



Ocugen, Inc. Signs Letter of Intent to Acquire Vaccine Manufacturing, R&D Hub in Ontario, Canada

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- Dormant Vaccine Manufacturing site currently owned by an affiliate of Liminal BioSciences intended to bring new capabilities to Ocugen's medicine portfolio of Canadian and U.S. companies
- COVAXIN™ (BBV152), if approved, to be the first product manufactured in new upgraded facility
- New facility includes potential for manufacturing for breakthrough gene therapies and serve as R&D hub
- Site development, refurbishment and manufacturing intended to bring significant new regional economic opportunities

MALVERN, Pa., Jan. 27, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing breakthrough gene therapies and vaccines, announced that it has signed a non-binding letter of intent (LOI) with Liminal BioSciences, Inc. a Canadian public company with shares listed on NASDAQ for the acquisition of their manufacturing site in Belleville, Ontario, for an undisclosed amount.

This site would enable Ocugen to expand its manufacturing and research and development capabilities to support its pipeline. This includes the manufacture of COVAXIN™ (BBV152), the company's COVID-19 vaccine candidate, which was submitted to Health Canada for regulatory review by Ocugen's Canadian affiliate, Vaccigen Ltd. This vaccine manufacturing facility has the potential to help Canada in its efforts to control the current and future pandemics for all Canadians.

"We believe establishing a manufacturing and R&D hub for our biotechnology platform is the right investment and next evolution of our business. This site, after transformation into a state-of-the-art hub, with the support of the regional talent pool can help bring our innovative products – from vaccines to our modifier gene therapy assets – to the patients we will serve globally," said Dr. Shankar Musunuri, Chairman, CEO and Co-Founder, Ocugen, Inc.

"We're here to deliver to Canadians medical innovation that is going to make a difference in their lives. It's also our intent to bring new opportunities for employment to the Belleville community that over time may bring significant economic growth to Ontario," commented Dr. Ajay Potluri, Chief Executive Officer, Vaccigen Ltd.

"We are excited to see Ocugen's plans to repurpose our dormant vaccine manufacturing facility and create vaccine manufacturing capacity in Canada. We thank Minister Champagne and his team at Innovation Science Economic Development (ISED) Canada who facilitated the introduction to Ocugen and Vaccigen.," said Alek Krstajic, Chairman of the Board, Liminal BioSciences.

"We believe this could be an exciting opportunity for everyone involved, Liminal BioSciences, Ocugen, the province of Ontario, and most of all, the people of Canada, and we're pleased to help facilitate this event by potentially selling a dormant vaccine manufacturing facility which is non-core to Liminal Biosciences and could be strategic to Ocugen," said Peter Thomson, whose company, Thomvest, is a majority shareholder of Liminal BioSciences.

Completion of the proposed transaction is subject to finalization of due diligence investigations by the parties, the negotiation and execution of definitive transaction agreements and other customary closing conditions including certain funding requirements. There can be no assurance that a definitive agreement will be entered into or that the proposed transaction will be consummated.

About COVAXIN™ (BBV152)

COVAXIN™ (BBV152) is an investigational vaccine candidate product in the U.S, currently under review by the U.S. Food and Drug Administration for emergency use authorization (EUA) for children 2-18 years of age. Additionally, an Investigational New Drug application (IND) is being discussed with the agency to support an immunobridging study among U.S. participants. It was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). COVAXIN™ (BBV152) is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform.

With more than 200 million doses having been administered to adults and children outside the U.S., COVAXIN™ (BBV152) is currently authorized under emergency use in more than 20 countries, and emergency use authorization is in process in more than 60 other countries. The World Health Organization (WHO) recently added COVAXIN™ (BBV152) to its list of vaccines authorized for emergency use. And, as many as 110 countries have agreed to mutual recognition.

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.

About Vaccigen Ltd.

Vaccigen Ltd. is the Canadian affiliate of Ocugen, Inc. We are working every day to make a difference in the lives of Canadians, starting with the commercialization of a COVID-19 vaccine. In the future, we will work to bring innovation against blindness derived from the assets within Ocugen's gene therapy platform. Our goal is to be here for the health of all Canadians during this public health crisis and for the future. Learn more at www.vaccigen.ca.

About Liminal BioSciences Inc.

Liminal BioSciences is a biopharmaceutical company focused on the discovery and development of novel, small molecule drug candidates for the

treatment of patients suffering from fibrotic or inflammatory diseases that have a high unmet medical need.

Liminal BioSciences has active business operations in Canada and the United Kingdom.

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 our non-binding letter of intent with Liminal BioSciences (Liminal) to acquire Liminal’s manufacturing site in Belleville, Ontario, including the anticipated terms of the potential acquisition, which are non-binding and subject to change, the potential manufacturing capability of such site, the potential regional economic opportunities that could result from our plans to further develop and refurbish the site following its acquisition, and the value of such site to our product pipeline, stockholders and the Canadian population, and are subject to risks and uncertainties that could cause actual results to differ materially from those express or implied by such statements, including, among other things, the risk that we may not be able to successfully negotiate and execute a definitive purchase agreement for the acquisition on acceptable terms, if at all, and the ultimate terms and timing for closing of the transactions contemplated thereby; the risk that we will not be able to successfully close the acquisition; risks associated with the planned development and refurbishing of the manufacturing site, including that the expected costs for such development will be greater than currently contemplated or that the planned development will take longer than expected or fail to be completed on a timely basis, if at all; and the risk that we will not be able to scale production for such site to adequately support manufacturing of our product candidates or the other products that are currently or may in the future be manufactured at such site. In addition, our business is subject to numerous other risks and uncertainties, including, 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; the risk that Health Canada does not accept our new drug submission (NDS) for COVAXIN™ or that we may not be able to adequately respond to or resolve the deficiencies noted by Health Canada with respect to our NDS, for which we are preparing responses; the risk that we may not resolve the current clinical hold on COVAXIN™ in the near term or at all, or that the U.S. Food and Drug Administration (FDA) could make other decisions that adversely impact our ability to advance the development of COVAXIN™ in the United States, and the implications that this clinical hold may have for our request for Emergency Use Authorization (EUA) of COVAXIN for pediatric use, including the timing and scope of any such authorization; risks associated with preliminary and interim data, 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 the data and results from the preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by the FDA or otherwise sufficient to support our EUA submission or planned BLA submission, assuming the clinical hold is lifted; the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support an EUA or BLA; any additional chemistry, manufacturing, and controls information that we may be required to submit to the FDA; whether and when a BLA for COVAXIN™ will be submitted to or approved by the FDA; whether developments with respect to the 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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