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MAIA Biotechnology Reports Pivotal Phase 3 Clinical Trial Progress in Advanced Non-Small Cell Lung Cancer

Strong pace of patient enrollment supports continued advancement toward regulatory milestones

Most recent assessment of novel telomere targeting agent sequenced with a checkpoint inhibitor showed 90.5% disease control rate (DCR) in heavily pretreated NSCLC

CHICAGO, Sept. 22, 2026 (GLOBE NEWSWIRE) -- MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced that enrollment has reached 65 patients in its ongoing pivotal Phase 3 trial, THIO-104, evaluating its novel telomere-targeting therapy as a third-line (3L) treatment for advanced non-small cell lung cancer (NSCLC). The THIO-104 trial currently has 38 trial sites activated in 6 foreign countries (Taiwan, Romania, Turkey, Georgia, Poland and Hungary).

"Reaching 65 randomized patients marks an important milestone in our Phase 3 trial. With additional clinical sites expected to begin enrolling patients, we remain on track to achieve our goal of more than 100 randomized patients by year-end," said Vlad Vitoc, M.D., Founder and Chief Executive Officer of MAIA. "As we've stated previously, statistical assessments of the Phase 3 trial point to a very high probability of technical success for regulatory approval of ateganosine.[1] We believe third-line NSCLC is an excellent market entry segment due to the substantial unmet medical need in this large immunotherapy-resistant and chemotherapy-resistant population. No current standard of care exists in this NSCLC treatment setting and competition for clinical trial patients is limited."

In its most recent assessment, ateganosine sequenced with a checkpoint inhibitor showed 90.5% interim disease control rate (DCR) in heavily pretreated 3L NSCLC in MAIA's ongoing phase 2 THIO-101 clinical trial. This measure contrasts with reported 25%–35% DCRs for standard third-line chemotherapy regimens.

In July 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for ateganosine for the treatment of NSCLC. This designation allows for more frequent FDA communication, potential rolling review, and eligibility for Accelerated Approval and Priority Review. If approved, ateganosine will hold FDA New Chemical Entity (NCE) five-year marketing exclusivity. An NCE is a small molecule drug with a novel active ingredient that hasn't been previously approved or marketed.

About Ateganosine

Ateganosine (THIO, 6-thio-dG or 6-thio-2'-deoxyguanosine) is a first-in-class investigational telomere-targeting agent currently in clinical development to evaluate its activity in non-small cell lung cancer (NSCLC). Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. The modified nucleotide 6-thio-2'-deoxyguanosine induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. Ateganosine-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment of ateganosine followed by PD-(L)1 inhibitors resulted in profound and persistent tumor regression in advanced, in vivo cancer models by induction of cancer type–specific immune memory. Ateganosine is presently developed as a second or later line of treatment for NSCLC for patients that have progressed beyond the standard-of-care regimen of existing checkpoint inhibitors.

About MAIA Biotechnology, Inc.

MAIA is a targeted therapy, immuno-oncology company focused on the development and commercialization of potential first-in-class drugs with novel mechanisms of action that are intended to meaningfully improve and extend the lives of people with cancer. Our lead program is ateganosine (THIO), a potential first-in-class cancer telomere targeting agent in clinical development for the treatment of NSCLC patients with telomerase-positive cancer cells. For more information, please visit www.maiabiotech.com.

About THIO-104 Phase 3 Clinical Trial

THIO-104 is a multicenter, open-label, randomized Phase 3 clinical trial, designed to evaluate ateganosine's telomere-targeting anti-tumor activity when followed by PD-(L)1 inhibition in patients with advanced third-line NSCLC who previously did not respond or developed resistance to treatment regimens containing checkpoint inhibitor and/or chemotherapy and have progressed. The trial has two primary objectives: (1) to assess the clinical efficacy of ateganosine compared to investigator's choice of chemotherapy, using median Overall Survival (OS) as the primary clinical endpoint (2) to evaluate the safety and tolerability of ateganosine in sequential combination with a checkpoint inhibitor. For more information on this Phase 3 trial, please visit ClinicalTrials.gov using the identifier NCT06908304.

Forward Looking Statements

MAIA cautions that all statements, other than statements of historical facts contained in this press release, are forward-looking statements. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements to be materially different from those anticipated by such statements. The use of words such as "may," "might," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward looking statements. However, the absence of these words does not mean that statements are not forward-looking. For example, all statements we make regarding (i) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (ii) our ability to advance product candidates into, and successfully complete, clinical studies, (iii) the timing or likelihood of regulatory filings and

approvals, (iv) our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (v) the rate and degree of market acceptance of our product candidates, (vi) the size and growth potential of the markets for our product candidates and our ability to serve those markets, and (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, are forward looking. All forward-looking statements are based on current estimates, assumptions and expectations by our management that, although we believe to be reasonable, are inherently uncertain. Any forward-looking statement expressing an expectation or belief as to future events is expressed in good faith and believed to be reasonable at the time such forward-looking statement is made. However, these statements are not guarantees of future events and are subject to risks and uncertainties and other factors beyond our control that may cause actual results to differ materially from those expressed in any forward-looking statement. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. In this release, unless the context requires otherwise, "MAIA," "Company," "we," "our," and "us" refers to MAIA Biotechnology, Inc. and its subsidiaries.

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[1] See latest MAIA investor presentation and 2026 shareholder letter at ir.maiabiotech.com/company-information/presentations.

Source: MAIA Biotechnology, Inc.