Ocugen Announces FDA Acceptance of Investigational New Drug Application for OCU310 (brimonidine/steroid combination therapy) and Initiates Proof of Concept Study for Treatment of Dry Eye Disease

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MALVERN, Pa., Sept. 25, 2017 /PRNewswire/ -- Ocugen, Inc., a clinical stage biopharmaceutical company developing novel treatments for sight-threatening diseases, today announced that the U.S. Food and Drug Administration (FDA) accepted its Investigational New Drug (IND) application for OCU310 (brimonidine/steroid combination therapy), a topical formulation for the treatment of dry eye disease (DED). In addition, the Company announced that its first patient was dosed in a proof of concept study. This randomized, placebo-controlled, double-blind, multi-center, proof of concept study will assess the tolerability and preliminary efficacy of OCU310 for the treatment of DED.

"We are very excited to begin our first clinical study and dose our first patient," said Daniel Jorgensen, MD, Chief Medical Officer at Ocugen. "Our goal is to assess whether a combination product has potential benefit, in treating dry eye patients, while exploring the most appropriate endpoints for future pivotal studies."

"This is an important milestone for Ocugen as we enter the clinic and evaluate a new therapy for patients with dry eye disease," said Dr. Shankar Musunuri, Chairman, CEO and Co-Founder of Ocugen. "We know that current treatments are not reaching the majority of the population affected with dry eye disease and we hope that our combination product may provide another therapeutic option for these patients."

About Dry Eye Disease
Dry eye disease (DED) is a common ocular disorder involving the aberrant production and stability of tear film, which results in damage to the ocular surface and is correlated with symptoms of ocular discomfort. Common signs and symptoms of DED include: eye redness, ocular pain, burning and stinging sensation, foreign body sensation, itchy or scratchy eye sensation, tired eyes, enhanced eye pressure, and painful mucous discharge.

DED prevalence increases with age. The most common causes of dry eye are contact lens usage, autoimmune disorders, systemic drug effects, and refractive surgeries, particularly in middle-aged and older adults. DED also occurs in a higher percentage of women than men, especially in women entering menopause or pregnancy; hormone imbalances during menopause or pregnancy can cause lacrimal gland and ocular surface inflammation and tear film abnormalities.

Currently there are only two pharmaceutical agents that are FDA approved for the treatment of dry eye disease: Restasis® (cyclosporine ophthalmic emulsion) and Xiidra™ (lifitegrast ophthalmic solution). Given the complexity, severity, and frequency of DED, and given the limited modes of action by which these two compounds treat dry eyes, there is a medical need for other dry eye therapies, particularly those with multiple modes of action that target the wider dry eye population and are effective and safe for long-term daily use.

About Ocugen, Inc.
Ocugen, Inc. is a rapidly growing, clinical stage biopharmaceutical company dedicated to developing innovative therapies and novel biologics for rare and underserved ocular disorders. Ocugen is aggressively pursuing new treatments for ocular graft versus host disease (OCU300), dry eye disease (OCU310), retinitis pigmentosa (OCU100) and wet AMD (OCU200). Our lead programs OCU300 and OCU310 are being developed through the FDA's 505(b)(2) pathway and expected to enter pivotal clinical trials in 2018. In addition, OCU300 received the first and only orphan drug designation for ocular graft versus host disease from the Food and Drug Administration (FDA) providing certain regulatory and economic benefits. For more information, please visit www.ocugen.com.

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