Ocugen, Inc. Announces Initiation of Rolling Submission to Health Canada for COVAXIN™

July 15, 2021

MALVERN, Pa., July 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 had initiated a rolling submission to Health Canada for COVAXIN™, the company's candidate vaccine against COVID-19, which it is co-developing with Bharat Biotech International Ltd. for the U.S. and Canadian markets. This follows the release by Bharat Biotech of Phase 3 clinical trial results, which demonstrated efficacy and safety in nearly 25,800 adults.

The rolling submission process was recommended and accepted under the Minister of Health's *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* and transitioned to a New Drug Submission for COVID-19, which permits companies to submit safety and efficacy data and information as they become available. Often referred to as a rolling review, this allows Health Canada to start its review right away, as information continues to come in, to accelerate the overall review process. Ocugen initiated the rolling submission through its affiliate, Vaccigen, Ltd**.** Health Canada will make a decision upon review of the evidence submitted that supports its safety, efficacy and quality.

"We thank Health Canada for their upcoming review of COVAXIN™ and look forward to working with them so that we can offer the possibility of another safe and effective option to be used in their fight against COVID-19 and its Delta variant," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer and Co-Founder of Ocugen.

About COVAXIN ™
COVAXIN™, a COVID-19 vaccine by Bharat Biotech, was 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, having been used to develop more than 300 million doses of its inactivated vaccines. It is a two-dose vaccine given four weeks apart.

In addition to generating strong immune response against multiple antigens, COVAXIN™ is designed to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. Phase 3 clinical trial data demonstrates efficacy and safety against COVID-19 and its Delta variant. COVAXIN™ is packaged in multi-dose vials that can be stored at 2-8°C.

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. COVAXIN™ is considered an investigational drug in Canada and the United States and has not been approved or authorized for use in those 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.

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, including the risk that such dates are not met due to impacts from the ongoing COVID-19 pandemic, as well as 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 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 a BLA for COVAXIN™ will be submitted to the FDA; whether and when a BLA may be approved by the FDA or an application for authorization under interim order for emergency use may be approved by Health Canada, which approvals will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; whether developments with respect to COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada or other jurisdictions; manufacturing capabilities or capacity, including whether sufficient doses of COVAXIN™ can be manufactured within our projected time periods; 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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