



Aura Biosciences Presents Updated Phase 1b/2 Clinical Data for AU-011 at the American Academy of Ophthalmology 2018 Annual Meeting

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CAMBRIDGE, MA – October 29, 2018 – Aura Biosciences, a leader in the development of novel targeted therapies in ocular oncology, today announced that updated clinical data from its Phase 1b/2 clinical trial evaluating the safety and efficacy of light-activated AU-011, the Company's lead product candidate for the primary treatment of choroidal melanoma, was highlighted in an oral presentation at the American Academy of Ophthalmology (AAO) 2018 Annual Meeting being held October 27-30, 2018, at McCormick Place in Chicago.

Brian P. Marr, M.D., Director, Division of Ophthalmic Oncology, New York-Presbyterian/Columbia University Medical Center, and principal investigator of the study, gave the oral presentation titled, "One-Year Results of a Phase 1b/2 Open-Label Clinical Trial of AU-011 for the Treatment of Primary Choroidal Melanoma." This open-label, multicenter trial is designed to investigate single and multiple ascending doses of light-activated AU-011 in approximately 36 adult subjects with clinically diagnosed primary choroidal melanoma.

The data presented at the meeting show that multiple administrations of light-activated AU-011 are well-tolerated with no related serious adverse events, severe adverse events or dose-limiting toxicities observed. Drug related adverse events were all expected and included anterior chamber inflammation, posterior chamber inflammation and increase in intraocular pressure, but all were manageable with standard-of-care treatments and resolved without clinical sequelae. Notably, the posterior inflammation appears to originate within and/or around the tumor which is consistent with AU-011's mechanism of action of acute tumor necrosis.

Treatment with light-activated AU-011 achieved preservation of best corrected visual acuity (BCVA) with a mean change of -1.06 letters at 6 months and a mean change of -0.75 letters at 12 months. BCVA was preserved even in high risk patients with tumors close to the fovea or the optic disk, a factor that typically correlates with a higher risk of irreversible severe vision loss following radioactive treatments. Importantly, all patients (100%) achieved stable disease at the prespecified preliminary efficacy endpoint at 3 months. Biological activity has been confirmed with long term tumor control in those patients with documented growth before treatment, reduction in tumor thickness and localized inflammation around the tumor. An expansion cohort of the study is currently underway. The Company plans to initiate a pivotal Phase 3 clinical program following the Phase 1b/2 study.

"The currently available treatments for choroidal melanoma come with the risk of severe vision loss, especially for patients with melanomas that are located close to the fovea or optic disk," commented Dr. Marr. "These 12-month data demonstrate that light-activated AU-011 continues to be well-tolerated, including with multiple administrations, has evidence of tumor control and preservation of visual acuity. We look forward to executing on the expansion phase of the study and generating more clinical data for this innovative targeted therapy."

"To date, light-activated AU-011 has shown a compelling degree of tolerability and vision preservation, especially given the alternative radioactive treatment options for choroidal melanoma," said Cadmus Rich, M.D., Chief Medical Officer of Aura. "We believe that a minimally invasive, non-radiation-based treatment option that enables early intervention while preserving vision has the potential to transform the therapeutic landscape for this difficult to treat, often deadly form of melanoma. We are actively preparing the Phase 3 study designs and look forward to initiating this pivotal program."

About Choroidal Melanoma

Choroidal melanoma is a rare and aggressive type of eye cancer. Choroidal melanoma is the most common primary ocular tumor and develops in the uveal tract of the eye. 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 on the exterior of the eye over the tumor. The alternative is enucleation, or total surgical removal of the eye. Choroidal melanoma metastasizes to the liver in about 40-50 percent of cases in the long term (source: OMF), 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 choroidal melanoma. The therapy consists of proprietary viral-like particle bioconjugates (VPB) that are activated with an ophthalmic laser. The VPBs bind selectively to unique receptors on cancer cells in the eye and are derived from technology originally pioneered by Dr. John Schiller of the Center for Cancer Research at the National Cancer Institute (NCI), recipient of the 2017 Lasker-DeBakey Award. Upon activation with an ophthalmic laser, the drug rapidly and specifically disrupts the cell membrane of tumor cells while sparing key eye structures, which may allow for the potential of preserving patients' vision and reducing other long-term complications of radiation treatment. AU-011 can be delivered using equipment commonly found in an ophthalmologist's office and does not require a surgical procedure, pointing to a potentially less invasive, more convenient therapy for patients and physicians. AU-011 for the treatment of choroidal melanoma has been granted orphan drug and fast track designations by the U.S. Food and Drug Administration and is currently in clinical development.

About Aura Biosciences

Aura Biosciences is developing a new class of therapies to selectively target and destroy cancer cells. Its lead program, AU-011 in primary choroidal 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.

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