

Bharat Biotech partners with Ocugen to develop COVID-19 vaccine for US

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Builds upon the promising safety and immunogenicity data in the Phase 1 and Phase 2 trials



Ocugen, Inc. and Bharat Biotech have announced that the companies have signed a binding letter of intent (LOI) to co-develop Bharat Biotech's COVID-19 vaccine candidate, COVAXIN™, an advanced stage whole-viron inactivated vaccine candidate, for the United States market.

COVAXIN™ has been evaluated in approximately 1,000 subjects in Phase 1 and Phase 2 clinical trials in India, with promising safety and immunogenicity data.

The vaccine candidate is currently part of a Phase 3 clinical trial in India involving 26,000 volunteers.

As per the LOI, Ocugen will have US rights to the vaccine candidate and, in collaboration with Bharat Biotech, will be responsible for clinical development, registration, and commercialization for the US market.

The companies have begun collaborating and will finalize details of the definitive agreement in the next few weeks. This collaboration leverages Ocugen's vaccine expertise, and its R&D and regulatory capabilities in the US.

In preparation for the development of COVAXIN™ in the US, Ocugen has assembled a Vaccine Scientific Advisory Board featuring leading academic and industry experts to evaluate the clinical and regulatory path to approval in the US market.