



## Independent Nonclinical Research on Lasofoxifene Presented at American Association for Cancer Research Annual Meeting 2026 Consistent with LeonaBio's Data

April 21, 2026

### Results showed lasofoxifene protected against hormone withdrawal-induced bone loss and maintained a robust anti-tumor response in primary and metastatic animal models of ER+ breast cancer

BOTHELL, Wash., April 21, 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, attended the American Association for Cancer Research Annual Meeting 2026 (AACR26), where independent researchers at Virginia Commonwealth University's Massey Comprehensive Cancer Center presented nonclinical data on lasofoxifene, including its potential for a bone protective role in metastatic breast cancer.<sup>1</sup>

"We are delighted to learn the findings of this independent research at AACR26, attended by an audience of the world's leading oncology researchers. We believe these data add to the body of evidence in support of lasofoxifene as a therapeutic candidate and align with the scientific rationale for LeonaBio's ongoing ELAINE-3 Phase 3 evaluation of lasofoxifene in metastatic estrogen receptor (ER)-positive breast cancer in patients with ESR1 mutations. The potential ability to combine robust anti-tumor activity with beneficial estrogenic activity in bone tissue has been a core tenant of lasofoxifene's development in breast cancer," said David Portman, M.D., a consultant to LeonaBio.

The presentation titled, "Lasofoxifene Acts as a Selective Estrogen Receptor Agonist in the Bone Microenvironment," highlights results reported by independent researchers at the Virginia Commonwealth University, who investigated the physiological relevance of lasofoxifene's selective estrogen receptor-agonist activity and its impact on metastatic progress in animal models.

"Our findings demonstrate that lasofoxifene exhibits unique, context-dependent estrogen receptor activity that both suppresses ER-driven tumor growth and preserves bone integrity in nonclinical models of ER-positive breast cancer," stated Emily K. Zboril, Department of Cellular, Molecular, and Genetic Medicine, Virginia Commonwealth University, Richmond, Virginia. "Notably, in models of ESR1-mutant disease, lasofoxifene significantly reduced metastatic tumor burden in bone while maintaining favorable effects on the bone microenvironment, supporting its potential to address two critical challenges faced by patients with metastatic breast cancer."

The complete poster can be accessed via the AACR26 website at [www.aacr.org](http://www.aacr.org).

#### About Lasofoxifene

Lasofoxifene is a novel, nonsteroidal selective estrogen receptor modulator (SERM) with a unique binding profile, designed to confer potent activity against both wild-type and mutant estrogen receptors, including the clinically significant ESR1 mutations commonly associated with resistance to endocrine therapy in metastatic breast cancer. Two Phase 2 studies—ELAINE-1 and ELAINE-2—have demonstrated its potential to address a critical unmet need in this patient population.

ELAINE-1, a randomized trial comparing lasofoxifene to fulvestrant, showed improved outcomes for lasofoxifene, including longer median progression-free survival (5.6 vs. 3.7 months), higher objective response rates (13.3% vs. 2.9%), and a durable complete response lasting more than 2.5 years. Patients also reported quality-of-life benefits and the treatment was well tolerated.

ELAINE-2, an open-label study evaluating lasofoxifene in combination with abemaciclib, demonstrated clinical benefits in heavily pretreated patients, with a median progression-free survival of approximately 13 months, an objective response rate of 56%, and a clinical benefit rate of 65.5%. The combination was generally well tolerated, with most adverse events being low grade.

Lasofoxifene is being advanced in a Phase 3 clinical trial as a targeted therapy for estrogen receptor-positive (ER+), HER2-negative, ESR1-mutated metastatic breast cancer, a population with limited treatment options following progression on aromatase inhibitors and CDK4/6 inhibitors. The ongoing ELAINE-3 trial ([NCT05696626](https://clinicaltrials.gov/ct2/show/study/NCT05696626)) is evaluating lasofoxifene in combination with the CDK4/6 inhibitor, abemaciclib, and is aiming to establish a new standard of care for this genetically defined patient group.

#### 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 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](http://www.leonabio.com).

#### Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act, 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 any subsequent clinical trials to show 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; the potential learnings from nonclinical studies and other nonclinical data and

their ability to inform and improve future clinical development plans; and LeonaBio's ability to obtain regulatory approval for any of its product candidates and to successfully commercialize any approved products. 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 nonclinical 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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<sup>1</sup> LeonaBio does not have any financial relationships with the researchers at Virginia Commonwealth University and did not contribute to their research. The lasofoxifene studied by the researchers was obtained from an independent source for research use only. LeonaBio's clinical study of lasofoxifene is not related to the research conducted at Virginia Commonwealth University.