



LeonaBio Presents on ATH-1105 at 5th Annual ALS Drug Development Summit

June 4, 2026

Introduces brelgometon as the International Nonproprietary Name (INN) for ATH-1105

BOTHELL, Wash., June 04, 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 Javier San Martin, MD, Chief Medical Officer of LeonaBio, delivered a presentation at the 5th Annual ALS Drug Development Summit taking place June 2-4, 2026 in Boston, Massachusetts. The presentation, titled "Advancing ATH-1105 in ALS: Strategic Trial Design, Biomarker Integration & Adaptive Methodologies," provided an overview of the company's brelgometon (ATH-1105) clinical development program in amyotrophic lateral sclerosis (ALS). Brelgometon is an oral, brain-penetrant positive modulator of the neurotrophic HGF system.

The presentation highlighted brelgometon's mechanism of action and the body of preclinical and Phase 1 clinical evidence supporting its advancement in a Phase 2 proof-of-concept study targeted for initiation in the second half of 2026.

"Our Phase 1 and preclinical data provide a compelling rationale for advancing brelgometon into Phase 2. Our Phase 2 design reflects both the translational science and the realities of ALS by integrating validated biomarkers such as neurofilament light chain alongside clinically meaningful endpoints," said Dr. San Martin. "We believe brelgometon represents a meaningful opportunity to potentially help address the significant unmet need in ALS, with a neuroprotective profile and translational rationale that distinguish it within the ALS development landscape."

The planned Phase 2 proof-of-concept and dose-ranging study of brelgometon will be a randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy, safety, and pharmacodynamic activity of brelgometon in people with ALS.

About Brelgometon (ATH-1105)

Brelgometon (ATH-1105) is a novel, orally available, brain-penetrant, next-generation small molecule drug candidate designed to positively modulate the neurotrophic HGF system for the potential treatment of neurodegenerative diseases, including ALS, Alzheimer's disease, and Parkinson's disease. Brelgometon is currently in clinical development for the potential treatment of ALS.

LeonaBio completed the first-in-human Phase 1 double-blind, placebo-controlled clinical trial of brelgometon (ATH-1105) (NCT06432647) in November 2024, enrolling 80 healthy volunteers to evaluate single and multiple oral ascending doses. Results from the Phase 1 trial demonstrated a favorable safety and tolerability profile as well as dose-proportional pharmacokinetics and central nervous system penetration. Brelgometon's potential is supported by a body of preclinical evidence demonstrating statistically significant improvements in nerve and motor function, biomarkers of inflammation and neurodegeneration, and survival in various models of ALS.

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a progressive, fatal neurodegenerative disease characterized by the degeneration of motor neurons in the brain and spinal cord, leading to loss of voluntary muscle control. Patients typically experience progressive muscle weakness, paralysis, and respiratory failure, with a median survival of two to five years from symptom onset. ALS remains a disease of high unmet medical need, with limited therapeutic options that modestly slow disease progression. Both sporadic and familial forms of ALS represent significant challenges for drug development given the heterogeneity of disease presentation and course.

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, 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 brelgometon (ATH-1105); 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; the potential learnings from preclinical studies and other nonclinical data and their ability to inform and improve future clinical development plans; and 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. 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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