Ocugen announces studies showing COVAXIN potentially effective against three key variants of SARS-CoV-2

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- *COVAXIN effectively neutralizes Brazil variant along with UK variant and India* double mutant variant
- *Potential effectiveness against multiple variants reduces the possibility of mutant virus escape*
- *According to World Health Organization, the double mutant variant of SARS-CoV-2 has spread to at least 17 countries*

MALVERN, Pa., May 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, today announced that in a new study, scientists at Indian Council of Medical Research (ICMR)-National Institute of Virology have found that COVAXIN demonstrated potential effectiveness against the Brazil variant of SARS-CoV-2, B.1.128.2. As previously disclosed, a study conducted by ICMR also suggested that COVAXIN was effective against the UK variant, B.1.1.7, as well as the Indian double mutant variant, B.1.617. It is notable that the Brazilian variant, B1.128.2, contains the E484K mutation that was found in New York.

In the ICMR studies, COVAXIN-vaccinated sera effectively neutralized several SARS-CoV-2 variants (B.1.617 (India, double mutant), B.1.1.7 (United Kingdom), B.1.1.28 (Brazil P2), and heterologous strain) in an in-vitro plaque reduction neutralization assay. These studies suggest that COVAXIN vaccination may be effective against multiple SARS-CoV-2 variants.

A Media Snippet accompanying this announcement is available by clicking on the image or link below:

“We are pleased to see the results of this study as it demonstrates the potential effectiveness of COVAXIN against multiple variants, further strengthening our belief that this vaccine can potentially eliminate the possibility of mutant virus escape,” said Dr. Satish Chandran, chair of the vaccine scientific advisory board of Ocugen.

“COVAXIN continues to show strong results in all the studies conducted to date. We continue to believe this vaccine is a critical tool to include in our national arsenal to fight this pandemic. The Ocugen team submitted a comprehensive drug master file with the FDA and is currently diligently preparing the EUA application,” said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-founder of Ocugen.

Ocugen is developing COVAXIN, Bharat Biotech’s COVID-19 vaccine candidate, for the U.S. market. In the recently shared second interim results of the Phase 3 clinical trial, COVAXIN demonstrated 78% overall efficacy and 100% in severe COVID-19 disease (including hospitalization).

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.

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 available data for several other vaccines, COVAXIN is packaged in multi-dose vials that can be stored at 2-8°C.

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.

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the 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 4 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 introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer. To learn more about Bharat Biotech, visit 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), 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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