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Aura Biosciences Reports Positive Phase 2 End of Study Results Evaluating Bel-sar as a First-Line Treatment for Early-Stage Choroidal Melanoma

Bel-sar Demonstrated 80% Tumor Control Rate, 90% Visual Acuity Preservation, and a Highly Favorable Safety Profile

Aura to Host a Virtual Ocular Oncology Investor Event Featuring Key Opinion Leaders Today at 8:00 am ET

BOSTON, Sept. 12, 2024 (GLOBE NEWSWIRE) -- Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision therapies for solid tumors designed to preserve organ function, today announced positive Phase 2 end of study results evaluating bel-sar (AU-011) for the first-line treatment of early-stage choroidal melanoma (CM), a vision and life-threatening ocular cancer. The results were presented at The Retina Society Annual Meeting, on Thursday, September 12, 2024, in Lisbon, Portugal.

The Phase 2 study (NCT04417530) is an open-label, ascending single and repeat dose escalation trial in patients with early-stage CM (small CM and indeterminate lesions) designed to evaluate the safety, tolerability, and efficacy of up to three cycles of bel-sar treatment. The trial included both single and multiple ascending dose cohorts, with a total of 22 patients enrolled. Patients were closely monitored over a twelve-month follow-up period to assess tumor control, visual acuity preservation, and tumor growth rate.

Tumor Control and Visual Acuity Preservation

The Phase 2 results demonstrated that bel-sar achieved an 80% tumor control rate (n=8/10) among Phase 3-eligible patients who received the therapeutic regimen, with complete cessation of growth following treatment among responders (post-treatment average growth rate of 0.011 mm/yr among responders compared to 0.351 mm/yr prior to study entry; $p<0.0001$). Visual acuity preservation was achieved in 90% of these 10 patients. Importantly, 80% of these 10 patients were at high risk for vision loss with tumors close to the fovea or optic disc, highlighting the potential for vision preservation with this novel class of drugs. Of note, the current standard of care is radiotherapy, which leads to visual acuity of <20/200 (the cutoff for legal blindness) in the treated eye in up to 87% of patients.[1] The Phase 2 results are a significant achievement considering the typically poor prognosis associated with choroidal melanoma, a rare and life-threatening ocular cancer, where there are no approved vision-preserving therapies to date.

Highly Favorable Safety Profile with No Dose-Limiting Toxicities

The safety profile of bel-sar was highly favorable in all participants regardless of dose. There were no treatment-related serious adverse events (SAEs) reported. Ocular treatment-related AEs (TRAEs) were mild (Grade 1), included anterior chamber inflammation (18%) or cell (9%) and resolved without sequelae. The vast majority (~70%) of the anterior chamber inflammation/cell events were self-limited, requiring no treatment, and resolved in a median of 6 days. For those events that did require treatment, topical steroid eye drops, administered for a median of 6 days, achieved complete resolution of the inflammation. Eye pain occurred in 9% of patients and was mild (Grade 1). Importantly, no treatment-related posterior inflammation events (no vitritis, choroiditis, retinitis, retinal pigment epithelium changes, or vasculitis) were reported.

“Many patients with early-stage choroidal melanoma currently face the difficult choice of whether to treat the cancer and risk losing their vision in the treated eye, or delay treatment and risk the tumor progressing,” said Dr. Ivana Kim, Director of the Ocular Melanoma Center, Mass Eye and Ear / Harvard Medical School. “The Phase 2 end of study data that I presented at The Retina Society Annual Meeting showed 80% tumor control rate, 90% vision preservation, and a highly favorable safety profile in early-stage CM. Bel-sar has the potential to become the first treatment that achieves the dual goals of treating the tumor while also preserving vision, which could change the treatment paradigm for patients with this disease.”

“We believe these Phase 2 results provide clinical evidence for bel-sar as a potential vision-sparing, first-line treatment option for patients with early-stage CM,” said Dr. Jill Hopkins, Chief Medical Officer and President of Research and Development at Aura Biosciences. “Bel-sar is potentially a first-in-class novel therapy and we are excited to continue to advance this program, which is currently enrolling patients in our ongoing global Phase 3 CoMpass trial.”

Aura received written agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the design and planned analysis of the global Phase 3 CoMpass trial indicating concurrence by the FDA with the adequacy of the study, if successful, to address the objectives necessary to support Aura’s planned biologics license application submission. Aura Biosciences is focused on enhancing treatment options and improving outcomes for patients with CM and other cancers.

Aura Virtual Ocular Oncology Investor Event

Aura will host a virtual ocular oncology investor event featuring Dr. Ivana Kim, MD (Mass Eye and Ear) and Dr. Prithvi Mruthyunjaya, MD, MHS (Stanford University Byers Eye Institute) to discuss the Phase 2 end of study data on Thursday, September 12, 2024, at 8:00 am Eastern Time. To register for the event, click here. A live question and answer session will follow the formal discussion.

The live webcast of Aura’s virtual ocular oncology investor event will be available on the “Investors & Media” page under the “Events & Presentations” section of Aura’s website at https://ir.aurabiosciences.com/events-and-presentations, where a replay of the webcast will be archived for 90 days following the presentation date.

About Aura Biosciences

Aura Biosciences is a clinical-stage biotechnology company focused on developing precision therapies for solid tumors that aim to preserve organ function. Our lead candidate, bel-sar (AU-011), is currently in late-stage development for primary choroidal melanoma, and in early-stage development in other ocular oncology indications and bladder cancer. Aura Biosciences is headquartered in Boston, MA. Our mission is to grow as an innovative global oncology company that positively transforms the lives of patients.

For more information, visit aurabiosciences.com. Follow us on X (formerly Twitter) @AuraBiosciences and visit us on 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 early-stage CM and other oncology indications; statements regarding Aura’s expectations for the Phase 3 clinical trial of bel-sar for early-stage CM; statements regarding Aura’s expectations for an improved quality of life of patients after treatment with bel-sar; statements regarding Aura’s beliefs and expectations for the urgent need for an effective local treatment in ocular and other oncology indications to preserve organ function; statements regarding Aura’s expectations for the estimated patient populations and related market opportunities for bel-sar; and the potential for regulatory approval 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 preclinical and 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 the 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 United States 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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[1] Jarczak J, Karska-Basta I, Romanowska-Dixon B. Deterioration of visual acuity after brachytherapy and proton therapy of uveal melanoma, and methods of counteracting this complication based on recent publications. Medicina (Kaunas). 2023;59(6):1131.