



## **Ocugen Secures Manufacturing Partnership for US Production of COVID-19 Vaccine Candidate, COVAXIN™**

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### **Jubilant HollisterStier to manufacture COVAXIN™ in the US**

MALVERN, Pa., June 15, 2021 (GLOBE NEWSWIRE) -- [Ocugen, Inc.](#) (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19, today announced that it has selected Jubilant HollisterStier of Spokane, Washington as its manufacturing partner for [COVAXIN™](#) to prepare for potential commercial manufacturing of COVAXIN™ for the US and Canadian markets.

"We are fully committed to bringing COVAXIN to the US and Canadian markets because we believe it has the potential to save lives by adding a weapon to the arsenal in the fight against emerging variants," said [J.P. Gabriel](#), Ocugen's Senior Vice President, Manufacturing and Supply Chain. "Securing US-based manufacturing capability is a critical step as we prepare to submit our regulatory submissions to the FDA and Health Canada. Based on Bharat Biotech's strong track record of developing and commercializing vaccines globally and Jubilant's proven track record in manufacturing, we are well-prepared to transition US manufacturing of COVAXIN to our new partner."

"We are excited to expand our basket of vaccine products and meet the increasing demand from our customers for COVID-19 vaccines in the US," said Amit Arora, President Jubilant HollisterStier.

"We are pleased to partner with Ocugen and support the ongoing fight against COVID-19. With two facilities in North America working to manufacture multiple COVID-19 vaccines and therapies, we remain committed to supporting efforts to eradicate this global pandemic," stated Pramod Yadav, CEO Jubilant Pharma Limited.

### **About COVAXIN™**

COVAXIN™, India's COVID-19 vaccine by Bharat Biotech, is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). COVAXIN™ is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform. This platform has an excellent safety track record of more than 300 million doses of various vaccines supplied. Based on a traditional vaccine platform that has a long-established safety profile, COVAXIN™ continues to show strong results in all the studies conducted to date including a vaccine efficacy rate of 78% overall efficacy and 100% in severe COVID-19 disease, including hospitalizations, in second interim results of Bharat Biotech's Phase 3 clinical trial.

In addition to generating strong immune response against multiple antigens, COVAXIN has been shown to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. With published data demonstrating a safety profile superior to published safety data from separate studies for several other vaccines, COVAXIN is packaged in multi-dose vials that can be stored at 2-8°C.

COVAXIN studies show potential effectiveness against three key variants of SARS-CoV-2. Scientists at the Indian Council of Medical Research (ICMR)-National Institute of Virology, using an in-vitro plaque reduction neutralization assay, have found that COVAXIN-vaccinated sera effectively neutralized the Brazil variant of SARS-CoV-2, B.1.128.2, the alpha variant, B.1.1.7, which was first identified in the United Kingdom, as well as the delta variant, B.1.617, which was first identified in India. These studies suggest that COVAXIN vaccination may be effective against multiple SARS-CoV-2 variants.

Based on the more than 30 million doses supplied in India and other countries, COVAXIN has an excellent safety record. COVAXIN is currently being administered under emergency use authorizations in 13 countries, and applications for emergency use authorization are pending in more than 60 additional countries.

### **About Ocugen, Inc.**

Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with one drug – "one to many" and our novel biologic product candidate aims to offer better therapy to patients with underserved diseases such as wet age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. We are co-developing Bharat Biotech's COVAXIN™ vaccine candidate for COVID-19 in the U.S. and Canadian markets. For more information, please visit [www.ocugen.com](http://www.ocugen.com).

### **About Jubilant HollisterStier**

Jubilant HollisterStier, a part of Jubilant Pharma Limited, is a leading integrated contract manufacturer of sterile injectables, ophthalmics, otics, sterile and non-sterile topicals and liquids. With facilities in North America, Jubilant HollisterStier provides specialized manufacturing for the pharmaceutical and biopharmaceutical industries. Services include a full-range of support to streamline the manufacturing process, from process qualifications through commercial release.

### **About Jubilant Pharma Limited**

Jubilant Pharma Limited (JPL), a company incorporated under the laws of Singapore and a wholly-owned subsidiary of Jubilant Pharmova Limited, is an integrated global pharmaceutical company engaged in manufacturing and supply of APIs, Solid Dosage Formulations, Radiopharmaceuticals, Allergy Therapy Products and Contract Manufacturing of Sterile Injectables and Non Sterile products through six US FDA approved manufacturing facilities in the US, Canada and India and a network of 48 radiopharmacies in the US. The Company has a team of around 5,200 multicultural people across the globe and is committed to deliver value to its customers spread across over 75 countries. It is well recognized as a 'Partner of Choice' by leading pharmaceutical companies globally.

### **Cautionary Note on Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary and interim data (including the interim data from Bharat Biotech’s Phase 3 trial in India), including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that the results of in-vitro studies will not be duplicated in human clinical trials; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from Bharat Biotech’s clinical trials will be published in scientific journal publications and, if so, when and with what modifications; whether we will be able to provide the U.S. Food and Drug Administration (FDA) with sufficient additional information regarding the design of and results from preclinical and clinical studies of COVAXIN, which have been conducted by Bharat Biotech in India in order for those trials to support a biologics license application (BLA), the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a BLA; any additional chemistry, manufacturing and controls information that we may be required to submit the timing of our BLA filing; whether and when an application for authorization under interim order for emergency use will be filed in Canada; whether and when any such applications may be approved by Health Canada; whether developments with respect to COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada or other jurisdictions; market demand for COVAXIN in the United States or Canada; decisions by the FDA or Health Canada impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN in the United States or Canada, including development of products or therapies by other companies. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled “Risk Factors” in the quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events or otherwise, after the date of this press release.

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