Ocugen Receives Provisional Approval and Priority Designation Under the Longevity and Regenerative Therapies Act in The Bahamas to Provide OCU400 to Patients for Treatment of Retinitis Pigmentosa

September 25, 2026

- Ocugen will provide its investigational modifier gene therapy OCU400 through an expanded access program (EAP), with the goal of enabling the first patient to be treated for retinitis pigmentosa (RP) within 90 days, following full approval by the Longevity and Regenerative Therapies Board (LARTA Board)
- In partnership with the LARTA Board, Ocugen intends to address global access and unmet need through commercial pricing evidenced with cost-effectiveness for a one-time broad treatment of RP
- A novel modifier gene therapy for RP, OCU400 is advancing through Phase 3, with topline data expected in 1Q 2027 and a Biologics License Application submission planned for 2Q 2027

MALVERN, Pa., Sept. 25, 2026 (GLOBE NEWSWIRE) -- Ocugen, Inc. (“Ocugen” or the “Company”) (NASDAQ: OCGN), a pioneering biotechnology leader in gene therapies for blindness diseases, today announced that OCU400 has been granted provisional approval and priority designation from the LARTA Board, the regulatory agency responsible for reviewing and approving longevity and regenerative therapy programs within the Commonwealth of The Bahamas. Ocugen will supply OCU400 through an EAP, with the goal of treating the first RP patient within 90 days, following full LARTA approval.

“Our partnership marks an important milestone for Ocugen – creating a unique opportunity to provide global access through the Bahamas to OCU400 for people suffering from retinitis pigmentosa,” said Dr. Shankar Musunuri, Chairman, CEO and Co-Founder of Ocugen. “This landmark collaboration demonstrates the potential of our differentiated gene therapy platform and represents an exciting step toward expanding the reach of our innovative, one-time treatments for patients with serious retinal diseases.”

LARTA Priority Designation
LARTA Priority Designation recognizes the scientific and clinical promise of a program and its potential to address significant unmet medical need. When granted alongside Provisional LARTA Approval, it places the program on a structured pathway of enhanced regulatory engagement and expedited coordination, designed to advance it towards Full Approval, operational readiness and responsible patient access.

About OCU400
OCU400 is a modifier gene therapy candidate, currently in Phase 3, targeting a broad RP indication – from early-to late-stage disease; pediatric to adult patients – and is designed to treat mutations caused by more than 100 genes. It is based on a nuclear hormone receptor gene called *NR2E3* which regulates diverse physiological functions within the retina, such as photoreceptor development and maintenance, metabolism, phototransduction, inflammation, and cell survival. Retinal cells in RP patients have a dysfunctional gene network, and OCU400 is designed to reset this network to reestablish a healthy cellular homeostasis. OCU400 has been granted Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA), and Orphan Medicinal Product Designation (OMPD) by the European Medicines Agency (EMA).

About Ocugen, Inc.
Ocugen, Inc. is a pioneering biotechnology company developing gene therapies for blindness diseases. The Company’s breakthrough modifier gene therapy platform has the potential to address significant unmet medical needs across large patient populations through a gene-agnostic approach. Unlike traditional gene therapies and gene-editing technologies that target a single gene mutation, Ocugen’s modifier gene therapies are designed to address the underlying disease biology by restoring balance across multiple gene networks. The Company is currently advancing programs for inherited retinal diseases and other causes of blindness that affect millions worldwide, including retinitis pigmentosa, Stargardt disease, and geographic atrophy, an advanced form of dry age-related macular degeneration. Discover more at www.ocugen.com and follow us on LinkedIn and X.

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 strategy, business plans and objectives for Ocugen’s clinical programs, plans and timelines for the preclinical and clinical development of Ocugen’s product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, including the timing of enrollment and data readouts, the ability to initiate new clinical programs, statements regarding the ability to treat the first patient 90 days after obtaining Provisional LARTA Approval and Priority Designation in The Bahamas, qualitative assessments of available data, potential benefits, expectations for ongoing clinical trials, anticipated regulatory filings and anticipated development timelines, statements regarding potential market size and commercial possibilities of Ocugen’s product candidates, 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 receipt

of Provisional LARTA Approval and Priority Designation may not lead to faster regulatory review and Full Approval; that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical 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 may not be predictive of the results or success of later clinical trials; and 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 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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