Ocugen Announces that the U.S. Food and Drug Administration Has Granted OCU410 Regenerative Medicine Advanced Therapy (RMAT) Designation for Treatment of Geographic Atrophy, Secondary to Dry Age-Related Macular Degeneration

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- RMAT designation is intended to help expedite development of new regenerative medicines that have potential to treat serious medical conditions with significant unmet need
- The designation could accelerate OCU410's regulatory path while further differentiating its one-time treatment for life approach from current therapies requiring chronic administration

MALVERN, Pa, July 29, 2026 (GLOBE NEWSWIRE) -- Ocugen, Inc. ("Ocugen" or the "Company") (NASDAQ: OCGN), a pioneering biotechnology leader in gene therapies for blindness diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted RMAT designation to Ocugen's investigational product OCU410 for the treatment of geographic atrophy (GA), secondary to dry age-related macular degeneration (dAMD).

"RMAT designation for OCU410 is a significant accomplishment that recognizes both the potential of our 'one treatment for life' novel gene therapy platform and the substantial unmet medical need for geographic atrophy," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "With an estimated 2 to 3 million people in the U.S. and Europe affected, a number expected to grow as the population ages, geographic atrophy is a leading cause of irreversible blindness in older adults, highlighting the urgent need for new treatment options. We look forward to continuing to work closely with the FDA to responsibly and efficiently advance the development program for patients suffering from this devastating disease."

The RMAT designation for OCU410 was supported by Phase 2 clinical data demonstrating clinically meaningful efficacy and a favorable safety profile, with no reported serious adverse events related to drug. Based on these data, the FDA determined that OCU410 met the criteria for RMAT designation by providing preliminary clinical evidence that the therapy has the potential to address a serious condition with significant unmet medical need. This designation recognizes the promise of OCU410 as a regenerative medicine therapy and supports an expedited development pathway.

In early July 2026, Ocugen reached alignment with the FDA on the design of the OCU410 Phase 3 registrational trial, with study initiation expected in the third quarter of 2026, and a Biologics License Application (BLA) filing anticipated in 2028.

About Regenerative Medicine Advanced Therapy (RMAT) Designation
The FDA established the RMAT designation to expedite the development and review of regenerative medicine therapies intended to treat, modify, reverse, or cure serious or life-threatening diseases or conditions. RMAT designation is granted to investigational regenerative medicine therapies supported by preliminary clinical evidence indicating the potential to address unmet medical needs. Products receiving RMAT designation are eligible for all the benefits of the Fast Track and Breakthrough Therapy programs, including increased interactions with the FDA to support efficient development, eligibility for rolling BLA review, and the potential for accelerated approval and Priority Review, where appropriate.

About Dry Age-Related Macular Degeneration (dAMD) and Geographic Atrophy (GA)
Geographic atrophy is an advanced form of dAMD characterized by progressive degeneration of the macula, leading to irreversible central vision loss. Millions of patients worldwide are affected by GA, with a particularly high burden in aging populations in the United States and Europe. Despite recent approvals, treatment options remain limited and require chronic intravitreal injections, underscoring the need for innovative, durable therapies that address multiple disease mechanisms. dAMD affects approximately 10 million Americans and more than 266 million people worldwide. It is characterized by the thinning of the macula, the portion of the retina responsible for clear vision in one's direct line of sight. dAMD involves the slow deterioration of the retina with submacular drusen (small white or yellow dots on the retina), atrophy, loss of macular function, and central vision impairment. dAMD accounts for 85-90% of all AMD cases.

About OCU410
OCU410 is an investigational, subretinal injection, AAV5-based gene therapy that delivers RORA (retinoid-related orphan receptor alpha), a nuclear receptor that regulates key pathways involved in retinal homeostasis, including oxidative stress response, complement regulation, inflammation, and lipid metabolism. OCU410 is being developed as a one-time gene therapy for patients with GA secondary to dAMD. OCU410 received Advanced Therapy Medicinal Product (ATMP) classification from the European Medicines Agency.

About Ocugen, Inc.
Ocugen, Inc. is a pioneering biotechnology company developing gene therapies for blindness. 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 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 RMAT designation may not lead to faster development or regulatory review; 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 annual and quarterly 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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