Ocugen Announces Publication of Positive Results of COVID-19 Vaccine Trial for Children 2-18 in The Lancet Infectious Diseases

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Ocugen's partner Bharat Biotech's Phase 2/3 study of COVAXIN™ (BBV152) in 526 children showed safety, efficacy, and superior response to that shown in adults

Ocugen has North American commercialization rights for COVAXIN™

MALVERN, Pa., June 21, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologicals, and vaccines, today announced the publication of positive pediatric Phase 2/3 study results in children aged 2–18 years for the COVID-19 vaccine COVAXIN™ (BBV152) in *The Lancet Infectious Diseases* ("The Lancet") . COVAXIN™ is developed and manufactured by Ocugen's partner Bharat Biotech International Limited ("Bharat Biotech"), a global leader in vaccine innovation based in Hyderabad, India, and is under clinical investigation by Ocugen in the United States for use in adults aged 18 years and older.

The Lancet article, entitled "Immunogenicity and reactogenicity of an inactivated SARS-CoV-2 vaccine (BBV152) in children aged 2–18 years: interim data from an open-label, non-randomised, age de-escalation phase 2/3 study," which was authored by Dr. Krishna Mohan Vadrevu, Siddharth Reddy, MSc, and others, was published on June 16, 2022.

Ocugen has commercial rights for COVAXIN™ throughout North America and COVAXIN™ has emergency use authorization in Mexico for adults. Ocugen is continuing to explore pediatric emergency use authorization in Mexico. This data demonstrates that the same dose is effective in both pediatrics and adults (ages two and older) and would be an ideal option as the majority of Americans are looking for traditional vaccine options. Ocugen is continuing its effort to bring this vaccine to the North American Market.

"We congratulate Bharat Biotech on the publication of the COVAXIN™ pediatric data in this prestigious peer-reviewed medical journal," said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder of Ocugen. "Not only is this a strong validation of the work they are doing, but it is a very encouraging development in the effort to contain this pandemic, which needs a greater variety of vaccine options to combat the multiple COVID-19 variants. We believe the distinct features of COVAXIN™ offer benefits that could help improve public health."

Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech, said, "We are glad to have Ocugen as a valuable partner to help bring COVAXIN™ to North America. Safety of the vaccine is critical for children, and we are glad to share that COVAXIN™ has proven data for safety and immunogenicity in children. We have now achieved our goal of developing a safe and efficacious COVID-19 vaccine for adults and children, for primary immunization and booster doses, making COVAXIN™ a universal vaccine. It has proven to be a highly safe vaccine based on data from more than 50 million doses administered to children in India."

The low reactogenicity might make COVAXIN™ more acceptable in pediatric populations than the more reactogenic mRNA vaccines as Bharat Biotech's pediatric Phase 2/3 study had no serious adverse events, deaths, or withdrawals due to an adverse event including no cases of Guillain-Barré syndrome, thromboembolic events, myocarditis, or pericarditis, or other adverse events of special interest being observed to date. We believe COVAXIN™ will be a valuable tool in the global immunization effort as it can be stored at 2–8°C, which is standard vaccine storage conditions. Follow-up studies to assess pediatric effectiveness are underway, but this study suggests that similar efficacy, measured by the ability of a vaccine to prevent disease, might be anticipated in children based on the observation of superior immunogenicity, measured by the ability of a vaccine to produce an immune response, as compared to adults.

The open-label, non-randomized study was conducted in six hospitals in India and included 526 healthy children. Two doses of COVAXIN™ were administered 28 days apart in three groups according to their ages, two to six years, six to 12 years, and 12 to 18 years. The results were compared with those from adults who participated in a previously reported Phase 2 study. The study is registered with the Clinical Trials Registry, India (CTRI/2021/05/033752) and ClinicalTrials.gov (NCT04918797).

About COVAXIN™(BBV152)
The COVID-19 vaccine candidate BBV152, known as COVAXIN™ outside the United States, is a whole-virion inactivated COVID-19 vaccine candidate that applies the same Vero cell manufacturing platform, which has been used in the production of polio vaccines for decades. COVAXIN™ was co-developed with Ocugen's partner, Bharat Biotech, in collaboration with the Indian Council of Medical Research – National Institute of Virology. COVAXIN™ has been granted Emergency Use Listing by the World Health Organization based on a submission by Bharat Biotech. COVAXIN™ is formulated uniquely such that the same dosage can be administered to adults and children alike, making it truly a universal vaccine. COVAXIN™ is a ready to use liquid vaccine stored at 2-8°C with a 12-month shelf life and multi dose vial policy.

About Ocugen, Inc.
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell 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. 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, but are not limited to, statements about COVAXIN™ efficacy, safety, and immunogenicity in children aged 2-18 years, Ocugen's ability to expand emergency use authorization for COVAXIN™ in Mexico to include children aged 2-18 years, Ocugen's intention to continue its effort to bring COVAXIN™ to the North American Market, and the potential advantages of COVAXIN™ over other vaccines. 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. 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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