LeonaBio to Highlight Lasofoxifene in ER-positive (ER+), HER2-negative, ESR1-mutated Metastatic Breast Cancer at DAVA Oncology's 4th Summit on Breast Cancer

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On Track to Complete Enrollment of the Phase 3 ELAINE-3 clinical trial in 4Q 2026 with Topline Data Expected in 2H 2027

BOTHELL, Wash., Aug. 12, 2026 (GLOBE NEWSWIRE) -- **LeonaBio, Inc.** (NASDAQ: LONA), a clinical-stage biopharmaceutical company dedicated to the development of novel therapeutics for diseases with high unmet medical needs, today announced that its lead product candidate, lasofoxifene, will be featured in multiple presentations at Dava Oncology's 4th Summit on Breast Cancer taking place from August 18-22, 2026, in Kona, Hawaii.

"We are honored to share the body of clinical and scientific evidence supporting lasofoxifene as a potential treatment for metastatic breast cancer with many of the world's leading breast cancer experts," said Mark Litton, Ph.D., President and Chief Executive Officer of LeonaBio. "Patients with metastatic breast cancer continue to face significant challenges as resistance emerges and treatment options become limited. We believe lasofoxifene has the potential to redefine the treatment paradigm for these patients through its differentiated mechanism of action and promising clinical profile. As we advance toward completion of enrollment in our pivotal Phase 3 ELAINE-3 trial, we remain focused on obtaining the data needed to bring a potential new therapeutic option to patients as quickly as possible."

Jessica Tao, M.D., a medical oncologist specializing in breast cancer at Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, will present on lasofoxifene, including the Phase 3 ELAINE-3 clinical trial of lasofoxifene in combination with abemaciclib in the treatment of ER-positive (ER+), HER2-negative, ESR1-mutated metastatic breast cancer on Wednesday, August 19, 2026, at 8:02 am Hawaii time.

In addition, David Portman, M.D., Founder and Chief Executive Officer of Sermonix and a consultant to LeonaBio, will lead an Industry Lunch Presentation on the development of lasofoxifene and its potential as a treatment for metastatic breast cancer on Thursday, August 20, 2026, at 12:25 pm Hawaii time.

"We are excited by the opportunities that success in ELAINE-3 could create, not only in potentially establishing lasofoxifene in combination with CDK4/6 inhibition as a new standard of care in metastatic breast cancer but also informing future testing in different combination strategies and additional breast cancer settings," concluded Dr. Litton.

About LeonaBio

LeonaBio, headquartered in the Seattle, Washington area, is a clinical-stage biopharmaceutical company dedicated to the development of novel therapeutics for diseases with high unmet medical needs, including treatment-resistant metastatic breast cancer and amyotrophic lateral sclerosis (ALS), with the goal of improving patients' lives. Our lead drug candidates, lasofoxifene and brelgometon (ATH-1105), are novel, small molecule therapies with the potential to address devastating diseases where current treatment options are limited or ineffective. With a strong commitment to scientific excellence and patient-centered innovation, we are dedicated to developing meaningful new therapies for those who need them most.

For more information, visit www.leonabio.com.

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding: the beneficial characteristics, safety and efficacy of LeonaBio's drug candidates; the potential of LeonaBio to complete the Phase 3 ELAINE-3 clinical trial for lasofoxifene and to meet the trial endpoints, potential of ELAINE-3 to serve as a registrational trial, and any subsequent clinical trials to show the clinical benefits of lasofoxifene to the satisfaction of the FDA to support its regulatory approval; LeonaBio's drug candidates as potential treatments for metastatic breast cancer, amyotrophic lateral sclerosis and other diseases; LeonaBio's future development plans and the timing thereof; anticipated development milestone timelines, such as the initiation of clinical trials and the timing of data releases, and LeonaBio's ability to meet such timelines; and LeonaBio's ability to obtain and maintain regulatory approval of its drug candidates in the United States and other jurisdictions and the timing thereof, and any related restrictions, limitations or warnings in the label of any approved drug candidate. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "on track," "would," "expect," "plan," "believe," "intend," "pursue," "continue," "suggest," "potential," "target" and similar expressions. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the possible failure to realize certain anticipated benefits of the license relating to lasofoxifene and the recent private placement financing, including with respect to future financial and operating results; the data from preclinical and clinical trials may not support the safety, efficacy and tolerability of LeonaBio's drug candidates; development of drug candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for drug candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; whether LeonaBio's trials are sufficiently powered to meet the planned endpoints; LeonaBio may not be able to recruit sufficient patients for its clinical trials; the outcome of legal proceedings that may in the future be instituted against LeonaBio, its directors and officers; possible negative interactions of LeonaBio's drug candidates with other treatments; FDA regulatory delays and uncertainty and new policies, including executive orders, changes in the leadership of federal agencies such as the FDA and SEC, staff layoffs, budget cuts to agency programs and research and changes in drug pricing controls; LeonaBio's assumptions regarding its financial condition and the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; adverse conditions in the general domestic and global economic markets, including as a result of tariffs; the impact of competition; the impact of drug candidate development and clinical activities on

operating expenses; the impact of new or changing laws and regulations; as well as the other risks detailed in LeonaBio's filings with the SEC from time to time. These forward-looking statements speak only as of the date hereof and LeonaBio undertakes no obligation to update forward-looking statements. LeonaBio may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the forward-looking statements.

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