Aura Biosciences Receives FDA Fast Track Designation for Belzupacap Sarotalocan (AU-011) for the Treatment of Non-Muscle Invasive Bladder Cancer

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 30, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation for belzupacap sarotalocan (AU-011), Aura's first VDC product candidate, for the treatment of Non-Muscle Invasive Bladder Cancer (NMIBC).

"We are pleased that belzupacap sarotalocan has been granted Fast Track designation. We believe that, given that NMIBC presents such a high unmet medical need, the opportunity for more frequent interactions with Division of Oncology at FDA and the potential for Priority Review will be valuable as we advance further into clinical development in patients with NMIBC," said Dr. Mark De Rosch, Chief Operating Officer and Head of Regulatory Affairs of Aura.

"NMIBC has no approved targeted therapies, and patients experience high levels of recurrence and progression, ultimately leading to cystectomy or the removal of the entire bladder," said Dr. Cadmus Rich, Chief Medical Officer and Head of R&D of Aura. "This milestone supports our goal to advance the development of belzupacap sarotalocan for patients with NMIBC in need of better and earlier targeted treatment options with the potential to help preserve the bladder."

Aura's planned Phase 1 clinical trial with belzupacap sarotalocan in this indication will evaluate the safety and early proof of mechanism, assess distribution, local necrosis and evidence of immune activation. Aura expects to initiate the trial in the second half of 2022, with initial Phase 1 data expected in 2023.

Fast Track designation is an FDA process designed to facilitate the development of products that address high unmet medical needs and may expedite the review of drugs intended to treat serious or life-threatening diseases. Features of Fast Track designation include opportunities for more frequent interactions with the FDA review team and, if supported by clinical data, eligibility for Priority Review. Belzupacap sarotalocan has also been previously granted Fast Track and Orphan Drug designations by the FDA for the treatment of choroidal melanoma and is currently in Phase 2 clinical development in this indication.

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 it as a 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 pursue development of 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 (NMIBC). 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 belzupacap sarotalocan for the treatment of cancers including choroidal melanoma and NMIBC and expectations with respect to the clinical development of belzupacap sarotalocan, including expectations regarding the potential benefits conferred by Fast Track designation and initiation of a Phase 1 clinical trial.

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, an improved quality of life of patients after treatment with belzupacap sarotalocan; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of belzupacap sarotalocan compared to the existing standard of care for patients with choroidal melanoma; 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 development and review 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 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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