Ocugen, Inc. Announces First Patient Dosed in Phase 1 Clinical Trial of OCU200—a Novel Integrin-Targeting Biologic for Diabetic Macular Edema

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MALVERN, Pa., Jan. 16, 2025 (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 first patient has been dosed in the OCU200 Phase 1 clinical trial for diabetic macular edema (DME).

“OCU200 has the potential to change the treatment landscape for DME, diabetic retinopathy (DR), and wet age-related macular degeneration (wet AMD) with its unique mechanism of action, binding the active component—tumstatin—to integrin receptors that play a crucial role in disease pathogenesis,” said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder of Ocugen. “OCU200 holds the promise to benefit all DME patients, including the 30-40% of patients who do not respond to current anti-VEGF therapies.”

The OCU200 Phase 1 clinical trial is a multicenter, open-label, dose-escalation study to assess drug safety via intravitreal injection in three cohorts: low dose (0.025 mg), medium dose (0.05 mg), and high dose (0.1 mg). All subjects will receive a total of two intravitreal injections of OCU200 six weeks apart. Patient follow-up will take place up to three months after the last injection.

Approximately 12 million people in the United States and 130 million people worldwide are affected by DME, DR or wet AMD. Patients affected by these diseases share common symptoms, such as blurriness in vision and progressive vision loss as the disease progresses. The formation of fragile and leaky new blood vessels leads to fluid accumulation in and around the retina, causing damage to vision.

“I am seeing an increasing rate of vision-threatening diseases associated with diabetes at my clinic and am eager to provide a new therapeutic option to these patients,” said Dr. David Almedia, Vitreoretinal Surgeon and Clinician Scientist, President and CEO of Erie Retina Research, and Founder and President of Case X Global in Erie, Pennsylvania. “There remains a considerable unmet medical need for DME and DR patients with currently available anti-VEGF treatments.”

OCU200 is a recombinant fusion protein that consists of two parts connected by a linker: tumstatin, the active component, acts as an anti-inflammatory, anti-VEGF agent by binding to integrin receptors; and transferrin, which targets the drug to the choroid and retina by binding transferrin receptors on endothelial cells. These features will potentially enable OCU200 to reduce the vascular permeability, inflammation, and neovascularization that drive the pathophysiology of DME, DR, and wet AMD at a significantly lower dose compared to currently approved therapies.

“We are enthusiastic about getting patients started in the OCU200 Phase 1 clinical trial and sharing not only safety but preliminary efficacy data as the study progresses,” said Dr. Huma Qamar, Chief Medical Officer at Ocugen. “OCU200 brings an innovative biologic candidate to Ocugen’s ophthalmology portfolio targeting blindness diseases.”

The Company intends to pursue approval to use OCU200 as a first-line therapy for DME, DR, and wet AMD.

About Ocugen, Inc.
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patients’ 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 X 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, including, but not limited to, statements regarding qualitative assessments of available data, potential benefits, expectations for ongoing clinical trials, anticipated regulatory filings and anticipated development timelines, 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, including, but not limited to, the risks that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; the ability of OCU200 to perform in humans in a manner consistent with nonclinical or preclinical study data; that unfavorable new clinical trial data may emerge in ongoing clinical trials or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive of the results or success of later clinical trials; and that that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities. 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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