Clover Provides Corporate Update and 2022 Priorities

February 14, 2022

- *Clover announces **universal COVID-19 vaccine booster** development plan to support global use of its COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum)*
- *The development plan is supported by clinical booster data demonstrating SCB-2019 (CpG 1018/Alum) induces at least **3-fold higher neutralizing antibodies** compared to AstraZeneca's COVID-19 vaccine, in people previously receiving two doses of AstraZeneca's vaccine*
- *Regulatory submissions for SCB-2019 (CpG 1018/Alum) are expected to include booster data and are expected to be completed in mid-2022 for the China NMPA and in Q3 2022 for the WHO and EMA, with product launches commencing thereafter upon receiving conditional approvals*

CHENGDU, China, Feb. 14, 2022 (GLOBE NEWSWIRE) -- Clover Biopharmaceuticals, Ltd. (Clover; HKEX: 02197), a global clinical-stage biotechnology company developing novel vaccines and biologic therapeutic candidates, today provided a corporate update and highlighted 2022 priorities.

"2021 was a transformative year for Clover and we are proud of the progress we have achieved. We announced positive global Phase 2/3 efficacy data for our COVID-19 vaccine candidate, signed an Advanced Purchase Agreement with GAVI to enable potential supply of over 400 million doses to the COVAX Facility, and received over US$850 million in cash from partnerships and financings including an Initial Public Offering on the Hong Kong Stock Exchange," stated **Joshua Liang, Chief Executive Officer and Executive Director of Clover Biopharmaceuticals**. "Our immediate priorities are to expedite global conditional approvals of our protein-based COVID-19 vaccine candidate and to complete its development as a universal COVID-19 vaccine booster. We also continue to advance and expand our portfolio of innovative vaccines and oncology therapies in parallel with expanding our global R&D infrastructure and capabilities to support our ambitions of becoming a leading innovative global biotech."

"As the global COVID-19 landscape continues to evolve, with waning immunity from prior vaccination and the continued emergence of new variants such as Omicron, the need for a safe and effective universal COVID-19 booster vaccine has become paramount," stated **Nicholas Jackson, President of Global R&D of Clover Biopharmaceuticals**. "Given the growing evidence demonstrating that SCB-2019 (CpG 1018/Alum) induces strong booster responses in previously-vaccinated and previously-infected individuals, combined with its favorable safety and reactogenicity profile and stability under standard refrigerated conditions, we believe that SCB-2019 (CpG 1018/Alum) could become an important universal COVID-19 booster vaccine for the global markets."

COVID-19 Vaccine Candidate

Universal COVID-19 Booster Vaccine Development: Clover plans to complete development of its COVID-19 vaccine candidate as a universal COVID-19 booster vaccine in 2022, to potentially enable its use as a booster dose, regardless of the vaccine technology used for the primary vaccination or previous SARS-CoV-2 infection history.

- Boosting individuals who previously had SARS-CoV-2 infection: Data from the Phase 2/3 SPECTRA trial demonstrated that vaccination with SCB-2019 (CpG 1018/Alum) in individuals previously infected with SARS-CoV-2 rapidly boosted neutralizing antibodies to levels resulting in a reduction in the risk of COVID-19 by 64.2% (against any strain) compared to prior-infection alone.
- Booster immune response in persons who previously received AstraZeneca's vaccine : Initial data from a Phase 2 investigator-led clinical trial in Brazil demonstrates that a single SCB-2019 (CpG 1018/Alum) booster dose induces at least 3-fold higher neutralizing antibodies against the prototype strain compared to a booster dose of AstraZeneca's COVID-19 vaccine in individuals who previously received two doses of AstraZeneca's vaccine. A fractional dose of SCB-2019 vaccine candidate also induced an immune response that appeared to be superior to AstraZeneca's COVID-19 vaccine. There were no observed safety concerns from the available safety data across the tested vaccine formulations. The study has enrolled 111 participants who had received a 2-dose primary immunization series with AstraZeneca's COVID-19 vaccine and were administered a booster with a standard dose of SCB-2019, a fractional SCB-2019 dose, or a fractional SCB-2019 dose with (Alum). The initial immunogenicity results are from an interim analysis in 76 participants, and additional data are expected in 1H-2022.
- Boosting individuals who previously received an inactivated vaccine: Initial data from a Phase 2 clinical trial in Brazil evaluating SCB-2019 (CpG 1018/Alum) as a booster in individuals who previously received two doses of Coronavac is expected by Q2-2022.
- Boosting individuals who previously received SCB-2019: The Phase 2/3 SPECTRA trial is currently enrolling up to 4,000 participants to evaluate SCB-2019 (CpG 1018/Alum) as a third booster dose. Initial data are anticipated by Q2-2022.
- Additional trials evaluating SCB-2019 (CpG 1018/Alum) as a universal booster (including as a booster in individuals who previously received mRNA vaccine) are planned in 2022.

