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Aura Biosciences Receives FDA Clearance of Investigational New Drug Application for Light-activated AU-011 for the Treatment of Ocular Melanoma

Landmark clinical trial has launched for rare disease with no approved targeted therapy

CAMBRIDGE, Mass. – Feb. 6, 2017 – Aura Biosciences, a biotechnology company developing a new class of therapies to target and selectively destroy cancer cells using viral nanoparticle conjugates, announced today that the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug application (IND) for the company's lead program, light-activated AU-011 in ocular melanoma (OM). This active IND enables Aura to begin initial clinical testing of AU-011, a unique targeted therapy that could transform the primary treatment of patients with OM, a rare and life-threatening disease.

"Early detection of ocular melanoma, combined with the administration of AU-011 as a potential vision-sparing therapy, could transform the treatment of patients with this devastating disease," said Brian Marr, M.D., Director of the Ophthalmic Oncology Service at Columbia University Medical Center. Dr. Marr is the principal investigator for the AU-011 clinical trial and also is a member of Aura's Clinical Advisory Board.

"Receiving IND clearance to enter the clinic for AU-011 is an important step in the development pathway for this novel class of drugs, and I'm thankful to our team of dedicated employees, as well as to our distinguished scientific and clinical advisors, for their contributions that have propelled us to this point," said Elisabet de los Pinos, Ph.D., founder and CEO of Aura. "With the advancement of AU-011, we are opening the door for innovation in a completely new therapeutic area where there are no FDA drugs approved today. Our hope is that AU-011 could be used to treat small primary melanomas early, with the potential to eliminate the tumor and preserve vision for patients."

The Phase 1b open-label, single ascending dose clinical trial currently enrolling is designed to evaluate the safety, immunogenicity and preliminary efficacy of two dose levels of AU-011 for the treatment of small-to-medium primary OM. Screening procedures for eligible patients are underway at five clinical trial sites across the country. For more information, visit www.clinicaltrials.gov or contact clinical@aurabiosciences.com.

About ocular melanoma (OM)
Ocular melanoma (OM), also known as uveal or choroidal melanoma, develops in the uvea, or uveal tract, of the eye, and is an aggressive and rare eye cancer. No targeted therapies are currently available, and current treatments are associated with serious morbidities. The most common treatment today is placing an invasive radioactive plaque against the exterior of the eye near the tumor, which requires multiple surgeries and can lead to cataracts, retinopathy and loss of vision. The alternative is enucleation, the removal of the eye. OM metastasizes to the liver in about half of all cases (source: OMF), and only 15 percent of patients whose OM has metastasized survive beyond five years after diagnosis (source: ACS).

About light-activated AU-011
AU-011 is a first-in-class targeted therapy in development for the primary treatment of ocular melanoma (OM), also known as uveal or choroidal melanoma, a rare and life-threatening disease. The therapy consists of viral nanoparticle conjugates that bind selectively to cancer cells in the eye. AU-011 has a necrotic mechanism of action and is administered through an intravitreal injection into the eye. Upon activation with an ophthalmic laser, the drug rapidly and specifically destroys the membranes of tumor cells while sparing

key eye structures, which may allow for the potential of preserving patients' vision. AU-011 for OM has been granted orphan drug designation by the U.S. Food and Drug Administration and is currently in clinical testing.

About Aura Biosciences
Aura Biosciences is developing a new class of therapies to target and destroy cancer cells selectively. Its lead program, AU-011 in ocular melanoma (OM), is being developed under a CRADA with the National Cancer Institute (NCI). For more information, visit www.aurabiosciences.com.

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