Aura Biosciences Announces Updated Phase 1b/2 Clinical Data for AU-011 Presented at the American Academy of Ophthalmology 2019 Annual Meeting

October 15, 2019

CAMBRIDGE, MA – October 15, 2019 – Aura Biosciences, a leader in the development of novel targeted therapies in ocular oncology, today announced the 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, at the American Academy of Ophthalmology (AAO) 2019 Annual Meeting, being held October 12-15, 2019 in San Francisco, CA.

"With its ability to provide tumor control and vision preservation, AU-011 holds significant potential as a new targeted therapy for the primary treatment of choroidal melanoma," said Cadmus Rich, MD, Chief Medical Officer and Head of Research and Development of Aura Biosciences. "The data presented this year by Dr. Duker provided information on Aura's proprietary technology platform and key insights that will inform the design and conduct of our pivotal Phase 3 program for AU-011, which we expect to commence in the second half of 2020. Dr. Schefler's presentation included an update on ongoing research we are conducting into suprachoroidal delivery which, may allow us to increase the range of tumor sizes that AU-011 can treat. Both of these presentations underscore our long-term vision and commitment to bringing this first-in-class technology to patients for this rare and life-threatening disease."

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

Jay S. Duker, M.D., Director New England Eye Center, and Professor and Chair, Tufts Medical Center, gave an oral presentation titled, "Novel Management of Choroidal Melanoma – AU-011," which highlighted the potential of Aura's viral like particle technology, updated data from the ongoing open-label Phase 1b/2 clinical trial, and described the novel design of the planned Phase 3 trial that Aura expects to initiate during the second half of 2020.

The Phase 1b/2 clinical data presented at AAO demonstrate that multiple administrations of light-activated AU-011 were well-tolerated. Among the patients evaluated for safety (n=46), the most common treatment-related adverse events (AEs) were expected and included anterior chamber inflammation, posterior chamber inflammation and increase in intraocular pressure; all were manageable with standard-of-care treatments and the majority 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. There was one treatment-related severe AE (vision loss; 2%) in one patient with a juxtafoveal tumor.

Tumor control and vision preservation data continue to be supportive of the planned Phase 3 registration trial. In the subset of patients with documented tumor growth prior to trial enrollment (n=17), treatment with AU-011 resulted in tumor control in 15 patients (88%; p=0.0117). The results from this ongoing Phase 1b/2 study will inform the design of Aura's planned pivotal Phase 3 program for AU-011.

"The data presented this year at AAO show that AU-011 is well tolerated with early signals of efficacy," said Dr. Duker. "AU-011 is administered via a simple, two-step procedure which includes an intravitreal injection followed by a laser application; all of which is completed in the physician's office. If approved, AU-011 represents the first potential new treatment for choroidal melanoma in several decades."

Exploring Suprachoroidal Delivery for AU-011

Amy C. Schefler, M.D., Weill Cornell Medical College and Retina Consultants of Houston, gave an oral presentation highlighting the data from the ongoing Phase 1b/2 study with intravitreal administration as well as new preclinical research demonstrating the potential advantages of delivering AU-011 using the suprachoroidal route of administration. Aura recently executed a licensing agreement with Clearside Biomedical for use of Clearside's suprachoroidal space (SCS) Microinjector™ for the treatment of intraocular cancers. Aura believes that by delivering AU-011 into the SCS, there is the potential for treating a larger number of patients with a good safety profile and a greater range of tumor sizes. Preliminary preclinical pharmacology data showed that AU-011 administered via the SCS Microinjector achieved full necrosis of tumor cells in all animals following laser activation. Further preclinical studies are currently ongoing and Aura expects to initiate clinical testing using suprachoroidal delivery for AU-011 during the first half of 2020.

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 is developing a new class of therapies to selectively target and destroy cancer cells. Its lead program, AU-011 for the treatment of 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** or follow us on **Twitter**.

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