Aura Biosciences Reports Topline Data from a Retrospective Study of Belzupacap Sarotalocan (AU-011) versus Plaque Radiotherapy Supporting the Value of a Vision Preserving Therapy for the Treatment of Patients with Early-Stage Choroidal Melanoma

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In this Retrospective Matched Case Control Study, Belzupacap Sarotalocan Achieved Statistically Significant Vision Preservation Compared to Plaque Radiotherapy, the Current Standard of Care

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 22, 2022-- Aura Biosciences Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, reported results from a retrospective, matched case control study. This retrospective analysis assessed the visual acuity of patients following treatment with plaque radiotherapy compared with prospective data on visual acuity in subjects with early-stage choroidal melanoma treated with belzupacap sarotalocan by intravitreal administration in the Phase 1b/2 trial (NCT03052127).

“These results point to the high unmet medical need for a first line vision preserving therapy for the treatment of early-stage choroidal melanoma given the high levels of irreversible visual acuity loss with the current standard of care with radiotherapy,” said Carol Shields, MD, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University. “Being able to treat the disease early, avoid radiotherapy and spare long-term vision loss in many patients, as well as potentially reducing the risk of metastatic disease, could represent a paradigm shift in our approach to the treatment of choroidal melanoma. This would be a significant improvement in the quality of life for patients with this life-threatening rare disease.”

Results from the Retrospective Study

Study Design

This retrospective, matched case control study compared visual acuity outcomes for 43 patients from Aura’s Phase 1b/2 trial evaluating intravitreal administration of belzupacap sarotalocan in patients with early-stage choroidal melanoma (AU-011-101, NCT03052127) to 150 patients from the subject database of a previously completed and published study where patients with small choroidal melanoma had been treated with plaque radiotherapy (Shields, et al. “Visual Outcome and Millimeter Incremental Risk of Metastasis in 1780 Patients With Small Choroidal Melanoma Managed by Plaque Radiotherapy.” JAMA Ophthalmology. September 27, 2018). Both cohorts of patients were at high risk for vision loss due to having the tumor edge within 3.0 mm of the fovea. The patients were matched for tumor height, tumor diameter, distance from the fovea and baseline visual acuity, which are among the core factors that impact visual acuity after treatment.

Key Findings:

- The vision results of patients with early-stage choroidal melanoma treated with radiotherapy showed the long term, progressive and irreversible loss of visual acuity in patients where tumors were close to the fovea.
- The loss of vision in radiotherapy patients was ≥3 lines in a majority of patients as early as 2 years and ≥6 lines as early as 3 years.
- We believe the comparison of the belzupacap sarotalocan and radiotherapy results supports the potential benefit of a targeted treatment achieving a statistically significant difference in visual acuity preservation as soon as two years including for both logMAR (Logarithm of the Minimum Angle of Resolution) vision ($p = 0.0094$) and change in logMAR vision ($p = 0.0323$).
- We believe the progressive loss of visual acuity with radiotherapy observed in this retrospective study underscores the urgent need for a vision preserving targeted therapy.
- The findings of this retrospective study were consistent with published clinical data supporting the irreversible loss of visual acuity after treatment with radiotherapy.

“We are committed to developing the first potential targeted therapy for patients with early-stage choroidal melanoma. We believe the visual acuity results of the retrospective matched case control study are exciting because they support the high unmet medical need for a long-term vision preserving therapy,” said Dr. Cadmus Rich, Chief Medical Officer and Head of R&D of Aura Biosciences. “Belzupacap sarotalocan is currently being evaluated in a Phase 2 dose escalation clinical trial (AU-011-202, NCT04417530) using suprachoroidal administration in patients with early-stage choroidal melanoma. We remain on track to initiate our pivotal trial by the end of 2022.”

Study Limitations include the retrospective nature and utilizing a matched case control design. The mean follow-up for patients treated with belzupacap sarotalocan in this initial analysis was 15.6 months. Due to the retrospective nature of this analysis, it is hypothesis-generating; no formal conclusions can be drawn. Aura has also initiated a prospective matched case control study to further evaluate the long-term visual acuity results of belzupacap sarotalocan from the Phase 2 trial AU-011-202 using suprachoroidal administration versus radiotherapy.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing virus-like drug conjugates (VDCs), a novel class of therapies, for the treatment of multiple oncology indications. Aura’s lead VDC candidate, AU-011 (belzupacap sarotalocan), consists of a virus-like particle conjugated with an anti-cancer agent. Belzupacap sarotalocan selectively targets and destroys cancer cells and activates the immune system with the potential to create long-lasting anti-tumor immunity. Belzupacap sarotalocan is currently in development for ocular cancers, with an ongoing Phase 2 dose escalation clinical trial evaluating first-line treatment of choroidal melanoma, a vision- and life-threatening form of eye cancer where standard of care with radiotherapy leaves patients with severe comorbidities, including major vision loss. Aura plans to pursue development of belzupacap sarotalocan across its ocular oncology franchise including for the treatment of patients with choroidal metastases. In addition, leveraging Aura’s technology platform, Aura is developing belzupacap sarotalocan more broadly across multiple cancers, starting with a planned Phase 1 clinical trial in patients with non-muscle invasive bladder cancer (NMIBC). Aura is headquartered in Cambridge, MA.

For more information, visit aurabiosciences.com, or follow us on Twitter and LinkedIn.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements that are not statements of historical fact may be deemed to be forward looking statements. Words such as “may,” “will,” “could”, “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “seeks,” “endeavor,” “potential,” “continue” or the negative of such words or other similar expressions that can be used to identify forward-looking statements. These forward looking statements include express or implied statements regarding Aura’s future expectations, plans and prospects, including, without limitation, statements regarding the therapeutic potential of belzupacap sarotalocan for the treatment of cancers including choroidal melanoma and NMIBC and expectations with respect to the clinical development of belzupacap sarotalocan.

The forward-looking statements in this press release are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Aura’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, an improved quality of life of patients after treatment with belzupacap sarotalocan; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of belzupacap sarotalocan compared to the existing standard of care for patients with choroidal melanoma; uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of Aura’s clinical trials may not be predictive of future results in connection with future clinical trials; whether Aura will receive regulatory approvals to conduct trials or to market products; whether Aura’s cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, assumptions and uncertainties regarding the impact of the continuing COVID-19 pandemic on Aura’s business, operations, strategy, goals and anticipated timelines; Aura’s ongoing and planned pre-clinical activities; and Aura’s ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties, and other factors include those risks and uncertainties described under the heading “Risk Factors” in Aura’s most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Aura with the SEC, which are available on the SEC’s website at www.sec.gov. Except as required by law, Aura disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Aura’s current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

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