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Aura Biosciences Announces Additional Data from Ongoing Phase 1 Trial in Non-Muscle Invasive Bladder Cancer to be Presented as a Late-Breaking Abstract at the 40th Annual European Association of Urology Congress

Aura will Participate in the Research Forum at the 40th Annual European Association of Urology Congress

Aura will Host a Virtual Urologic Oncology Investor Event Featuring Key Opinion Leaders at 4:30 pm Eastern Time on March 24, 2025

BOSTON, March 03, 2025 (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 that additional Phase 1 data evaluating bel-sar (AU-011) for the treatment of patients with non-muscle invasive bladder cancer (NMIBC) will be presented at the 40th Annual European Association of Urology (EAU) Congress being held March 21-24, 2025, in Madrid, Spain. Aura will also participate in the EAU Research Forum during the Congress.

The EAU late-breaker presentation details are as follows:

Title: *Safety and efficacy of Bel-sar (AU-011), a Virus-like-Drug-Conjugate (VDC), in patients with Non-Muscle Invasive Bladder Cancer (NMIBC)*

Presenter:

- Seth Lerner, MD, Scott Department of Urology, Dan L. Duncan Comprehensive Cancer Center, Baylor College of Medicine, Houston, TX, USA

Date/Time: Saturday, March 22, 2025, from 3:30 pm to 3:35 pm Central European Standard Time (10:30 am to 10:45 am Eastern Time)

The EAU Research Forum details are as follows:

Title: *Virus-like Drug Conjugates (VDC), a paradigm shifting approach for the treatment of bladder cancer: Mechanism, First Insights, and Future Directions*

Presenters and Moderator:

- Shahrokh F. Shariat, MD, Dept. of Urology, Medical University of Vienna, Vienna, Austria
- Laura Bukavina, MD, Glickman Urological Institute Cleveland Clinic Cleveland, OH, USA
- Peter Black, MD, Department of Urologic Sciences, University of British Columbia, Vancouver, British Columbia, Canada
- Sabine D. Brookman-May, MD, Aura Biosciences, Boston, MA, USA; Dept. of Urology, University of Munich, LMU, Munich, Germany

Date/Time: Sunday, March 23, 2025, from 12:30 pm to 12:45 pm Central European Standard Time (7:30 am to 7:45 am Eastern Time)

The presentations will be available here, following the live presentations.

Virtual urologic oncology investor event on Monday, March 24, 2025, at 4:30 pm Eastern Time

Aura will host a virtual urologic oncology investor event featuring Neal Shore, MD, FACS (Carolina Urologic Research Center), Gary Steinberg, MD, FACS (Rush University) and Jennifer A. Linehan, MD (Saint John's Cancer Institute), who will join company management to discuss additional data from the ongoing Phase 1 trial in NMIBC, a multi-center, open-label clinical trial designed as a window of opportunity study to assess the safety and feasibility of local administration of bel-sar as a monotherapy prior to transurethral resection of bladder tumor (TURBT), the standard of care procedure. The study is designed to evaluate different approaches to optimize the feasibility of local administration and includes histopathological evaluation after a single dose to assess bel-sar's biological activity and dual mechanism of action including the characterization of the immune response.

At the event, Aura will also provide a bladder cancer program update, including the planned Phase 1b/2 trial expansion and future development plans. A live question and answer session will follow the discussion. To register for the event, click here.

The live webcast of Aura's virtual urologic 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 Neal Shore, MD, FACS

Neal Shore, MD, FACS graduated from Duke University and Duke University Medical School. He completed his general surgery/urology residency at New York Hospital-Cornell Medical Center/Memorial Sloan Ketering Cancer Center. He serves as the Medical Director for the Carolina Urologic Research Center. Dr. Shore has conducted more than 400 clinical trials, focusing mainly on genitourinary oncology, and has authored more than 350 peer-reviewed publications and numerous book chapters. He serves on the Society for Immunotherapy of Cancer (SITC) Guidelines Committee for Bladder Cancer, as well as the boards of the Bladder Cancer Advocacy Network, the APCCC Scientific Steering Committee, Maple Tree Cancer Alliance, Alessa Therapeutics, Photocure, and the Duke Global Health Institute. He is the Chair of both the Prostate Cancer Academy and the Bladder/Kidney Cancer Academy, and the co-chair of the annual AUA International Prostate Forum. He has served/serves on the editorial boards of Reviews in Urology, Urology Times, Chemotherapy Advisor, OncLive, PLOS ONE, Urology Practice, JUOP and World Journal of Urology. He is the Editor of Reviews in Urology and serves as an Editor of Everyday Urology-Oncology. He is a Fellow of the American College of Surgeons.

About Gary Steinberg, MD, FACS

Gary Steinberg, MD, FACS received his medical degree from the University of Chicago Pritzker School of Medicine and completed urology residency and urologic oncology fellowship at The Brady Urological Institute- Johns Hopkins University. He is a professor in the Department of Urology at Rush University in Chicago. Dr. Steinberg is a national authority in the surgical treatment of bladder cancer and continent urinary tract reconstruction and is a recognized expert in translational bladder cancer research as well as innovative clinical trials. A prolific researcher, Dr. Steinberg has made significant contributions to our understanding of both non-muscle invasive and invasive bladder cancer and serves as the principal investigator on numerous clinical trials, working to identify new novel therapies as well as molecular biomarkers to detect the disease. Dr. Steinberg has authored or coauthored more than 200 articles as well as nearly two dozen chapters for medical textbooks. Currently, he serves on the editorial board of multiple urologic oncology journals and is the immediate past chairperson of the scientific advisory board of the Bladder Cancer Advocacy Network.

About Jennifer A. Linehan, MD

Jennifer Linehan is a board-certified urologist and associate professor of urology and urologic oncology at Saint John's Cancer Institute. She specializes in general urology and urologic oncology, with expertise in robotic and laparoscopic surgery, as well as cancer research. Dr. Linehan earned her medical degree from the University of Arizona, where she also completed her general surgery internship and urology residency. She has received multiple awards for compassionate care and research in kidney cancer. Dedicated to personalized patient care, Dr. Linehan works with multidisciplinary teams to provide innovative and comprehensive treatment. She is certified by the American Board of Urology and actively contributes to research and education.

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 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 bladder cancer; statements regarding Aura’s plans and expectations for its ongoing and future clinical trials of bel-sar in bladder cancer; statements regarding the timing and plans to present data with respect to its Phase 1 clinical trial of bel-sar for the treatment of bladder cancer, as well as a bladder cancer program update, including the planned Phase 1b/2 trial expansion and future development plans; statements regarding the timing and content of the EAU late breaker presentation, EAU Research Forum, and Aura’s virtual urologic oncology investor event; 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; statements regarding Aura’s expectations for the estimated patient populations and related market opportunities for bel-sar; and statements regarding the timing of the announcement of additional NMIBC data from Aura’s ongoing Phase 1 trial of bel-sar, as well as a bladder cancer program update, including the planned Phase 1b/2 trial expansion and future development plans.

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, additional 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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