Aura Announces Global Phase 3 Trial Design with Suprachoroidal Route of Administration Based on Positive Phase 2 Interim Data of Belzupacap Sarotalocan in Early-Stage Choroidal Melanoma

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BOSTON--(BUSINESS WIRE)--Nov. 10, 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 it has initiated startup activities for the global Phase 3 trial. After presenting positive interim data at the American Academy of Ophthalmology from its ongoing Phase 2 trial, Aura has aligned with regulatory agencies and finalized the design of the global Phase 3 trial. The trial will evaluate the efficacy and safety of belzupacap sarotalocan (bel-sar) with suprachoroidal administration, for the first-line treatment of early-stage choroidal melanoma (CM).

“Finalizing the study design and selecting the optimal route of administration for the Phase 3 trial are key milestones in progressing towards a potential approval for bel-sar as a first-line vision preserving therapy in patients with early-stage choroidal melanoma,” said Dr. Cadmus Rich, Chief Medical Officer of Aura Biosciences. “We are pleased to have aligned with regulatory agencies on the overall Phase 3 trial design, including the primary and key secondary endpoints. We remain focused on improving the standard of care for patients with early-stage choroidal melanoma, a life-threatening disease that has no approved therapies.”

The Phase 3 trial has a three arm randomized and masked design, where the primary analysis will compare bel-sar to sham. Aura is planning to enroll approximately 75 adult patients with eary-stage CM, including patients with indeterminte lesions and small choroidal melanoma. Patients will be enrolled with documented growth as an enrichment strategy intended to increase the efficiency of the trial which will include an adaptive design to further increase the probability of success.

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 a global Phase 3 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 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.

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 bel-sar for the treatment of cancers including choroidal melanoma; any express or implied statements regarding the Company’s expectations for the Phase 2 and Phase 3 clinical trials of bel-sar; 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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Investor and Media:

Alex Dasalla
Head of Investor Relations and Corporate Communications
adasalla@aurabiosciences.com

Argot Partners
Matthew DeYoung
aura@argotpartners.com

Source: Aura Biosciences, Inc.