Aura Biosciences Announces First Patient Dosed in Global Phase 3 CoMpass Trial Evaluating the Safety and Efficacy of Belzupacap Sarotalocan (Bel-sar) for First-Line Treatment of Early-Stage Choroidal Melanoma

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BOSTON--(BUSINESS WIRE)--Dec. 7, 2023-- 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 the first patient has been dosed in the global Phase 3 CoMpass trial evaluating the safety and efficacy of bel-sar for the first-line treatment of adult patients with early-stage choroidal melanoma.

“Dosing of the first patient in this global Phase 3 trial is a major milestone for Aura, and for patients with early-stage choroidal melanoma, a life-threatening rare disease with no approved targeted therapies,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. “With the SPA agreement from the FDA, and a strong endorsement from the ocular oncology community, we continue to move bel-sar closer to potentially being approved as a first-line vision preserving treatment for patients living with this disease.”

The CoMpass trial is designed as a superiority trial comparing bel-sar versus a sham control. The trial is a global Phase 3, randomized, multi-center, masked study, intended to enroll approximately 100 patients randomized 2:1:2 to receive high dose regimen of bel-sar, low dose regimen of bel-sar with suprachoroidal (SC) administration or a sham control. Aura received written agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the overall design of the CoMpass trial.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing 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 is enrolling patients in the global Phase 3 trial evaluating first-line treatment of early-stage choroidal melanoma, a vision- and life-threatening form of eye cancer where the standard of care with radiotherapy leaves patients with severe comorbidities, including significant 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 and muscle invasive bladder cancer. Aura is headquartered in Boston, MA.

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

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, choroidal metastasis, muscle invasive bladder cancer and non-muscle invasive bladder cancer; any express or implied statements regarding Aura’s expectations for the Phase 3 clinical trial of bel-sar for early-stage choroidal melanoma; and the potential approvability of 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, 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; the risk that governmental authorities may disagree with Aura’s clinical trial designs, even where Aura has obtained agreement with governmental authorities on the design of such trials, such as the Phase 3 SPA agreement with FDA; 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; Aura’s ongoing and planned preclinical 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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