

Aura Biosciences Announces Dosing of First Patient in Phase 2 Study Evaluating Suprachoroidal Administration of AU-011 in Patients with Choroidal Melanoma

Study Being Led by Leading Ocular Oncologist, Carol L. Shields, M.D., Director, Ocular Oncology Service, Wills Eye Hospital

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))-- 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 dosing of the first patient in a Phase 2 study evaluating the safety and efficacy of suprachoroidal (SC) administration of AU-011, the Company's lead product candidate, as a potential first-line treatment for patients with primary choroidal melanoma.

"I am honored to have enrolled the first subject in this exciting trial of AU-011 that, if approved, may offer patients the first targeted therapy that has the potential to not only control tumors but also to preserve vision in the majority of those treated — which could usher in a very beneficial paradigm shift in the management of this challenging disease," commented Timothy S. Fuller, M.D. from Texas Retina Associates in Dallas TX. "In addition, the suprachoroidal injection is a straightforward procedure that ocular oncologists should easily be able to perform."

Carol L. Shields, M.D., Director, Ocular Oncology Service at Wills Eye Hospital, Professor of Ophthalmology at Thomas Jefferson University, and Lead Investigator of the study, commented, "Choroidal melanoma is the most common intraocular cancer in adults and is of grave concern for patients based on its potential to develop into metastatic disease. We are very excited to partner with Aura Biosciences in the launch of this innovative clinical trial on behalf of the patients who need a new first line treatment option for early stage disease, where all current treatments are extremely invasive and result in severe vision loss in many patients. We believe this approach could provide an opportunity for the early treatment of a broader range of patients with this deadly disease."

"Dosing of the first patient in this Phase 2 study is a key milestone for both Aura and the AU-011 development program," said Cadmus C. Rich, M.D., M.B.A., Chief Medical Officer and Head of R&D for Aura Biosciences. "The suprachoroidal delivery route is compelling because it offers certain potential advantages over intravitreal injection, including higher bioavailability of drug to the posterior segment of the eye where choroidal melanomas are located, and reduced exposure of non-targeted tissues which may lead to an improved safety profile."

The first cohort of this Phase 2 study (NCT04417530) demonstrated favorable safety data with no safety findings and no adverse events noted. The objectives of the study include the assessment of safety and preliminary efficacy of the treatment of choroidal melanoma utilizing suprachoroidal administration of AU-011. Other objectives include determining the highest tolerated dosing regimen, as well as assessing immunogenicity.

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 AU-011 (belzupacap sarotalocan)

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 Suprachoroidal Administration

In addition to intravitreal administration, Aura is also investigating 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 offer certain advantages over intravitreal injection, 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 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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