Ocugen Initiates Phase 3 Clinical Trial of OCU310 for Dry Eye Disease

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MALVERN, Pa., Oct. 1, 2018 /PRNewswire/ -- Ocugen, Inc., a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies to address rare and underserved eye diseases, today announced that it has initiated a Phase 3 clinical trial for its second lead product candidate, OCU310 for patients with dry eye disease (DED). OCU310 is an investigational twice-daily, steroid-free, preservative-free eye drop of 0.2% brimonidine tartrate formulated with Ocugen's proprietary nanoemulsion technology, OcuNanoE™.

Dry eye disease is a common ocular disorder involving the aberrant production, composition and instability of tear film, which results in damage to the ocular surface and is correlated with symptoms of ocular pain or discomfort and signs of ocular surface inflammation. DED can cause long-term damage to the ocular surface, and in severe cases, can result in vision impairment. It is estimated that there are approximately 35 million adult patients affected by DED in the U.S., with an estimated 16 million patients diagnosed.

Daniel Jorgensen, MD, MPH, Chief Medical Officer of Ocugen, said, "We believe OCU310 could be an important treatment option for the management of DED, based on brimonidine's multiple modes of action, our OcuNanoE™ formulation technology, and the favorable results of our recent Phase 2 study."

Shankar Musunuri, PhD, MBA, Chairman, CEO and Co-Founder of Ocugen, said, "We are pleased to advance our second lead product candidate into Phase 3 clinical development. OCU310 has the potential to improve the signs and symptoms in patients with DED as early as 28 days as opposed to existing therapies. We expect to report topline data in the second half of 2019."

About the OCU310 Phase 3 Program
Ocugen plans to conduct two identical placebo-controlled Phase 3 trials with approximately 240 patients per study. Given the early potential therapeutic benefits of brimonidine tartrate (0.2%) observed in the Phase 2 study, the Phase 3 efficacy and safety results will be assessed after 28 days of treatment (primary endpoint assessment visit). The primary endpoints of the Phase 3 trials are the change from baseline to four weeks (Day 28) in Symptom Assessment iN Dry Eye (SANDE) score and the change from baseline to four weeks (Day 28) in lissamine green conjunctival staining scores. Ocugen expects to report topline data in the second half of 2019.

About OCU310
OCU310 is an investigational twice-daily, steroid-free, preservative-free eye drop of brimonidine tartrate (0.2%) OcuNanoE™ nanoemulsion being developed for the relief of signs and symptoms of DED. Brimonidine tartrate is approved for other indications by the FDA and has demonstrated a favorable safety profile via topical ocular delivery. In early 2018, Ocugen completed a Phase 2 placebo-controlled proof-of-concept clinical study in which patients with DED were dosed with brimonidine tartrate (0.2%) twice a day for 84 days. The study met its primary endpoint of tolerability. Though not statistically powered, the study also met several prospectively defined, exploratory endpoints for common signs and symptoms of DED, supporting selection of endpoints for phase 3.

About Ocugen, Inc.
Ocugen, Inc., is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases. The Company's lead clinical candidate (OCU300) is currently in Phase 3 for patients with ocular graft versus host disease (oGVHD) and is the first and only therapeutic with orphan drug designation for oGVHD, providing certain regulatory and economic benefits. The Company's second lead candidate (OCU310) is also in Phase 3 for patients with dry eye disease. Both OCU300 and OCU310 leverage Ocugen's patented OcuNanoE – Ocugen's ONE Platform™ technology to enhance the efficacy of topical ophthalmic therapeutics. Ocugen is also developing novel biologic therapies for retinitis pigmentosa (OCU100) and wet AMD (OCU200), as well as a groundbreaking modifier gene therapy platform with potential to address a broad spectrum of inherited retinal disorders (OCU400). For more information, please visit www.ocugen.com.

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