



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

• Jubilant HollisterStier to manufacture COVAXIN® for the US and Canadian markets

**MALVERN, PA, June 15, 2021 -** <u>Ocugen, Inc.</u> (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 entered into an agreement with Jubilant HollisterStier of Spokane, Washington for manufacturing of vaccine candidate <u>COVAXIN®</u> for the US and Canadian markets.

"We are fully committed to bringing COVAXIN to the US and Canadian markets because it has the potential to save lives by adding a weapon to the arsenal in the fight against emerging variants." said J.P. Gabriel, 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'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 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.

# **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 with an excellent safety track record of more than 300 million doses supplied. Based on a well-established, and time-tested 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 the 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 available data 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 have found that COVAXIN demonstrated potential effectiveness against the Brazil variant of SARS-CoV-2, B.1.128.2, the UK variant, B.1.1.7, as well as the Indian double mutant variant, B.1.617. In ICMR studies, COVAXIN-vaccinated sera effectively neutralized several SARS-CoV-2 variants including B.1.617, India, double mutant, B.1.1.7, United Kingdom, B.1.1.28, Brazil P2, and heterologous strain) in an in-vitro plaque reduction neutralization assay. These studies suggest that COVAXIN vaccination may be effective against multiple SARS-CoV-2 variants.

## 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<sup>™</sup> vaccine candidate for COVID-19 in the U.S. market. For more information, please visit <u>www.ocugen.com</u>.

## **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 forwardlooking 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 Phase 3 interim data), including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; 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 the U.S. Food and Drug Administration (FDA) will be satisfied with the design of and results from preclinical and clinical studies of COVAXIN, which have been conducted by Bharat Biotech in India; whether and when any biologics license and/or emergency use authorization applications may be filed in the United States for COVAXIN; whether and when any such applications may be approved by the FDA; decisions by the FDA impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN in the United States, 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.

#### **Ocugen Contact:**

<u>Ocugen, Inc.</u> Sanjay Subramanian CFO and Head of Corp. Dev. <u>IR@Ocugen.com</u>

Media Contact: LaVoieHealthScience Lisa DeScenza Idescenza@lavoiehealthscience.com +1 9783955970