COVAXIN™ (BBV152) Booster Dose Study Demonstrates Robust Immune Responses and Long-Term Safety

January 8, 2022

- *Participants receiving a booster dose six months after second dose of COVAXIN™ saw significant increase (>10-fold across Alpha, Beta, Delta and Delta Plus variants) in neutralizing titers compared to baseline at six months*
- *Persistence of memory B and T cell immune responses at six months post second dose*
- *Pronounced SARS-CoV-2-specific T cell response to COVAXIN™ before and after the booster dose may confer durable and long-term protective efficacy*
- *No serious adverse events such as hospitalizations or deaths were reported*
- *Effectiveness of COVAXIN™ against the Omicron strain is currently being studied and will be reported shortly*

MALVERN, Pa., Jan. 08, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics and vaccines, announced that its partner, Bharat Biotech, posted positive results from a Phase 2 analysis of the vaccine candidate, COVAXIN™ (BBV152), in participants ages 12-64, receiving a booster dose six months following a second dose on the pre-print server, medRxiv. The analysis found that participants receiving a booster dose saw a significant increase in neutralizing titers, an important predictor of vaccine efficacy.

“As the COVID-19 virus continues to evolve, so does our understanding of the efficacy of vaccines and the critical role they play in protecting people from serious disease, hospitalization and death,” said Dr. Shankar Musunuri, Chairman, CEO and Co-Founder, Ocugen, Inc. “These booster data provide critical information about how COVAXIN™ can be used in the ongoing battle against COVID-19. We are encouraged by these results which continue to suggest that COVAXIN™ remains an important, broad-spectrum vaccine candidate with durability.”

Additional data from the analysis found that more than 75 percent of all participants had a detectible neutralizing antibody response six months post their second dose of COVAXIN ™. After receiving the booster, participants also saw an increase in antibody titers (at day 28) that were higher than those achieved after the two-dose primary series. Wild-type neutralizing antibodies ($PRNT_{50}$) GMTs at one month after a booster dose against Alpha, Beta, Delta and Delta plus variants were increased 10·9, 161·0, 264·7, and 174·2 fold from baseline at six months post second dose, respectively.

“Although protection against severe disease remains high six months following the second dose, a decline in efficacy against symptomatic disease over time and the continued emergence of variants are expected and consistent with what we are seeing with other vaccines. Based on emerging data, a third dose may be beneficial to maintain the highest levels of protection,” said Huma Qamar, MD, MPH, CMI, Associate Vice President, Clinical Development, Ocugen, Inc.

The booster dose analysis also found no serious adverse events, including hospitalization or death, were reported.

About COVAXIN™ (BBV152)
COVAXIN™ (BBV152) is an investigational vaccine candidate product in the U.S. It was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). COVAXIN™ (BBV152) is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform.

With more than 180 million doses having been administered to adults outside the U.S., COVAXIN™ (BBV152) is currently authorized under emergency use in 17 countries, and applications for emergency use authorization are pending in more than 60 other countries. The World Health Organization (WHO) recently added COVAXIN™ (BBV152) to its list of vaccines authorized for emergency use. And, as many as 110 countries have agreed to mutual recognition of Covid-19 vaccination certificates with India that includes vaccination using COVAXIN™ (BBV152). The trade name, COVAXIN™, has not been evaluated by the FDA.

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.

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, including statements about data published on the preprint server, medRxiv, by Bharat Biotech, which found that COVAXIN™, when administered as a booster dose, generated a five-fold increase in neutralizing titers, an important predictor of vaccine efficacy, and the potential for this data to support our application to the U.S. Food and Drug Administration (FDA) for emergency use authorization (EUA) of COVAXIN™ in pediatric patients or our planned biologics license application (BLA), assuming the clinical hold is lifted, for approval of COVAXIN™ for use in adult patients, as well as statements regarding the potential short and long-term benefits of receiving a booster dose of COVAXIN™. 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; the risk that we may not resolve the current clinical hold on COVAXIN™ in the near term or at all, or that the FDA could make other decisions that adversely impact our ability to advance the development of COVAXIN™ in the United States, and the implications that this clinical hold may have for our request for EUA of COVAXIN for pediatric use, including the timing and scope of any such authorization; 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 the data and results from the preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by the FDA or otherwise sufficient to support our EUA submission or planned BLA submission, assuming the clinical hold is lifted; the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support an EUA or BLA; any additional chemistry, manufacturing, and controls information that we may be required to submit to the FDA; whether and when a BLA for COVAXIN™ will be submitted to or approved by the FDA; whether developments with respect to the 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:
Ken Inchausti
Head, Investor Relations & Communications
+1 484 237 3398
ken.inchausti@ocugen.com

Please submit investor-related inquiries to: IR@ocugen.com