Aura Biosciences Presents Interim Phase 2 Safety Data Evaluating Suprachoroidal Administration of AU-011 in Patients with Choroidal Melanoma at the ASRS 2021 Annual Meeting

October 11, 2021

CAMBRIDGE, MA – October 11, 2021 – Aura Biosciences, a clinical-stage oncology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today announced the presentation of interim Phase 2 data with 7 months average follow up evaluating the safety of suprachoroidal (SC) administration of AU-011, the Company's lead product candidate for the first-line treatment of primary choroidal melanoma, as a part of the American Society of Retina Specialists (ASRS) 2021 Annual Meeting.

There have been no related serious adverse events, dose limiting toxicities, or grade 3 adverse events observed during the study. "These interim data presented today demonstrate that suprachoroidal administration may improve the therapeutic index and optimize treatment parameters," 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. "I believe this approach may provide an opportunity for patients who need a new first line treatment for early-stage disease, where all current treatments are extremely invasive and unfortunately result in severe vision loss in many patients."

Phase 2 Trial Design and Timing

The Phase 2 trial is comprised of an open-label, dose escalation phase and a randomized, masked dose expansion phase that is assessing the safety and efficacy of ascending single- and repeat-doses of AU-011 via SC administration, followed by one or two laser applications per treatment. The randomized, dose expansion portion will be masked, sham-controlled and is designed to evaluate the safety and efficacy of the highest dose regimen of AU-011. Cohorts 1-5 have been fully enrolled (13 patients) and cohort 6 is currently enrolling in the Phase 2 study. The primary objective of the study is to assess safety and efficacy of AU-011 via SC administration for purposes of treating primary indeterminate lesions and choroidal melanoma.

The randomized phase of the trial is planned to begin in the second half of 2022 in patients with documented growth to establish the safety and efficacy of AU-011 and serve as the first pivotal trial for the treatment of indeterminate lesions and choroidal melanoma. The maximum treatment regimen anticipated for the randomized phase is three cycles of three weekly treatments of AU-011 at a dose of 80µg with 2 laser administrations.

Details from the ASRS 2021 Presentation:

Title: A Phase 2 Safety and Efficacy Trial of AU-011, a Virus-Like Drug Conjugate (VDC), with a Dose Escalation and a Randomized, Masked Expansion Phase
Presenter: Prithvi Mruthyunjaya, Stanford University
Session: Ocular Oncology Symposium
Date and Time: Monday, October 11, 2021 at 4:35pm ET

The presentation can 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 mortality rate in metastatic disease, lack of approved therapies, and the comorbidities of radioactive treatment options.

About AU-011

AU-011 is a first-in-class virus-like drug conjugate (VDC) therapy in clinical development for the first line treatment of choroidal melanoma. The virus-like component of the VDC selectively binds unique heparin sulphate proteoglycans (HSPGs), which are modified and overexpressed on the tumor cell surface of malignant cells in the choroid and AU-011 delivers a potent cytotoxic drug that is activated with infrared light. Upon activation with an ophthalmic laser, the cytotoxic drug rapidly and specifically disrupts the cell membrane of malignant cells with a pro-immunogenic cell death that can activate the immune system generating long term anti-tumor immunity. The unique specificity of tumor binding by the VDC enables the preservation of 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 is currently in Phase 2 clinical development and the company plans to expand the clinical program into choroidal metastasis.

About Suprachoroidal Administration

The suprachoroidal space (SCS®) injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. Aura believes that delivering AU-011 into SCS within the eye, has the potential to offer certain advantages, including higher bioavailability at the tumor site and reduced exposure of non-targeted tissues, which may lead to an improved therapeutic index for AU-011. Collectively, these features could allow for the treatment of a wider range of tumor sizes, 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. In preclinical research presented as part of the ARVO 2020 virtual program, AU-011 showed excellent distribution in the SCS, complete necrosis of tumors following laser activation in an animal model of choroidal melanoma and no clinical signs of anterior segment or posterior segment inflammation.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage oncology company developing a novel technology platform based on virus-like drug conjugates (VDCs) to target and destroy cancer cells selectively while activating the immune system to create long lasting anti-tumor immunity. The VDC technology platform is based on the discoveries of NIH Distinguished Investigator Dr. John Schiller of the Center for Cancer Research at the National Cancer Institute (NCI). The company has the goal of developing this technology in multiple cancer indications with an initial focus in ocular oncology, a group of rare diseases for which there are no approved drugs. Aura's lead product candidate belzupacap sarotalocan (AU-011) is currently in Phase 2 development for the first line treatment of choroidal melanoma, a vision and life-threatening form of eye cancer where standard of care radioactive treatments leave patients with major vision loss and severe comorbidities. AU-011 was well tolerated in a Phase 1b/2 trial, demonstrating high rates of tumor control and vision preservation. Future pipeline applications for Aura's technology include additional ocular oncology indications like choroidal metastases and solid tumor indications like non-muscle invasive bladder cancer. Aura is headquartered in Cambridge, MA. For more information, visit **www.aurabiosciences.com** or follow us on **Twitter**.

Investor and Media Contact:
Matthew DeYoung
Argot Partners
212-600-1902 | matthew@argotpartners.com