



Aura Biosciences Announces Interim Phase 1b/2 Data on Light-Activated AU-011 for Primary Ocular Melanoma

November 11, 2017

CAMBRIDGE, Mass.—([BUSINESS WIRE](#))—Aura Biosciences, a biotechnology company developing a new class of therapies to target and selectively destroy cancer cells using viral nanoparticle conjugates, today announced interim safety data from an open-label Phase 1b/2 study of its lead program, light-activated AU-011 for the treatment of primary ocular melanoma. The findings were presented by Carol Shields, M.D., Director of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology of Thomas Jefferson University in Philadelphia, during a late-breaking session at the American Academy of Ophthalmology (AAO) 2017 Annual Meeting in New Orleans. The first and second patients in this study were dosed earlier this year by Dr. Shields at Wills Eye Hospital in Philadelphia. The subsequent patients were dosed at centers in Boston, Detroit, Houston and Denver.

AU-011, an investigational, first-in-class targeted therapy, is in development for the treatment of primary ocular melanoma, a rare and life-threatening disease. The Phase 1b/2 open-label, ascending single and repeat dose trial of AU-011, will evaluate the safety (primary objective) and preliminary efficacy (secondary objective) in up to 24 adult patients who have a clinical diagnosis of ocular melanoma.

Interim data presented today at AAO show that the drug candidate was generally well-tolerated, with no serious adverse events reported, in the first six patients at three to six months post-treatment of AU-011. The most commonly reported adverse events consisted of anterior and posterior intraocular inflammation, which was managed with administration of topical and/or oral steroid treatment. All patients maintained visual acuity. The preliminary efficacy measurement of tumor thickness on B-scan ultrasound at three months post-treatment shows that all patients had stable disease at three months, and only one patient experienced tumor progression at five months.

"These preliminary findings are an encouraging step forward in our effort to evaluate the potential of AU-011 for the treatment of ocular melanoma," said Dr. Shields. "Today there are no treatment options available for patients that can effectively target tumor cells while still preserving vision. We are excited to build on these initial results as this important research progresses."

"Aura's goal is to give physicians first-in-class tools that can transform the treatment of ocular melanoma and other cancers when the disease is diagnosed early," said Cadmus Rich, M.D., Chief Medical Officer of Aura. "These are promising early data, and our team is pleased to continue our Phase 1b/2 study with Dr. Shields and our other collaborators at leading ophthalmology centers of excellence across the country."

About ocular melanoma

Ocular melanoma, also known as uveal or choroidal melanoma, develops in the uvea, or uveal tract, of the eye, and is a rare and aggressive eye cancer. No targeted therapies are available at present, and current radiotherapy treatments can be associated with severe visual loss and other long-term sequelae such as dry eye, glaucoma, cataracts and radiation retinopathy. The most common current treatment is plaque radiotherapy, which involves surgical placement of a radiation device against the exterior of the eye over the tumor. This technique can control the melanoma but can also lead to radiation-related cataract, retinopathy and loss of vision. The alternative is enucleation, or removal of the eye. Ocular melanoma metastasizes to the liver in about 40 percent of cases in the long-term (source: [OME](#)), and only 15 percent of patients whose melanoma 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, 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 and is derived from technology originally pioneered by Dr. John Schiller of the Center for Cancer Research at the National Cancer Institute (NCI). 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 ocular melanoma has been granted orphan drug and fast track designations 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, is being developed under a CRADA with the National Cancer Institute (NCI), part of the National Institutes of Health. For more information, visit www.aurabiosciences.com.

Media Contact

Lynnea Olivarez, 956-330-1917
Ten Bridge Communications
lynnea@tenbridgecommunications.com