



Aura Biosciences Announces Successful Outcome of End of Phase 2 Meeting with FDA for AU-011 for the Treatment of Patients with Choroidal Melanoma

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CAMBRIDGE, MA – January 4, 2019 – Aura Biosciences, a leader in the development of novel targeted therapies in ocular oncology, today announced that it has received written confirmation from the U.S. Food and Drug Administration (FDA) regarding agreement on the design of its Phase 3 registration trials designed to evaluate light-activated AU-011 for the treatment of patients with choroidal melanoma. This written confirmation is the result of successful outcome of an “End of Phase 2” meeting with the FDA.

The STARBRIGHT registration program will consist of two small identical clinical trials designed to assess the safety and efficacy of AU-011 versus sham control for the treatment of patients with small choroidal melanoma and high risk indeterminate lesions. Both trials, which will be titled STARBRIGHT1 and STARBRIGHT3, will be global, multicenter, randomized and masked, and will be conducted in parallel. The primary endpoint will be comprised of a combination of tumor control and vision preservation.

In addition to the design of the Phase 3 trials, the FDA agreed with Aura’s proposed safety database. The FDA also agreed that no further non-clinical studies are needed.

“We are pleased to have received such clear guidance from the FDA with respect to the Phase 3 STARBRIGHT program to be able to meet the scientific and regulatory requirements for marketing approval in the U.S.” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura.

The currently available treatments for choroidal melanoma come with the risk of severe vision loss, especially for patients with melanomas located close to the fovea or optic disk. The ongoing Phase 1b/2 study with light-activated AU-011 has shown that the drug was well-tolerated, with clear evidence of tumor control and preservation of visual acuity at long term follow up.

“We believe that a minimally invasive, non-radiation-based treatment option that enables early intervention while preserving vision has the potential to transform the therapeutic landscape for this difficult to treat, often deadly form of melanoma,” said Cadmus Rich, M.D., Chief Medical Officer of Aura. “Overall, the meeting removed any remaining uncertainty on the regulatory path to approval and highlighted FDA’s commitment to guide Aura toward a potential first drug approved for patients with this highly unmet medical need.”

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 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 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.

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