Aura Biosciences Announces Orphan Drug Designation Granted to AU-011 by European Commission for the Treatment of Uveal Melanoma (Includes Choroidal Melanoma)

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 21, 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 the European Commission has granted Orphan Drug Designation to AU-011, its first VDC product candidate, for the treatment of uveal melanoma. The designation of uveal melanoma includes choroidal melanoma as well as melanomas of the iris and the ciliary body. Choroidal melanoma represents approximately 90% of uveal melanomas.

“There are currently no approved drug therapies for the treatment of early-stage choroidal melanoma, and receiving Orphan Drug Designation from EMA underscores the unmet need that AU-011 could fill for patients with this life-threatening disease,” said Mark De Rosch, Ph.D., Chief Operating Officer and Head of Regulatory Affairs. “We have alignment with U.S. and European agencies on our pivotal program and are on track to initiate this program before the end of 2022.”

The European Commission grants Orphan Drug Designation for medicinal products intended to treat life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 people in the European Union (EU) and when no satisfactory method of diagnosis, prevention, or treatment of the condition can be authorized. The designation provides certain benefits and incentives in the EU, including protocol assistance, fee reductions, and ten years of market exclusivity once the medicine is on the market.

AU-011 was previously granted Orphan Drug Designation for the treatment of uveal melanoma by the U.S. Food and Drug Administration.

About AU-011

AU-011 is a first-in-class virus-like drug conjugate (VDC) therapy in clinical development for the first line treatment of choroidal melanoma. The virus-like component of the VDC selectively binds unique heparin sulphate proteoglycans (HSPGs), which are modified and overexpressed on the tumor cell surface of malignant cells in the choroid and AU-011 delivers a potent cytotoxic drug that is activated with infrared light. Upon activation with an ophthalmic laser, the cytotoxic drug rapidly and specifically disrupts the cell membrane of malignant cells with a pro-immunogenic cell death that can activate the immune system generating long term anti-tumor immunity. The unique specificity of tumor binding by the VDC enables the preservation of key eye structures, which may allow for the potential of preserving patients’ vision and reducing other long-term complications of radiation treatment. AU-011 can be delivered using equipment commonly found in an ophthalmologist’s office and does not require a surgical procedure, pointing to a potentially less invasive, more convenient therapy for patients and physicians. AU-011 for the treatment of choroidal melanoma is currently in Phase 2 clinical development and the company plans to expand the clinical program into choroidal metastasis.

About Aura Biosciences

Aura Biosciences, Inc. (NASDAQ: AURA) 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, AU-011 (belzupacap sarotalocan), consists of a virus-like particle conjugated with an anti-cancer agent. AU-011 selectively targets and destroys cancer cells and activates the immune system with the potential to create long-lasting anti-tumor immunity. AU-011 is currently in development for ocular cancers, with an ongoing Phase 2 clinical 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 develop AU-011 across its ocular oncology franchise including for the treatment of patients with choroidal metastases. In addition, leveraging Aura’s technology platform, Aura is developing AU-011 more broadly across multiple cancers, starting with a planned Phase 1 clinical trial in patients with non-muscle invasive bladder cancer. Aura is headquartered in Cambridge, 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 AU-011 for the treatment of choroidal melanoma, expectations regarding the timing of the Company’s AU-011 pivotal program and further clinical development plans.

The forward-looking statements in this press release are neither promises nor guarantees, and you 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; 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 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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