Aura Biosciences Announces Positive Interim Phase 2 Safety and Efficacy Data of Belzupacap Sarotalocan (Bel-sar) for the First-Line Treatment of Patients with Early-Stage Choroidal Melanoma with Suprachoroidal Administrationat the Macula Society 46th Annual Meeting

February 16, 2023

BOSTON--(BUSINESS WIRE)--Feb. 16, 2023-- Aura Biosciences, Inc. (“Aura”) (Nasdaq: AURA), a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today announced the presentation of positive interim Phase 2 safety and efficacy data of bel-sar with 9-10 months of follow up evaluating two key clinical endpoints: tumor control and visual acuity preservation using the suprachoroidal (SC) route of administration for the first-line treatment of patients with early-stage choroidal melanoma (indeterminate lesions and small choroidal melanoma (IL/CM)). The results were presented at the Macula Society 46th Annual Meeting held February 15-18, 2023, in Miami, FL.

“The data presented today with an average of nine months of follow up for patients treated with three cycles of therapy, show an excellent response to the therapy with 89-100% tumor control. In addition, the safety profile to date has been favorable with only one patient losing visual acuity and no treatment-related SAEs or significant AEs, which is encouraging given that the majority of these patients had tumors close to the fovea or optic disk and would have likely experienced severe and irreversible vision loss with the current standard of care with radiotherapy,” said Dr. Ivana Kim, Director of the Ocular Melanoma Center, Massachusetts Eye and Ear. “These latest results strongly support the potential of bel-sar to be used as a first line treatment option for patients with early-stage choroidal melanoma.”

“We are excited with the interim efficacy data of the Phase 2 study which strongly supports the assumptions for the success of the global Phase 3 trial,” said Dr. Cadmus Rich, Chief Medical Officer of Aura Biosciences. “Collectively, we believe these interim data provide strong confidence to support the launch of a global Phase 3 trial which is on track to begin enrollment this year.”

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

Updated 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 bel-sar up to three cycles of treatment via SC administration for the first-line treatment of early-stage choroidal melanoma. 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) were assigned to receive 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. The results, with an average of nine months of follow up in patients who received three cycles of therapy in Cohorts 5 and 6, and who match the criteria for the planned global Phase 3 trial, showed a statistically significant reduction in the tumor growth rate (-0.289 mm/yr, p = <0.0001) compared to each patient’s documented growth rate at study entry, and a 100% (8/8) tumor control rate. In addition, the visual acuity preservation rate was 88% (7/8) 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 tolerability profile of bel-sar was generally favorable, with no dose-limiting toxicities, treatment-related SAEs or significant AEs reported as of January 10, 2023. 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 bel-sar 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.

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. Bel-sar is designed to selectively target and destroy cancer cells and activate the immune system with the potential to create long-lasting anti-tumor immunity. Bel-sar is currently in development for ocular cancers, and Aura has initiated activities for the global Phase 3 trial evaluating first-line treatment of early-stage 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 bel-sar across its ocular oncology franchise including for the treatment of patients with choroidal metastasis. In addition, leveraging Aura’s technology platform, Aura is developing bel-sar more broadly across multiple cancers, including in patients with non-muscle invasive bladder cancer (NMIBC). Aura is headquartered in Boston, MA.

Forward-Looking Statements

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 bel-sar for the treatment of cancers including choroidal melanoma, non-muscle invasive bladder cancer and choroidal metastases; any express or implied statements regarding the Company’s expectations for the Phase 2 and Phase 3 clinical trials of bel-sar for early-stage choroidal melanoma; and Aura’s expectations regarding the estimated patient populations and related market opportunities for bel-sar.

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 bel-sar; 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 bel-sar 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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