Regulatory and Manufacturing: Clover remains actively engaged with the China NMPA, EMA and the WHO regarding data needed to support conditional approval for SCB-2019 (CpG 1018/Alum) and anticipates including booster clinical data in its regulatory submissions. Clover expects to complete regulatory submissions by mid-2022 for the China NMPA and by Q3-2022 for the WHO and EMA, with product launch commencing thereafter upon receiving conditional approvals.

Clover received feedback from the WHO in December 2021 following their GMP inspection of the Clover Changxing manufacturing facility. Clover has engaged contractors from a leading global CDMO to supplement internal expertise and anticipates that the facility will be ready for additional pre-approval GMP inspections from the NMPA and the WHO by Q2-2022.

International travel and associated quarantine requirements due to the pandemic impacted the timing of a potential GMP inspection of Clover's Changxing manufacturing facility by the EMA. In early 2022, Clover decided to utilize an established CDMO site familiar to the EMA and WHO regulatory authorities to support and advance its EMA submission. This plan provides Clover with a second pathway to potentially receive WHO EUL, a strategic approach to help ensure Clover can launch its COVID-19 vaccine globally as soon as possible.

Clover remains committed to fulfill its commitment to the COVAX Facility as well as making its COVID-19 vaccine available for procurement in China. In parallel, Clover is also evaluating potential regulatory submissions to specific countries for Emergency Use Authorizations (EUAs) or conditional approvals. To meet the expected global demand, Clover has engaged multiple CDMO sites in order to augment its internal manufacturing capacity.

Commercial & Development Partnerships: Demand for COVID-19 vaccines remains strong globally for primary vaccination and booster doses. We believe SCB-2019 (CpG 1018/Alum) has the potential to be differentiated with its high efficacy, potential best-in-field safety and tolerability, and need for standard refrigeration storage and transportation conditions. After signing an Advanced Purchase Agreement (APA) with GAVI in June 2021 that enables potential supply of over 400 million doses globally to the COVAX Facility, Clover has continued to expand existing and establish new global partnerships to ensure fair and equitable global distribution of SCB-2019 (CpG 1018/Alum) to those most in need.

- Expanded CEPI Funding: In November 2021, CEPI committed up to an additional US$36.9 million (for a total investment of up to US$397.4 million) to support the development of SCB-2019 (CpG 1018/Alum) through licensure for use as a primary vaccination for all age groups (including pediatric, adolescent, adult, and elderly) and as a potential booster candidate.
- UNICEF LTA Signed: In December 2021, Clover entered into a long-term agreement (LTA) with UNICEF to support the supply of Clover's COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum), to the COVAX Facility.
- GAVI APA Milestone Payment Received: In December 2021, Clover received a milestone payment of US$64 million from GAVI upon achieving certain milestones bringing the total funding received to-date from GAVI under the APA to US$224 million.

Other Clinical Updates for SCB-2019: In conjunction with universal COVID-19 booster evaluation, Clover continues to generate data on SCB-2019 (CpG 1018/Alum) for additional populations. Further studies are ongoing or planned to support SCB-2019 (CpG 1018/Alum) as a primary vaccination for all age groups (pediatric, adolescent, adult, and elderly) as well as in subpopulations, based upon the favorable safety profile observed in SPECTRA.

