Ocugen Announces Phase 3 Confirmatory Clinical Trial Agreement for NeoCart®

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Important next step for Ocugen's regenerative cell therapy in orthopedics since announcing pipeline expansion in May 2022

MALVERN, Pa., Dec. 16, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines, today announced that the U.S. Food & Drug Administration (FDA) agreed to Ocugen's proposed control and overall design for the Phase 3 study of NeoCart ®, a regenerative cell therapy for the repair of full-thickness lesions of the knee cartilage in adults.

"We are eager to get started on the final phase of NeoCart ® development and pleased at the outcome of our discussions with the FDA," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "With this guidance, Ocugen has a clear path forward for the first candidate in our regenerative cell therapy program."

The Phase 3 study will be a randomized, controlled trial to demonstrate the superiority over standard of care, chondroplasty, in subjects with articular cartilage defects. Ocugen plans to enroll subjects with one or two articular cartilage lesions with a total surface area of 1-3 cm^2.

Ocugen is building a current Good Manufacturing Practice cell therapy manufacturing facility to support establishment of the clinical and commercial manufacturing process for NeoCart®. The Company plans to file an Investigational New Drug amendment to initiate a Phase 3 clinical trial in late 2023/early 2024.

Earlier this year, the FDA granted a regenerative medicine advanced therapy (RMAT), designation to NeoCart®. NeoCart® combines breakthroughs in bioengineering and cell processing to enhance the autologous cartilage repair process by merging a patient's own cells with a fortified 3-D scaffold designed to accelerate healing and reduce pain.

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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