

Cytiva supports Clover Biopharma to scale up output of COVID-19 vaccine candidate

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Clover aims to double its commercial manufacturing capacity in preparation for global Phase 2/3 trials



US-based Cytiva, a global life sciences leader, is supporting Shanghai-based Clover Biopharmaceuticals, a global clinical-stage biotechnology company, to help accelerate the development and manufacturing of a protein-based S-Trimer subunit vaccine candidate. With promising preliminary safety and immunogenicity results from the Phase 1 clinical study, Clover aims to quickly expand its current 2 x 2000L capacity of the Cytiva FlexFactory, which went into service in January 2020.

Cytiva will help Clover add two more 2000L bioreactors for a total of 4 x 2000L manufacturing capacity through the Cytiva FlexFactory, which will provide a total solution including process equipment, services, and consumables to ensure safety, efficiency, scaled-up capacity for vaccine development.

Clover's COVID-19 S-Trimer vaccine was developed by combining the trimeric SARS-CoV-2 spike (S)-protein with the company's proprietary Trimer-Tag[®] technology. As the first company in the world to produce a COVID-19 vaccine candidate that is successfully recognized by antibodies produced by previously-infected patients, Clover demonstrates that S-Trimer has preserved the native structure of the viral spike (S) protein and thus may elicit a protective immune response as a vaccine.

Clover's Phase 1 clinical study has completed enrollment of 150 adult and elderly participants. Based on positive preliminary results, an additional 280 participants will be enrolled in a Phase 1 dose-expansion study at a selected S-Trimer dose-level. The company intends to initiate a global Phase 2/3 vaccine efficacy study before the end of 2020.

The clinical trials and Clover's COVID-19 vaccine program are supported by funding and collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI). The agreement between CEPI and Clover anticipates that the vaccine – if proven to be safe and effective – will be made available for procurement and allocation through the COVAX Facility to those who need it most around the world.