Aura Biosciences Presents Interim Phase 1b/2 Data at the American Society of Retina Specialists (ASRS) Annual Meeting

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CAMBRIDGE, Mass., July 23, 2018 — Aura Biosciences, a leader in the development of novel targeted therapies in ocular oncology, presented interim data from an open-label Phase 1b/2 study of its lead program, light-activated AU-011 for the treatment of primary choroidal melanoma, at the 36th annual American Society of Retina Specialists (ASRS) meeting in Vancouver, Canada. The findings were presented by Amy Schefler, M.D., Clinical Assistant Professor at Weill Cornell Medical College/Methodist Hospital and Clinical Assistant Professor at University of Texas-Houston.

Dr. Schefler provided an update on the Phase 1b/2 open-label, multicenter trial, which has been designed to evaluate the safety and efficacy of single and multiple ascending doses in 30 adult subjects with clinically diagnosed small to medium primary choroidal melanoma.

Interim data presented at ASRS show that in an expanded set of subjects AU-011 continues to be well-tolerated with no related serious adverse events, no severe adverse events and no dose-limiting toxicities observed, including the cohorts in the multiple ascending dose phase of the study. Adverse events were manageable with standard-of-care treatments and there have been no long-term clinical sequelae. Pre-treatment visual acuity was maintained in all subjects that have been followed for 6 to 12 months.

Early efficacy results continue to be promising, with several subjects in the multiple-ascending-dose cohorts showing evidence of reduction in tumor height and 100% of the patients meeting the endpoint of stable disease at three months.

“All current treatment options for patients with this cancer result in significant vision loss from radiation-related side effects, ” said Dr. Schefler. “A treatment that is office-based, minimally invasive, and has a low risk of side effects would be a dramatic improvement in the therapeutic landscape for this deadly disease.”

Aura plans to complete the enrollment of this trial in October and then prepare for a Phase 3 program that is planned to satisfy the registration requirements in the United States and Europe.

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 patented viral capsid conjugates (VCC) with IR-700DX dye molecules that are activated with an ophthalmic laser. The VCCs 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. The IR-700DX dye molecules are produced by LI-COR Biosciences and are licensed exclusively to Aura for treating ocular cancers. 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 the 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.

Media Contact
Lisa Raffensperger, (617) 903-8783
Ten Bridge Communications