Ocugen Announces FDA Removes Clinical Hold on Phase 2/3 Clinical Trial for COVAXIN™ (BBV152)

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Dosing to Resume Immediately

MALVERN, Pa., May 23, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene therapies, biologicals, and vaccines, today announced that the U.S. Food and Drug Administration (FDA) lifted the clinical hold on the Company's Phase 2/3 clinical trial, OCU-002, for COVAXIN™ (BBV152).

"We're extremely pleased that we can proceed with our clinical trials for COVAXIN™, our whole virus inactivated COVID-19 vaccine candidate. The need for delivering an additional, differentiated vaccine option, we believe, remains a priority," said Dr. Shankar Musunuri, Chairman, CEO and Co-Founder, Ocugen, Inc. "Thank you to our clinical trial partners and site collaborators for their ongoing support. Ocugen will now work with study sites to fully resume this clinical development program immediately."

People interested in learning about how to participate in this clinical trial (NCT05258669) can visit the clinical trials section of Ocugen.com.

About COVAXIN™ (BBV152)
COVAXIN™ (BBVI52) 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 350 million doses having been administered to adults outside the U.S., COVAXIN™ is currently approved for adults in India and authorized under emergency use in 25 countries. Applications for emergency use authorization are pending in more than 60 other countries. COVAXIN™ is listed by the World Health Organization (WHO) as 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.

About Ocugen, Inc.
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene therapies, biologicals and vaccines that improve health and offer hope for people and global communities. We are making an impact through courageous innovation, taking science in new directions in service of patients. Our breakthrough modifier gene therapy platform has the potential to treat multiple diseases with one drug and we are advancing research in other therapeutic areas to offer new options for people with unmet medical needs. Discover more at www.ocugen.com and follow us on Twitter and LinkedIn.

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. Ocugen 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, but are not limited to, statements about Ocugen's intention to begin dosing patients in its Phase 2/3 immune-bridging and broadening trial for COVAXIN™ in the coming weeks*, and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements, including, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, ability to timely enroll clinical trial participants, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates; the risk that Health Canada does not accept its New Drug Submission ("NDS") for COVAXIN™ or that Ocugen may not be able to adequately resolve the deficiencies noted by Health Canada with respect to its NDS, for which Ocugen has provided responses that are currently under review by Health Canada; the risk that Ocugen may not be able to successfully commercialize COVAXIN™ in Mexico for adults over the age of 18 pursuant to Ocugen's agreement with Bharat Biotech and the risk that Ocugen does not obtain emergency pediatric use for COVAXIN™ in Mexico for children between two and 18 years of age on a timely basis, if at all; the risk that Ocugen's Phase 2/3 immuno-bridging and broadening clinical trial for COVAXIN™ is not completed on a timely basis, if at all; or that the U.S. Food and Drug Administration places a new clinical hold on such trial in the future, for any reason; 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 is 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 regulatory authorities or otherwise sufficient to support Ocugen's submissions for regulatory approvals or authorizations in the United States, Canada or Mexico; the size, scope, timing and outcome of any additional clinical trials or studies that Ocugen may be required to conduct to support regulatory approvals or authorizations; any additional chemistry, manufacturing, and controls information that Ocugen may be required to submit to regulatory authorities ; whether and when a Biologics License Application for COVAXIN™ will be submitted to or approved by the FDA; the risk that Ocugen may not be able to successfully negotiate and execute definitive transaction agreements for the acquisition of the manufacturing site on acceptable terms, if at all, and the ultimate terms and timing for closing of the transactions contemplated thereby; the risk that*

Ocugen will not be able to successfully close the acquisition of the manufacturing site; risks associated with the planned development and refurbishing of the manufacturing site, including that the expected costs for such development may be greater than currently contemplated or that the planned development may take longer than expected or fail to be completed on a timely basis, if at all; and the risk that Ocugen will not be able to scale production for such manufacturing site to adequately support manufacturing of its product candidates or the other products that may in the future be manufactured at such manufacturing site; whether developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, Mexico or other jurisdictions; market demand for COVAXIN™ in the United States, Canada or Mexico; decisions by the regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States, Canada or Mexico, including development of products or therapies by other companies Such *statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from our current expectations, such as market and other conditions. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (the "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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