- Adolescents (12-18 Years): In January 2022, Clover amended SPECTRA to evaluate the immunogenicity and safety of SCB-2019 (CpG 1018/Alum) for primary vaccination in an adolescent (12-18 years) subgroup in an expanded 1,200 adolescent population. Initial data is anticipated in the first half of 2022.
- Pediatrics: Clover has alignment with the EMA Pediatric Committee on its Pediatric Investigation Plan (PIP) and plans to initiate clinical development and enrollment of pediatric participants dosed with SCB-2019 (CpG 1018/Alum) in the first half of 2022, with preliminary results by the second half of 2022.
- SPECTRA Final Efficacy Data Published in *The Lancet*: In January 2022, final efficacy analysis and safety data for two doses of SCB-2019 (CpG 1018/Alum) utilized for primary vaccination in the global Phase 2/3 SPECTRA trial was published in the peer-reviewed journal, The Lancet.

Omicron and Variants of Concern: Clover is pursuing a multi-prong strategy to evaluate and tackle the Omicron variant and the ongoing emergence of variants of concern. We continue to evaluate various modalities and generate additional clinical and preclinical data to inform our strategy against Omicron and potential future variants.

- SCB-2019 (CpG 1018/Alum) Universal Booster: All ongoing and planned booster clinical trials will include testing for neutralization of the Omicron variant, with data readouts expected throughout the first half of 2022.
- Variant-Adapted COVID-19 Vaccine Candidates: Clover has produced and is evaluating multiple variant-adapted protein-based vaccine candidates (including Omicron-specific), utilizing the validated Trimer-Tag™ platform technology. Future development will be guided by data generated and the need for variant-adapted and broadly protective COVID-19 vaccine candidates.

Corporate and Pipeline

Oncology Pipeline: Clover is continuing the clinical development of its oncology assets including the planned advancement of SCB-313 into a Phase 2 trial for malignant ascites in 2022, as well as the planned initiation of a new Phase 1 trial in bladder cancer. SCB-313 is Clover's lead oncology asset utilizing the Trimer-Tag™ technology platform and targets the tumor necrosis factor-related apoptosis-inducing ligand (TRAIL).

- SCB-313 Ascentage Pharma Collaboration: In December 2021, Clover formed a clinical collaboration with Ascentage Pharma to evaluate Clover's SCB-313, a recombinant human TRAIL-Trimer fusion protein, in combination with Ascentage Pharma's APG-1387, a second mitochondria-derived activator of caspase (SMAC)-mimetic/inhibitor of apoptosis proteins

(IAP) antagonist, in a Phase 1b/2 clinical trial for advanced peritoneal carcinomatosis.

- SCB-219 IND Approved by CDE: In December 2021, the CDE approved the IND for SCB-219 (novel TPO-mimetic Fc fusion protein) for the treatment of chemotherapy-induced thrombocytopenia (CIT) and idiopathic thrombocytopenic purpura (ITP). The company plans to advance the program into a Phase 1 clinical trial in mid-2022.

Corporate:

- Leadership Growth: In February 2022, Clover appointed Dr. Nicholas Jackson, Ph.D., as President of Global Research and Development to lead the expansion of global R&D capabilities and accelerate the development of new and existing vaccine and oncology pipeline programs.
- Shanghai R&D Center: In January 2022, Clover announced the construction of a new R&D Center in Zhangjiang Hi-Tech Park to expand its preclinical development, process development, and pilot manufacturing capabilities.
- UK Antibody Innovation Center: Clover has initiated the establishment of an Antibody Innovation Center facility in the United Kingdom to develop novel monoclonal antibody platform technologies, which will be utilized for developing monoclonal antibodies in oncology and infectious diseases.
- HKEX Initial Public Offering: In November 2021, Clover successfully completed its Initial Public Offering on the Hong Kong Exchange (HKEX: 02197), raising US$258 million in gross proceeds from top-tier institutional investors including Orbimed, Hillhouse, Temasek, and Rock Springs Capital.

About SCB-2019 (CpG 1018/Alum)

SCB-2019 (CpG 1018/Alum), our COVID-19 vaccine candidate, is anticipated to potentially be one of the first protein-based COVID-19 vaccines commercialized globally through the COVAX Facility. Employing the Trimer-Tag™ technology platform, Clover developed the SCB-2019 antigen, a stabilized trimeric form of the S-protein (referred to as S-Trimer™) based on the original strain of the SARS-CoV-2 virus. Clover created its COVID-19 vaccine candidate by combining SCB-2019 with Dynavax's (Nasdaq: DVAX) CpG 1018 advanced adjuvant and aluminum hydroxide (alum).

About Clover Biopharmaceuticals

Clover Biopharmaceuticals is a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates. 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.

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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