BIOPHARMACEUTICALS

Clover and CEPI Expand Partnership for COVID-19 Vaccine Candidate to Include Evaluation as a Booster

November 18, 2021

- CEPI commits up to an additional US\$36.9 million for a total investment of up to \$397.4 million to support the development of Clover's COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum)
- CEPI funding supports development of SCB-2019 (CpG 1018/Alum) for primary vaccination across all age groups (pediatric, adolescent, adults, and elderly) and development as a potential booster

CHENGDU, China and OSLO, Norway, Nov. 18, 2021 (GLOBE NEWSWIRE) -- <u>Clover Biopharmaceuticals, Ltd. (Clover; Stock code: 2197.HK)</u>, a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates, and <u>CEPI</u>, the Coalition for Epidemic Preparedness Innovations, today announced that CEPI will provide up to an additional US\$36.9 million in funding to support continued development of SCB-2019 (CpG 1018/Alum) through licensure. This brings CEPI's total potential funding in SCB-2019 (CpG 1018/Alum) up to US\$397.4 million, which represents one of CEPI's largest investments in a COVID-19 vaccine manufacturer to date. Previous CEPI funding has supported preclinical and clinical testing of the vaccine, in addition to scaling up the manufacturing process. Pending WHO Emergency Use Listing (EUL), Clover will supply up to 414 million doses of the vaccine to the COVAX Facility for equitable distribution.

Clover is utilizing the funding from CEPI to develop SCB-2019 (CpG 1018/Alum) as a primary vaccination for all age groups (pediatric, adolescent, adults and elderly) and as a potential booster for previously-infected individuals and populations that have received SCB-2019 (CpG 1018/Alum) for the primary vaccination (homologous booster). In September 2021, Clover announced SPECTRA, a global pivotal phase 2/3 clinical trial evaluating the efficacy, safety, and immunogenicity of SCB-2019 (CpG 1018/Alum) met the primary and secondary endpoints and that a single dose of SCB-2019 (CpG 1018/Alum) in individuals who had previously been infected by SARS-CoV-2 induced a rapid and strong boosting effect on neutralizing antibody titers¹. Evaluation of SCB-2019 (CpG 1018/Alum) as a homologous booster will be conducted as an expansion arm of SPECTRA and initiate in the near-term. Clover is also in the process of planning multiple heterologous booster studies with SCB-2019 (CpG 1018/Alum).

"Clover appreciates the continued partnership with CEPI and their support for developing SCB-2019 (CpG 1018/Alum) as a potential COVID-19 booster vaccine. We believe that SCB-2019 (CpG 1018/Alum) is well-positioned to be evaluated as a universal COVID-19 booster vaccine, given the significant efficacy against variants as well as the favorable safety profile demonstrated in the Phase 2/3 SPECTRA trial. If successful, SCB-2019 (CpG 1018/Alum) could be an important tool to provide continued protection against COVID-19 for those most in need globally," said Joshua Liang, CEO of Clover Biopharmaceuticals.

Dr. Richard Hatchett, CEO of CEPI noted, "While multiple safe and effective COVID-19 vaccines are now available we know that COVID-19 is here to stay, so further R&D is needed to inform vaccination strategies that will help control the virus in the long-term. I'm pleased to further expand CEPI's R&D partnership with Clover which will maximize the potential impact of this vaccine as we seek to protect those most at risk from COVID-19, wherever they are in the world."

About SCB-2019 (CpG 1018/Alum)

SCB-2019 (CpG 1018/Alum), Clover's 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 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 our website: www.cloverbiopharma.com and follow the company on LinkedIn.

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines against future epidemics. Prior to COVID-19 CEPI's work focused on developing vaccines against Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus - it has over 20 vaccine candidates against these pathogens in development. CEPI has also invested in new platform technologies for rapid vaccine development against unknown pathogens (Disease X).

During the current pandemic, CEPI initiated multiple programmes to develop vaccines against SARS-CoV-2 and its variants with a focus on speed, scale, and access. These programmes leverage the rapid response platforms previously developed by CEPI's partners prior to the emergence of COVID-19 as well as new collaborations. The aim is to advance clinical development of a diverse portfolio of safe and effective COVID-19 candidates and to enable fair allocation to these vaccines worldwide through COVAX.

CEPI's 5-year plan lays out a \$3.5 billion roadmap to compress vaccine development timelines to 100 days, develop a universal vaccine against COVID-19 and other *Betacoronaviruses*, and create a "library" of vaccine candidates for use against known and unknown pathogens. The plan is available at endpandemics.cepi.net.

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About the COVAX Facility

COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO.

Forward-looking Statements (relating to Clover)

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 in this [document], the words "aim," "anticipate," "believe," "could," "estimate," "expect," "going forward," "intend," "may," "might," "ought to," "plan," "potential," "predict," "project," "seek," "should," "wull," "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:

Cindy Min SVP, Public Affairs media@cloverbiopharma.com

Naomi Eichenbaum VP, Investor Relations investors@cloverbiopharma.com

CEPI

Email:<u>press@cepi.net</u> Phone: +44 7387 055214

¹ https://ir.cloverbiopharma.com/news-releases/news-release-details/clovers-covid-19-vaccine-candidate-demonstrates-79-efficacy



Source: Clover Biopharmaceuticals