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MAIA Biotechnology Achieves Patient Enrollment Milestones in Ongoing Phase 2 and Pivotal Phase 3 Clinical Trials in Non-Small Cell Lung Cancer

Enrollment completed in Part C of THIO-101 Phase 2 study; 65% of 2026 enrollment target reached in pivotal THIO-104 Phase 3 study

CHICAGO, Oct. 07, 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 it has reached an enrollment milestone with 150 patients treated with ateganosine sequenced with an immune checkpoint inhibitor (CPI) in the ongoing Phase 2 and pivotal Phase 3 clinical trials of its novel telomere-targeting agent ateganosine as a treatment for non-small cell lung cancer (NSCLC).

Enrollment is complete for the Part C of Phase 2 trial, THIO-101, which evaluates ateganosine sequenced with the CPI cemiplimab. MAIA recently announced 90.5% interim disease control (DCR) for the combination therapy in the efficacy evaluable population who had at least one tumor scan after starting treatment. Ateganosine's measures of efficacy are close to triple the reported outcome for standard-of-care treatment with chemotherapy.

THIO-104 is MAIA's pivotal Phase 3 trial evaluating ateganosine in sequence with a CPI in third line (3L) NSCLC patients whose disease has progressed following chemotherapy and CPI treatment. MAIA announced the first patient dosed in December 2025, and enrollment and dosing continues to advance at a strong pace. To date, 65 patients have been enrolled. The trial is targeting 100 patients enrolled and dosed by year-end.

"Our Phase 2 THIO-101 trial is on track to be the first completed clinical study of a telomere-targeting agent in the field of cancer drug discovery and treatment," said Vlad Vitoc, M.D., Founder and CEO of MAIA. "Our strategic focus on third-line NSCLC addresses a critical treatment gap for patients who have progressed after immunotherapy and chemotherapy, with no established standard of care today. Clinical data to date supports ateganosine's potential to define a new treatment category for this difficult-to-treat population.

"For THIO-104, we have reached 65% of our enrollment target of 100 patients by year-end 2026, and remain on track with our target to conduct an interim analysis in 2027," Dr. Vitoc added.

The U.S. Food and Drug Administration (FDA) granted Fast Track designation for ateganosine for the treatment of NSCLC in July 2025. The 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 has not 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 THIO-101 Phase 2 Clinical Trial

THIO-101 is a multicenter, open-label, dose finding Phase 2 clinical trial. It is the first trial designed to evaluate ateganosine's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of ateganosine administered prior to cemiplimab (Libtayo[®]) will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or developed resistance and progressed after first-line treatment regimen containing another checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety and tolerability of ateganosine administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of ateganosine using Overall Response Rate (ORR) as the primary clinical endpoint. The expansion of the study will assess overall response rates (ORR) in advanced NSCLC patients receiving third line (3L) therapy who were resistant to previous checkpoint inhibitor treatments (CPI) and chemotherapy. Treatment with ateganosine followed by cemiplimab (Libtayo[®]) has shown an acceptable safety profile to date in a heavily pre-treated population. For more information on this Phase II trial, please visit [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05208944) using the identifier NCT05208944.

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.

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.

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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