Aura Biosciences to Present Belzupacap Sarotalocan (AU-011) Data from Multiple Studies at the 22nd EURETINA Congress

September 1, 2022

On Track to Initiate Pivotal Trial in Early-Stage Choroidal Melanoma in Q4 2022

On Track to Submit IND in Choroidal Metastasis in 2H 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 1, 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 multiple presentations of data evaluating its first VDC candidate, belzupacap sarotalocan (AU-011), for the first-line treatment of patients with early-stage choroidal melanoma [indeterminate lesions and small choroidal melanoma (IL/CM)]. The presentations include interim safety data from the ongoing Phase 2 trial using suprachoroidal (SC) administration, final safety and efficacy data from the Phase 1b/2 trial using intravitreal (IVT) administration, and preclinical results that highlight belzupacap sarotalocan's targeted cytotoxicity towards tumor cells derived from the most common cancer types known to metastasize to the choroid, supporting its potential use for the treatment of choroidal metastases, a key second ocular oncology indication. The presentation also includes preclinical data that supports the activity of belzupacap sarotalocan as a single agent as well as in combination with checkpoint inhibitors, highlighting the possibility to treat not only primary tumors in the eye but potentially distant metastases by an abscopal effect. The results will be presented at the 22nd EURETINA Congress, being held September 1-4, 2022, in Hamburg, Germany.

"We are excited to present for the first time in Europe the final safety and efficacy data from the Phase 1b/2 trial evaluating IVT administration of belzupacap sarotalocan for the treatment of early-stage choroidal melanoma, along with interim safety data from the ongoing Phase 2 trial using SC administration. In Europe, early-stage choroidal melanoma is a high unmet medical need with no approved therapies. We continue to progress with our Phase 2 SC trial, and we plan to finalize a decision on the route of administration and initiate our pivotal program in Q4 of this year," said Dr. Cadmus Rich, Chief Medical Officer and Head of R&D of Aura Biosciences. "Preclinical data that will be presented at EURETINA provides further evidence that belzupacap sarotalocan has shown anti-tumor activity across multiple tumor types that are known to metastasize to the choroid, supporting clinical development in this second ocular oncology indication. We look forward to submitting the IND in choroidal metastases in the second half of this year."

"I am encouraged by the interim safety data observed in the Phase 2 suprachoroidal study to date. These results further support belzupacap sarotalocan's potential as a vision-preserving first line treatment option for patients with suspicious pigmented choroidal lesions whose only option is radiotherapy, which usually causes severe and irreversible vision loss. Preliminary data from the dose-escalation phase of the Phase 2 SC trial have shown minimal inflammation with most adverse events of intraocular inflammation reported as Grade 1 across all treatment regimens," said Dr. Martine Jager, Professor of Ophthalmology at Leiden University. "Additional preclinical data from a research collaboration with the University of Leiden (Netherlands) highlights the possibility of using belzupacap sarotalocan in combination with immune checkpoint inhibitors to treat not only the primary lesions in the choroid but also potentially treat distant lesions by an abscopal effect."

Details for EURETINA 2022 presentations:

Title: Clinical Evaluation of AU-011, a First-in-Class Targeted Therapy for Choroidal Melanoma, with Intravitreal or Suprachoroidal Route of Administration
Presenter: Martine Jager, Professor of Ophthalmology at Leiden University
Session: Miscellaneous Free Paper Session
Date/Time: Friday, September 2, 2022 from 17:14-17:20 CEST

Title: New treatment of melanocytic lesions – AU011
Presenter: Martine Jager, Professor of Ophthalmology at Leiden University
Session: Tumors
Date/Time: Saturday, September 3, 2022 from 8:52-9:02 CEST

The presentations will be available on the "Scientific Presentations" section of "VDC Platform" page of the Aura Biosciences website on Saturday, September 3, 2022.

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 (AU-011), consists of a virus-like particle conjugated with an anti-cancer agent. Belzupacap sarotalocan is designed to selectively target and destroy cancer cells and activate the immune system with the potential to create long-lasting anti-tumor immunity. Belzupacap sarotalocan is currently in development for ocular cancers, with an ongoing Phase 2 dose escalation 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 belzupacap sarotalocan across its ocular oncology franchise including for the treatment of patients with choroidal metastases. In addition, leveraging Aura's technology platform, Aura is developing belzupacap sarotalocan 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 expected timing of updates on the Company’s data from its Phase 2 and Phase 1b/2 clinical trials and Retrospective Match Case Control Study of belzupacap sarotalocan (AU-011), the significance of interim data from the ongoing Phase 2 suprachoroidal study, the therapeutic potential of belzupacap sarotalocan for the treatment of cancers including choroidal melanoma and NMIBC and expectations with respect to the timing of its Phase 2 suprachoroidal study and pivotal program the clinical development of belzupacap sarotalocan.

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 Aura’s ongoing clinical trials may not be predictive of final data and results; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 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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Source: Aura Biosciences Inc.