

Bharat Biotech plans to take COVAXIN to US market

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Ocugen and Bharat Biotech to share US commercialization profits



Ocugen, Inc., a US based biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to fight COVID-19, and Bharat Biotech, a global leader in vaccine innovation, have announced they have entered into a definitive agreement to co-develop, supply, and commercialize Bharat Biotech's COVAXIN™, an advanced stage whole-virion inactivated COVID-19 vaccine candidate, for the United States market.

Under the terms of the agreement, Ocugen will have US rights to the vaccine candidate and will be responsible for clinical development, regulatory approval (including EUA) and commercialization for the US market.

Bharat Biotech will supply initial doses to be used in the US upon Ocugen's receipt of an EUA. In addition, Bharat Biotech will support the technology transfer for manufacturing in the US. In consideration for the exclusive license to the US market, Ocugen will share the profits from the sale of COVAXIN™ in the US market with Bharat Biotech, with Ocugen retaining 45% of the profits.

The collaboration will leverage the vaccine expertise of Ocugen's leadership team. In preparation for the development of COVAXIN™ in the US, Ocugen's Vaccine Scientific Advisory Board and Ocugen management have initiated discussions with the U.S. Food & Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority (BARDA) to develop a regulatory path to EUA and, eventually, biologics license application (BLA) approval in the US market for COVAXIN™.

Ocugen is also in active discussions with manufacturers in the US to produce a significant number of doses of COVAXIN™ to support its US immunization program.

"The COVID-19 pandemic has affected humanity at large. As a company determined to protect global public health, it has always been important for us to develop vaccines for a global cause. Our goal for all vaccines developed at Bharat Biotech is to provide global access. COVAXIN™ has generated excellent safety data with robust immune responses to multiple viral proteins that persist. With the recent progression of COVAXIN use under EUA in India, I am confident that we will be able to work with Ocugen to develop a plan to bring COVAXIN to the US market.," said Dr. Krishna Ella, Chairman & Managing Director of Bharat Biotech.