Ocugen Expands Ophthalmology Portfolio

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Announces License Agreement with University of Illinois at Chicago (UIC) for OCU300; Patent Allowed for OCU200, Novel, Preclinical Biologic in Development for Wet AMD

MALVERN, Pa. & AURORA, Colo.--(BUSINESS WIRE)--Ocugen, Inc., a biopharmaceutical company developing treatments for sight-threatening diseases, today announced that it licensed a clinical-stage asset from the University of Illinois at Chicago(UIC) to be developed for the treatment of ocular graft versus host disease (oGVHD) and other dry eye diseases. The company also announced its patent application has been allowed for OCU200, a preclinical asset in development to treat wet age-related macular degeneration and other neovascular diseases.

Ocugen executed an exclusive worldwide license agreement with UIC on OCU300, which will be developed as a re-purposed drug under the U.S. Food and Drug Administration's 505(b)(2) regulatory pathway. According to a post-hoc analysis of OCU300 administered to patients with oGVHD in an exploratory observational study, there was beneficial effect in approximately 90 percent of patients without significant side effects.

Ocular graft versus host disease is a common complication that occurs in patients who have undergone allogenic hematological stem cell transplantation (allo-SCT), or bone marrow transplants. Ocular GVHD develops in approximately 40 percent to 60 percent of patients following allo-SCT and its most common clinical manifestations include keratoconjunctivitis sicca and cicatricial conjunctivitis, which combine to leave patients with dry, tearless eyes, vision issues and potential ocular scarring. Ocular GVHD may lead to severe ocular surface disease, which can significantly diminish quality of life and restrict daily activities.

"Patients who develop oGVHD after receiving a bone marrow transplant suffer from significantly irritating and discomforting symptoms of severe dry eye, which can cause long-term vision problems," said Dr. Shankar Musunuri, Chairman and CEO of Ocugen. "With OCU300, we have a clear and rapid development path forward, and we hope to bring these patients a new treatment option that has the potential to provide significant relief."

Ocugen plans to conduct a dose-finding study for OCU300 in coming months and anticipates initiating phase 3 clinical trials in 2017, a dry-eye related indication.

In addition, Ocugen also announced today that it received allowance for its patent application entitled "Transferrin-Tumstatin Fusion Protein and Methods for Producing and Using the Same." This patent covers compositions of matter, methods of production, and methods of use for OCU200, an anti-angiogenic tumstatin fusion protein, in preclinical development for treatment of wet age-related macular degeneration (AMD) and other neovascular diseases.

About Ocugen, Inc.
Ocugen is advancing two novel biologicals and a marketed drug product as a re-purposed drug under the U.S. Food and Drug Administration's 505(b)(2) regulatory pathway to treat sight threatening ocular disorders. OCU100 is a recombinant form of lens epithelium derived growth factor. It received orphan-drug status from the U.S. Food and Drug Administration for treatment of retinitis pigmentosa (RP), a rare eye disease. Its second asset, OCU200, is an anti-angiogenic tumstatin fusion protein being developed for treatment of wet age-related macular degeneration (AMD). OCU300 is being developed through the FDA's 505(b)(2) pathway for the treatment of ocular graft versus host disease (oGVHD).

Contacts

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