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MAIA Biotechnology Receives FDA Clearance to Open U.S. Enrollment in Ongoing Phase 2 THIO-101 Trial Expansion

Additional data from THIO-101 trial expansion studies may further support a potential Accelerated Approval filing with FDA

FDA-cleared IND updates detail latest efficacy data and enriched manufacturing protocols

CHICAGO, June 03, 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 the U.S. Food and Drug Administration (FDA) has cleared an amendment to update its investigational new drug (IND) application which enables MAIA to open U.S. enrollment for the expansion of the Phase 2 THIO-101 trial of its lead candidate, ateganosine, as a treatment for advanced non-small cell lung cancer (NSCLC). Ateganosine is a novel dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity. Ateganosine sequenced with a monoclonal antibody checkpoint inhibitor is being evaluated as a therapy for patients in ongoing Phase 2 and Phase 3 clinical trials.

MAIA obtained FDA clearance of its updated IND highlighting MAIA's improved efficiencies to its manufacturing capabilities, including new manufacturers, formulation and storage conditions for ateganosine, and MAIA is now cleared to enroll patients in the U.S. for the expansion of the Phase 2 THIO-101 study of patients receiving advanced third-line (3L) NSCLC treatment. In addition to the U.S., the THIO-101 study is ongoing at 44 clinical sites in six countries. MAIA recently activated its [first U.S. clinical](#) site at Summit Medical Group in New Jersey.

In July 2025, the 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. The additional data from the expansion studies may further support a filing for FDA Accelerated Approval.

"Up to five U.S. clinical sites are planned for THIO-101 Parts C and D this year, and we expect to activate a second U.S. site in the coming weeks," said Vlad Vitoc, M.D., Founder and Chief Executive Officer of MAIA. "To date, data has shown [overall survival \(OS\) beyond two years](#) for eight patients treated with ateganosine in Parts A and B of THIO-101. We believe this bodes well for Parts C and D evaluations which are specific to third-line treatment care only, where the unmet need for improved clinical outcomes is most urgent."

K. Robinson Lewis, Senior Vice President and Head of Regulatory and Quality for MAIA, commented, “We are excited about the prospects for our U.S. trials following FDA clearance of our amended IND. The unmet need for effective third-line NSCLC treatments is widespread in the U.S. Based on strong clinical data documented so far, we are confident in the potential of our therapy to address this significant and substantially underserved patient population.”

In parallel with THIO-101, MAIA is actively screening and enrolling patients in a pivotal Phase 3 clinical trial, THIO-104, 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 third-line NSCLC patients.

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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