Ocugen Expands COVAXIN™ Commercialization Rights to Include Canada

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- *Ocugen to have exclusive co-development, manufacturing, and commercialization rights to COVAXIN™ in Canada, in addition to its existing US rights*

MALVERN, Pa. and HYDERABAD, India, June 03, 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, and Bharat Biotech, a global leader in vaccine innovation, today announced that they have entered into an amendment to their Co-development, Supply, and Commercialization Agreement to expand Ocugen's exclusive territory to commercialize COVAXIN™ to now also include Canada, in addition to Ocugen's existing rights to commercialize COVAXIN™ in the United States.

"This amendment to expand our rights to commercialize COVAXIN™ into Canada speaks to our strong relationship with Bharat Biotech and our joint dedication to bring this unique yet traditional vaccine to additional countries. As we work towards the submission of the emergency use application in the US, we will simultaneously seek authorization under interim order for emergency use in Canada. We believe COVAXIN™ has the potential to play a key role in saving lives from COVID-19 in the US and Canada, as well as across the globe, due to the strong immune response it generates against multiple antigens," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-founder of Ocugen.

"COVAXIN™ has demonstrated an excellent safety record in human clinical trials and in vaccine administration under emergency use in India. Our goal for all vaccines developed at Bharat Biotech is to provide global access. With its potential effectiveness against multiple existing and emerging variants, we believe that COVAXIN™ is an important vaccine for everyone, including children, based on its unique yet traditional vaccine platform. We are diligently working with Ocugen to bring COVAXIN™ to the US market and now to the Canadian market," said Dr. Krishna Ella, Chairman & Managing Director of Bharat Biotech.

As consideration for Bharat Biotech's grant of the rights to commercialize COVAXIN™ in Canada, Ocugen will make an upfront payment and milestone payment upon first commercial sale in Canada to Bharat Biotech, in addition to sharing the profit from sales of COVAXIN™ in Canada. Similar to the US profit share arrangement, Ocugen will retain 45% of the profits from sales of COVAXIN™ in Canada.

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 UK variant, B.1.1.7, as well as the Indian double mutant variant, B.1.617. 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. market. For more information, please visit http://ocugen.com/

About Bharat Biotech:

Bharat Biotech has established an excellent track record of innovation with more than 140 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 116 countries, and World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 6 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and public private partnerships resulted in the introduction of path breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC® and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The recent acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the largest rabies vaccine manufacturer in the world. To learn more about Bharat Biotech visit https://www.bharatbiotech.com/.

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 Phase 3 interim data referred to in this press release), 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 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 and 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 the FDA or Health 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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