Aura Biosciences Announces Interim Phase 2 Data Evaluating Suprachoroidal Administration of Belzupacap Sarotalocan (AU-011) for the First-Line Treatment of Patients with Early-Stage Choroidal Melanoma Presented at AAO 2022

October 3, 2022

Aura to Host Virtual Investor Day at 11:30 a.m. Eastern Time

BOSTON--(BUSINESS WIRE)--Oct. 3, 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, today announced that interim Phase 2 data evaluating the safety and efficacy of suprachoroidal (SC) administration using its first VDC product candidate, belzupacap sarotalocan (AU-011), for the first-line treatment of patients with early-stage choroidal melanoma (indeterminate lesions and small choroidal melanoma (IL/CM)), were presented at the American Academy of Ophthalmology (AAO) 2022 Annual Meeting held September 30-October 3, 2022, in Chicago, IL.

“The Phase 2 interim safety and efficacy data that was presented at AAO is very encouraging for patients with primary choroidal melanoma, as the majority of patients are diagnosed with early-stage disease and have no vision-preserving treatment options. Interim data showed a statistically significant reduction in tumor growth rate and a robust tumor control response with a high rate of visual acuity preservation at the therapeutic regimen,” said Dr. Ivana Kim, Director of the Ocular Melanoma Center, Massachusetts Eye and Ear. “Belzupacap sarotalocan offers a favorable safety profile supporting the potential to become the first vision-preserving treatment for early-stage choroidal melanoma, where patients have had to rely on radiotherapy for the last few decades.”

“Preliminary analysis of the data from the Phase 2 trial using suprachoroidal administration supports tolerability up to three cycles of therapy and shows a dose-dependent anti-tumor response. The results provide further clinical evidence to support the potential use of belzupacap sarotalocan as a novel targeted therapy in patients with early-stage disease with this targeted route using suprachoroidal administration,” said Dr. Cadmus Rich, Chief Medical Officer and Head of R&D of Aura Biosciences. “We believe that the data to date provides proof of concept for an additional intraocular route of administration and further supports belzupacap sarotalocan’s target product profile.”

The presentation can be accessed on the Company’s website: link

Interim Safety and Efficacy Data from the Ongoing Phase 2 Trial with SC Administration

This Phase 2 trial (NCT04417530) is assessing the safety and preliminary efficacy of single- and multiple ascending-doses of belzupacap sarotalocan up to three cycles of treatment via SC administration for the first-line treatment of early-stage choroidal melanoma (IL/CM). A total of 20 adult patients have been enrolled in the trial including the single dose Cohorts 1-3 (n=6) and multiple dose escalation Cohorts 4-6 (n=14). Cohorts 5 and 6 received up to three cycles of therapy, which was considered the therapeutic regimen for evaluation. One patient in Cohort 5 (n=3) received two cycles of therapy and two patients in Cohort 5 received three cycles of therapy (40 µg/dose). All patients from Cohort 6 (n=8) received three cycles of therapy at the highest dose (80 µg/dose). One patient from Cohort 6, who discontinued after one cycle due to unrelated serious adverse events (SAEs), is not included. All patients in Cohorts 5 and 6 had active growth at study entry, as an enrichment strategy to evaluate preliminary efficacy. This group of patients with active growth treated at the therapeutic regimen of three cycles was evaluated for tumor growth rate, tumor control, and visual acuity preservation as the defined clinical endpoints to evaluate preliminary efficacy. These endpoints have been discussed with the U.S. Food and Drug Administration and are planned to be used in the pivotal program. The results, with an average of six months follow up in patients that received three cycles of therapy in Cohorts 5 and 6, showed a statistically significant reduction in the tumor growth rate (-0.296 mm/yr, p = 0.0007) compared to each patient’s documented growth rate at study entry, and an 88.9% (8/9) tumor control rate. In addition, the visual acuity preservation rate was 88.9% (8/9) in these cohorts, with the majority of patients being at high-risk for vision loss with tumors close to fovea or optic disk. The overall safety profile of belzupacap sarotalocan was generally favorable, with no dose-limiting toxicities or treatment-related SAEs reported as of August 19, 2022. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in 20% of the patients. Treatment-related AEs were predominantly mild and resolved without sequalae. We believe these interim results indicate that belzupacap sarotalocan may offer a targeted vision preserving therapy for the first-line treatment of primary CM, where 80% of patients are diagnosed early and have no approved therapies to date.

Details for the Virtual Investor Day:

The Company will host a virtual Investor Day today at 11:30 a.m. Eastern Time to discuss belzupacap sarotalocan, its first VDC product candidate, for the first-line treatment of patients with early-stage choroidal melanoma. The Company’s executive management team will be joined by three distinguished ocular oncology thought leaders:

- Carol Shields, MD, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University (USA)
- Ivana Kim, MD, MBA, Director of the Ocular Melanoma Center, Massachusetts Eye and Ear & Associate Professor of Ophthalmology, Harvard Medical School (USA)
- Martine Jager, MD, PhD, Professor of Ophthalmology, Leiden University (Netherlands) & Past President of the International Society of Ocular Oncology and the Association for Research in Vision and Ophthalmology

To access the virtual Investor Day, please dial (888) 660-6585 (U.S. and Canada) or (929) 203-0858 (international) at least 10 minutes prior to the start time and refer to conference ID 9748492. A live video webcast will be available in the Investor section of the Company’s website at https://ir.aurabiosciences.com/events-and-presentations. A webcast replay will also be available on the corporate website at the conclusion of the call.

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, belzupacap sarotalocan (Bel-Sar; AU-011), consists of a virus-like particle conjugated with an anti-cancer agent. Belzupacap sarotalocan is designed to selectively target and destroy cancer cells and activate 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 metastasis. In addition, leveraging Aura's technology platform, Aura is developing belzupacap sarotalocan more broadly across multiple cancers, including in patients with non-muscle invasive bladder cancer (NMIBC). Aura is headquartered in Boston, 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; any express or implied statements regarding the Company's expectations for the Phase 2 clinical trial belzupacap sarotalocan; and Aura's expectations regarding the estimated patient populations and related market opportunities for 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; the risk that interim data from ongoing clinical trials may not be predictive of final data from completed 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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