

China's Clover Biopharma to launch protein-based COVID-19 vaccine by 2021-end

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SCB-2019 is anticipated to potentially be one of the first protein-based COVID-19 vaccines commercialized globally through the COVAX Facility



China-based Clover Biopharmaceuticals has announced that its wholly-owned subsidiary, Zhejiang Clover Biopharmaceutical, Inc., has received a Pharmaceutical Manufacturing Permit from the Zhejiang Medical Products Administration for the production of Clover's protein-based COVID-19 vaccine candidate at its facility in Changxing, Zhejiang province, China (Changxing facility).

Clover's in-house, commercial-ready biologics manufacturing Changxing facility has a centrally-automated and flexible start-to-finish platform based on single-use technologies.

The Changxing facility was designed to adhere to current Good Manufacturing Practices (cGMP) standards in accordance with NMPA, FDA, and EMA regulations. At peak capacity, the Changxing facility will have the potential to annually produce more than one billion doses of antigen for Clover's COVID-19 vaccine candidate, SCB-2019.

Pending positive results from SPECTRA, Clover's global pivotal Phase 2/3 clinical COVID-19 vaccine candidate trial, the Company plans to submit conditional regulatory approval applications for SCB-2019 (CpG 1018/Alum) to the NMPA, EMA, and WHO thereafter. Pending conditional approval, Clover expects to commence product launch of SCB-2019 (CpG 1018/Alum) which may occur as early as year-end 2021.