Ocugen Mucosal Vaccine Candidate OCU500 Selected by NIH/NIAID Project NextGen for Inclusion in Clinical Trials

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- *NIAID is conducting early phase clinical trials on select next generation vaccine candidates with the intent to identify the most effective platforms and delivery routes*
- *OCU500 will be tested as both inhaled and intranasal vaccine candidates*
- *Clinical trials scheduled to start in early 2024*

MALVERN, Pa., Oct. 10, 2023 (GLOBE NEWSWIRE) -- Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines, today announced that the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health, will conduct a trial comparing the administration of Ocugen's mucosal vaccine candidate, OCU500, via two different mucosal routes, inhalation into the lungs and as a nasal spray.

Ocugen is developing a novel anti-viral mucosal vaccine platform initially targeting COVID-19 and influenza (flu). The intent is to provide protection against severe disease, increase durability and prevent transmission of viral threats. OCU500 is based on a novel chimpanzee adenovirus-vectored (ChAd) technology. Earlier clinical studies to prevent COVID-19 employing a similar vector administered via inhalation demonstrated increased mucosal antibodies, systemic antibodies, and durable immune response up to one year using one fifth (1/5) of the dose compared to the same vaccine given via intramuscular administration. Additionally, Ocugen believes that this vaccine can be rapidly scaled-up as new variants emerge.

"We believe our novel mucosal vaccine platform technology has the potential to prevent infection and spread of COVID-19, and improve durability for an annualized vaccine similar to flu," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "This is the first vaccine candidate using our inhaled platform technology, which we hope to expand in order to address multiple respiratory threats, including flu. We have benefited from a strong collaborative relationship with NIAID and BARDA since the start of Project NextGen and we look forward to participating in this initiative."

NIAID will be conducting clinical trials to evaluate several early stage vaccine candidates. The study involving Ocugen's vaccine will be administered via both intranasal and inhaled routes and is designed to help answer an important question – does an inhaled COVID-19 vaccine provide greater immune response than the same vaccine administered through a nasal spray. Upon completion of the trial NIAID and Ocugen will assess the results and determine next steps for OCU500.

Project NextGen is a $5 billion multi-government agency initiative to develop the next generation of vaccines and therapeutics to combat the spread of COVID-19. NIAID, with funding from Project NextGen, will cover the full cost of the clinical trials, including operations and related analysis. Ocugen will be responsible for providing clinical trial materials and upon completion will have full right of reference to the findings, which Ocugen believes will provide clinical evidence to support the further development of the Company's lead mucosal vaccine candidate.

The announced collaboration comes at a time when COVID-19 infection rates are rising with the emergence of new variants. Durability of existing vaccines continues to be of concern with antibody protection waning several months following vaccination while vaccine compliance rates have declined since the initial wave. According to a recent Harris poll, 66% of Americans would prefer to have more vaccine options. The poll also found that 52% of Americans would be more open to getting an intranasal or inhaled, versus injectable COVID-19 vaccine.

Ocugen looks forward to this important next step in the development of its novel mucosal vaccine platform and further supporting the Company's commitment to advancing public health.

About Ocugen, Inc.
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patient's lives through courageous innovation—forging new scientific paths that harness our unique intellectual and human capital. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with a single product, and we are advancing research in infectious diseases to support public health and orthopedic diseases to address 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 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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