SCB-2020S (CAS-1) that were in line with data for SCB-2019. A favorable safety and tolerability profile for SCB-2020S and CAS-1 was also observed. The results demonstrated clinical proof-of-concept for (1) antigen strain-change utilizing the Trimer-Tag™ technology platform and (2) the immunogenicity and safety of Clover's in-house CAS-1 adjuvant. Clover expects the study data to support the further development of Clover's planned multivalent SARS-CoV-2 vaccine candidate, as well as the planned use of CAS-1 adjuvant in other new vaccines internally and via partnerships.

Corporate & Financial Updates

- Cash Position: As of December 31, 2022, Clover's unaudited cash and cash equivalents was approximately US$270 million (RMB 1.9 billion), supporting and positioning the company for success beyond 2023. Clover has already stockpiled key raw materials (supporting potential production of over 100 million doses of SCB-2019) and expects to begin converting its inventory into revenue and cash with the commercial launch in Q1 2023.

- R&D and G&A Expenditures in 2023: Clover expects both R&D and G&A expenditures in 2023 to decrease significantly compared to 2022 and 2021, 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.

About 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. In December 2022, SCB-2019 (CpG 1018/Alum) was included for emergency use authorization in the People's Republic of China and included in the National Health Commission's fourth dose booster implementation plan.

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.

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

Elaine Qiu
Director, Investor Relations
investors@cloverbiopharma.com

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[2] Nguyen, D., Lamothe, P., Woodruff, M. et al. (2022). COVID-19 and plasma cells: Is there long-lived protection? *Immunological Reviews.*Jul8(309)1:40-63.

[3] US: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection, Canada: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a6.2, UK: https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a, Australia: https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/clinical-guidance/clinical-recommendations, Israel: https://corona.health.gov.il/en/vaccine-for-covid/over-12/, South Africa: https://globalenvironmentandtechnology.app.box.com/s/nn930h2cpff35uooq7sdd12mhxepssn2/file/1063790237613, WHO: https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-(covid-19)-vaccines