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MAIA Biotechnology Awarded $2.3 Million Grant by National Institutes of Health for THIO-101 Phase 2 Trial of Cancer-Fighting Agent

THIO-101 Phase 2 trial to enroll patients in the U.S. as part of the expansion of the study in third-line treatment for advanced non-small cell lung cancer (NSCLC)

CHICAGO, Sept. 24, 2025 (GLOBE NEWSWIRE) -- MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, announced today that the National Institutes of Health (NIH) has awarded a $2.3 million grant for the expansion of its THIO-101 Phase 2 clinical trial evaluating ateganosine as a third-line treatment for patients with advanced non-small cell lung cancer (NSCLC).

The grant is intended to support expenses related to the enrollment of U.S. patients who are resistant to chemo and immunotherapy. The NIH grant allocations will be distributed over three years from 2025-2027.

"We are thrilled to receive this prestigious NIH grant for the expansion of our Phase 2 trial. It's a great honor to have the support of the National Institutes of Health as we seek to further validate the efficacy of our lead agent ateganosine and its potential to be a breakthrough treatment within the vastly underserved NSCLC market," said CEO Vlad Vitoc, M.D. "With the clearance of FDA Investigational New Drug (IND) for THIO-101 in 2023, we can begin enrolling U.S. patients in the expansion phase of the trial immediately."

"The NIH grant is a tremendous achievement and a testament to the dedication, collaboration, and hard work of everyone involved in the clinical development of ateganosine," added Victor Zaporojan, M.D., MAIA's senior medical director. "Ateganosine represents a potential solution for the significant unmet clinical need in third-line NSCLC, where no established standard of care exists and where the overall survival outcomes observed with ateganosine have not been achieved by other therapies. By enrolling patients in the United States, our trial will gain access to a substantially larger patient pool across multiple continents, further strengthening the impact and relevance of our study."

In Parts A and B of THIO-101, median overall survival (OS) for the 22 patients in third-line treatment was 17.8 months as of June 30, 2025, with a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. Studies of standard-of-care chemotherapy treatments for NSCLC in a similar setting have shown overall survival of 5 to 6 months. The first patient in the expansion of the trial was dosed in July 2025 in Taiwan.

Research referenced in this press release is supported by the National Cancer Institute of the National Institutes of Health under Award Number R44CA309843. The content is solely the responsibility of MAIA and does not necessarily represent the official views of the National Institutes of Health.

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 using the identifier NCT05208944.

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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