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MAIA Biotechnology Reports Consistent Strong Efficacy in Expanded Phase 2 THIO-101 Study in Non-Small Cell Lung Cancer

MAIA advances novel telomere-targeting agent under FDA's Fast Track designation

Further data from THIO-101 Part C may support accelerated approval filing with FDA

CHICAGO, Nov. 17, 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 updated interim efficacy data from Part C of its Phase 2 THIO-101 expansion trial evaluating its novel telomere-targeting therapy, ateganosine, as a third-line (3L) treatment for advanced non-small cell lung cancer (NSCLC). THIO-101 Part C is evaluating additional patients to confirm the strong efficacy data observed in Parts A and B of the study.

The Phase 2 trial assesses advanced NSCLC patients who were nonresponsive or developed resistance and progressed after prior immune checkpoint inhibitor therapy and chemotherapy. Patients are treated with ateganosine 180mg followed by cemiplimab (Libtayo®) in cycles of 21 days. The sequential administration of ateganosine followed by PD-(L)1 inhibition is intended to enhance and prolong the antitumor immune response.

"It is encouraging to see an 88% disease control rate (DCR) as the THIO-101 data continue to mature. DCR serves as an excellent data surrogate for Overall Survival (OS) efficacy according to a historical meta-analysis[1] and our own analysis of previous data," said Vlad Vitoc, M.D., Founder and Chief Executive Officer of MAIA. "To date, the trial's combined study data have consistently demonstrated stable disease or better at the first tumor assessment following treatment initiation. Importantly, the Part C interim efficacy results are well aligned with the outcomes observed in Parts A and B, now across a substantially larger patient population. Consistency of the results as our patient pool expands further strengthens the compelling efficacy signals we are seeing for both of our trials in NSCLC."

For Parts A, B, and C of THIO-101 as of October 01, 2026, the observed disease control rate (DCR) for third-line NSCLC patients resistant to chemo and immunotherapy is 88% (38 of 43 patients) in the efficacy evaluable population who had at least one tumor scan after starting treatment. This DCR measure contrasts with reported 25%–35% disease control for standard 3L chemotherapy regimens.[1]

MAIA has completed enrollment in Part C of its Phase 2 THIO-101 expansion, which

enrolled patients in Hungary, Poland, Turkey, Georgia, Romania, Taiwan, and in the United States. Concurrently, an ongoing pivotal Phase 3 clinical trial of third line ateganosine treatment, THIO-104, with the same target population as THIO-101 Part C, is advancing toward regulatory milestones including 2027 interim survival analysis.

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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[1] Matsumoto H, et al. Transl Lung Cancer Res 2021;10:2278–89

Source: MAIA Biotechnology, Inc.