Ocugen to pursue a BLA path in the US for its COVID-19 vaccine candidate

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- *Company intends to work with the FDA towards filing a Biologics License Application (BLA) in the US*
- *Company to engage with Health Canada to seek authorization under Interim Order for use in Canada*

MALVERN, Pa., June 10, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN) (Company), 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 upon recommendation from the U.S. Food and Drug Administration (FDA), it will pursue submission of a biologics license application (BLA) for its COVID-19 vaccine candidate, COVAXIN™. The Company will no longer pursue an Emergency Use Authorization (EUA) for COVAXIN™.

The FDA provided feedback to Ocugen regarding the Master File the Company had previously submitted and recommended that Ocugen pursue a BLA submission instead of an EUA application for its vaccine candidate and requested additional information and data. Ocugen is in discussions with the FDA to understand the additional information required to support a BLA submission. The Company anticipates that data from an additional clinical trial will be required to support the submission.

“Although we were close to finalizing our EUA application for submission, we received a recommendation from the FDA to pursue a BLA path. While this will extend our timelines, we are committed to bringing COVAXIN™ to the US. This differentiated vaccine is a critical tool to include in our national arsenal given its potential to address the SARS-CoV-2 variants, including the delta variant, and given the unknowns about what will be needed to protect US population in the long term,” said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-founder of Ocugen.

Ocugen recently announced that it secured exclusive rights to commercialize COVAXIN™ in Canada and has initiated discussions with Health Canada for regulatory approval. The Company will pursue expedited authorization for COVAXIN™ under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* in Canada.

“In clinical trials to date, the emerging safety profile of COVAXIN™ is supportive of it being generally well tolerated with a good safety profile, with Ministry of Health and Family Welfare of Republic of India reporting no potential thromboembolic events following the administration of over 6.7 million doses of COVAXIN™ in that country,” said Dr. Bruce Forrest, Acting Chief Medical Officer and member of the vaccine scientific advisory board of Ocugen.

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 http://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, as well as risks associated with preliminary and interim data (including the interim data from Bharat Biotech’s Phase 3 trial in India 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 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.

Ocugen Contact:
Ocugen, Inc.
Sanjay Subramanian
CFO and Head of Corp. Dev.
IR@Ocugen.com

Media Contact:
LaVoieHealthScience
Sharon Correia
scorreia@lavoiehealthscience.com
617-865-0038