Ocugen On Track to Submit Emergency Use Authorization Application to U.S. FDA for its COVID-19 Vaccine Candidate, COVAXIN™

May 27, 2021

- *Active discussions with FDA related to COVAXIN initiated late last year*
- *Master file submitted to FDA on March 26, 2021; awaiting feedback from FDA*

MALVERN, Pa., May 26, 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 confirmed its plan to submit its Emergency Use Authorization (EUA) application for COVAXIN to the U.S. Food & Drug Administration (FDA) in June.

“Since we have been in discussions with the FDA since late last year, we do not believe that the FDA’s recently revised guidance regarding EUAs raises any concerns about our ability to submit the EUA for COVAXIN as planned, which is currently in process and which we expect to submit to the FDA in June. We believe that the FDA’s new guidance confirms that Ocugen continues to meet all criteria for submission of an EUA. Once the EUA application has been submitted, Ocugen intends to commence pre-biologics license application (BLA) discussions with the FDA,” said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-founder of Ocugen.

“FDA’s guidance refers specifically to vaccines based on the spike protein. COVAXIN is a unique yet traditional vaccine using an inactivated version of the whole virus with a novel adjuvant that provides a broadly protective immune response beyond the spike protein, offering potential effectiveness against multiple existing and emerging variants and reducing the possibility of mutant virus escape,” 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 with an excellent safety track record of more than 300 million doses 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.

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 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, 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 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.

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