Aura Biosciences Announces Enrollment Completion in Phase 3 CoMpass Trial of Bel-sar in Early Choroidal Melanoma

June 1, 2026

Enrollment of 108 patients completed in the registration-enabling Phase 3 CoMpass trial

Topline data from the 15-month primary endpoint expected in the second half of 2027

BOSTON, June 01, 2026 (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 it has completed enrollment of 108 patients in the Phase 3 trial evaluating belzupacap sarotalocan (bel-sar) as a frontline treatment for patients with early choroidal melanoma. Topline data for the 15-month primary endpoint are anticipated in the second half of 2027.

“Completing enrollment in our Phase 3 CoMpass trial marks a significant milestone for Aura as we advance bel-sar toward a potential regulatory approval in early choroidal melanoma,” said Dr. Jill Hopkins, Chief Medical Officer and President of R&D of Aura Biosciences. “We believe bel-sar has the potential to become the first approved frontline, vision-preserving therapy for this disease, addressing a critical unmet need for patients who today often face treatment options that can result in irreversible vision loss. We are deeply grateful to the patients, investigators, and clinical sites participating in the CoMpass trial and look forward to reporting topline data in the second half of 2027.”

The ongoing CoMpass trial is the first registration-enabling study in patients with early choroidal melanoma. The global, randomized Phase 3 trial is evaluating bel-sar versus sham control in the frontline setting under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). Aura previously received Orphan Drug Designation from both the FDA and the European Medicines Agency, as well as Fast Track designation from the FDA for the treatment of early choroidal melanoma.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company focused on developing precision therapies for solid tumors that aim to preserve organ function. Aura’s lead candidate, bel-sar (AU-011), is currently in late-stage development for early choroidal melanoma and in early-stage development in other ocular oncology indications and bladder cancer. Aura is headquartered in Boston, MA. Aura’s 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, @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 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 multiple cancers; statements regarding Aura’s plans and expectations for its ongoing and future clinical trials of bel-sar; statements regarding the timing and plans for Aura’s Phase 3 CoMpass trial in early choroidal melanoma, including the timing of topline data; statements regarding the potential regulatory approval of bel-sar in early choroidal melanoma; statements regarding Aura’s expectations for an improved quality of life of patients after treatment with bel-sar and changes to the treatment paradigm for patients; and statements regarding Aura’s expectations for 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, 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 early or 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 special protocol assessment agreement with the U.S. Food and Drug Administration; 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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