



Aura Biosciences Presents Updated AU-011 Clinical Data at ARVO 2020

June 12, 2020

CAMBRIDGE, MA – June 12, 2020 – Aura Biosciences, a clinical-stage biopharmaceutical company developing a novel class of tumor targeted therapies for initial application in primary tumors such as choroidal melanoma, today announced the virtual presentation of updated clinical data from its ongoing Phase 1b/2 clinical trial evaluating the safety and efficacy of light-activated AU-011, the Company's lead product candidate for the first line treatment of primary choroidal melanoma, as part of the Association for Research in Vision and Ophthalmology (ARVO) 2020 Annual Meeting.

"The clinical data presented this year at ARVO show that AU-011 has a favorable preliminary safety profile, controls tumor growth rate, and preserves vision in the vast majority of patients, including those at high risk for vision loss with tumors close to the fovea or optic nerve," said Prithvi Mruthyunjaya, MD, MHS, Associate Professor of Ophthalmology and Director, Ocular Oncology Service, Byers Eye Institute at Stanford University, and presenter of the abstract. "We believe these data support further clinical investigation in pivotal studies."

Updated Results from the Phase 1b/2 Study Evaluating AU-011

This open-label, multicenter trial is designed to investigate single and multiple ascending doses of light-activated AU-011, administered via intravitreal injection, in adult subjects with clinically diagnosed primary choroidal melanoma. The updated data demonstrate that multiple administrations of light-activated AU-011 were generally well-tolerated. Among the patients evaluated for safety (n=56), the most common treatment-related adverse events (AEs) were expected and included vitreous inflammation, anterior chamber inflammation and increase in intraocular pressure; all were manageable with standard-of-care treatments and the majority resolved without clinical sequelae. There were two treatment-related serious AEs (vision loss; 3.6%). Tumor control and vision preservation data continue to be supportive of the planned pivotal study.

Expanding Development of AU-011 to Include Suprachoroidal Administration

In addition to intravitreal administration, Aura is also planning to investigate AU-011 using the suprachoroidal (SC) route of administration. Aura believes that delivering AU-011 into the suprachoroidal space (SCS) within the eye, has the potential to maximize bioavailability at the tumor site and could allow for the treatment of a wider range of tumor sizes (small to medium size tumors), and therefore, a larger number of patients. The Company is partnered with Clearside Biomedical for use of Clearside's SCS Microinjector™ for administration of AU-011 into the SCS. Preclinical research regarding the ocular distribution and efficacy in a rabbit model of AU-011 using the SC administration is also being presented as part of the ARVO 2020 virtual program. The data showed excellent distribution of AU-011 in the SCS and complete necrosis of tumors following laser activation in a rabbit model of choroidal melanoma. Further preclinical studies are currently ongoing and Aura expects to initiate a Phase 2 clinical study evaluating SC delivery of AU-011 during the third quarter of 2020.

Cadmus Rich, MD, MBA Chief Medical Officer and Head of Research and Development at Aura Biosciences commented, "The suprachoroidal delivery route is exciting because it offers certain potential advantages over intravitreal injection, including high bioavailability of drug to the posterior segment of the eye where the choroidal melanoma is located and minimal exposure of non-targeted tissues which, based on preclinical toxicology studies, may lead to less intraocular inflammation and an improved safety profile. We believe that the SC administration of AU-011 will ultimately allow us to treat a larger number of patients with choroidal melanoma. We look forward to initiating a first-in-human Phase 2 study to assess this additional route of administration this year."

Details for the ARVO 2020 presentation is as follows:

Title: An Ongoing Phase 1b/2 Open-Label Clinical Trial to Evaluate the Safety and Efficacy of AU-011 for the Treatment of Choroidal Melanoma – Study Update

Presenter: Prithvi Mruthyunjaya, Stanford University

Abstract #: 4025

Session: Uveal melanoma

URL: <https://learning.arvo.org/diweb/catalog/item?id=5255133>

Title: Ocular distribution and efficacy after suprachoroidal injection of AU-011 for treatment of ocular melanoma

Presenter: Anneli Savinainen, Aura Biosciences

Abstract #: 3615

Session: Uveal melanoma – Advances in Therapy

URL: <https://learning.arvo.org/diweb/catalog/item?id=5251650>

The presentations can be accessed by ARVO members on the [ARVO Learn website](https://learning.arvo.org/). The presentations can also be accessed by visiting the "Presentations" section of "News and Publications" page of the Aura Biosciences website.

About Choroidal Melanoma

Choroidal melanoma is a rare and aggressive type of eye cancer. Choroidal melanoma is the most common primary intraocular tumor in adults 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 in approximately 50 percent of cases with liver involvement in 80-90% of cases and, unfortunately, metastatic disease is universally fatal (source: OMF). There is a very high unmet need for a new vision sparing targeted therapy that could enable early treatment intervention for this life-threatening rare disease given the lack of approved therapies, and the comorbidities of radioactive treatment options.

About Light-Activated AU-011

AU-011 is a first-in-class targeted therapy in development for the treatment of primary 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, Inc. is a clinical-stage biopharmaceutical company developing a new class of oncology therapies based on a novel tumor targeting technology for initial application in primary tumors such as ocular and bladder cancers with the potential to treat other cancers. The Company's proprietary technology platform utilizes viral-like particle bioconjugates (VPBs) that have a dual selectivity mechanism with targeted binding to cancer cells, followed by activation using a common laser. These potent cytotoxic therapies result in acute tumor cell necrosis, while sparing surrounding healthy tissue and activating the immune system to generate an anti-tumor response. Aura's lead product candidate belzupacap sarotalocan (AU-011) is currently in Phase 2 development for the treatment of choroidal melanoma, a vision and life-threatening form of eye cancer for which there are currently no approved therapies. In a Phase 1b/2 study, AU-011 demonstrated compelling efficacy, including high rates of tumor control and vision preservation, along with a favorable safety profile, in patients with choroidal melanoma. The development of AU-011 is partially supported by funding awarded under a CRADA from the U.S. National Institutes of Health's National Cancer Institute. Future pipeline applications for Aura's technology include choroidal metastases and primary bladder carcinoma. Aura is headquartered in Cambridge, MA. For more information, visit www.aurabiosciences.com or follow us on [Twitter](#).

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