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MAIA Biotechnology Announces First Patient Dosed in THIO-104 Phase 3 Pivotal Trial Evaluating Ateganosine as Third-Line Treatment for Advanced Non-Small Cell Lung Cancer

Key milestone achieved as Company advances clinical program to full approval trial of ateganosine sequenced with a checkpoint inhibitor in comparison to chemotherapy

CHICAGO, Dec. 11, 2025 (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 the first patient has been dosed in the Company's THIO-104 Phase 3 pivotal trial evaluating the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) as a third-line treatment for advanced non-small cell lung cancer (NSCLC).

The multicenter, open-label trial of patients who are resistant to CPI and chemotherapy treatments, is designed to assess overall survival for ateganosine sequenced with a CPI compared to investigator's choice of chemotherapy in a 1:1 randomization of up to 300 patients. MAIA has received regulatory approval to screen patients in Taiwan, Turkey, select European Medicines Agency (EMA) countries, and Georgia. Screening and enrollment are now underway.

"Our strategy to bring our telomere-targeting treatment to market is proceeding according to plan as we advance our ateganosine program to a Phase 3 trial. This larger trial will provide us a robust dataset to support our case for commercial approval by the U.S. FDA," said Vlad Vitoc, M.D., CEO of MAIA. "We have many sites in several countries already screening patients, and with our first patient dosed, we have achieved a key milestone along our path to potential FDA commercial approval. We expect to see Phase 3 results consistent with Phase 2 trial data showing median survival of 17.8 months compared to approximately six months of survival from chemotherapy. We are confident that ateganosine could become the new treatment standard for patients suffering from this devastating disease."

Ateganosine sequenced with a CPI has shown exceptional efficacy in third-line NSCLC patients. As of September 17, 2025, the observed progression free survival (PFS) in THIO-101 was 5.6 months, more than double the standard of care PFS of 2.5 months. One patient that began therapy in March 2023 has shown survival of 30 months, or 912 days.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ateganosine for the treatment of NSCLC.

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-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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