Ocugen, Inc. Provides an Update on its Investigational New Drug Application with U.S. FDA to Initiate a Phase 3 Clinical Trial Evaluating COVID-19 Vaccine Candidate COVAXIN™ (BBV152)

November 26, 2021

MALVERN, Pa., Nov. 26, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics and vaccines, announced that the U.S. Food and Drug Administration (FDA) has issued a clinical hold on the Company's Investigational New Drug application (IND) to evaluate the COVID-19 vaccine candidate, BBV152, known as COVAXIN™ outside the United States.

The FDA plans to identify the specific deficiencies that are the basis for clinical hold and information on how to address those deficiencies. The Company expects to receive formal written communication with the additional information from the FDA and plans to work with the FDA in an effort to resolve its questions as promptly as possible.

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™ is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform.

With more than 100 million doses having been administered to adults outside the U.S., COVAXIN™ 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™ 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™. The trade name COVAXIN™ has not been evaluated by the FDA.

As recently published in, *The Lancet*, COVAXIN™ (BBV152) demonstrated 77.8% overall efficacy, 63.6% efficacy against asymptomatic disease and 65.2% efficacy against the Delta variant in the Phase 3 clinical trial of nearly 25,800 participants. Adverse events reported in the trial were low, with 12.4% of subjects experiencing commonly known side effects and less than 0.5% of subjects experiencing serious adverse events, which is consistent with data from other vaccines that apply whole-virion technology. Both adverse events and serious adverse events reported in the vaccine group were reported at similar rates to the placebo group. The trial was conducted in India and sponsored by Bharat Biotech.

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 statements about our expectations regarding the status of our Phase 3 clinical trial included in our Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) for COVAXIN™, the timing of discussions with the FDA regarding the current clinical hold and whether or not and under what requirements, if any, our further clinical development of COVAXIN™ will be permitted by the FDA. 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 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 inversely impact our ability to advance the development of COVAXIN™ in the United States, the implications that this clinical hold may have for our request for emergency use authorization for COVAXIN for pediatric use; 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 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 we will be able to provide the 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) or emergency use authorization (EUA); the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a BLA, including our planned Phase 3 clinical trial which is currently subject to clinical hold; any additional chemistry, manufacturing and controls information that we may be required to submit to 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; 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