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MAIA Biotechnology Highlights Ongoing Momentum of Ateganosine Clinical Program at SITC 2025

Company confirms 12 patients enrolled in Phase 2 THIO-101 to date as expansion trial adds new countries

Posters for Phase 2 and Phase 3 clinical trials available

CHICAGO , Nov. 21, 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 highlights from two poster presentations delivered at SITC 2025, an annual conference hosted by the Society for Immunotherapy of Cancer, held November 5-9, 2025, in National Harbor, MD. The Trials in Progress posters focus on MAIA's ongoing Phase 2 THIO-101 expansion (Part C) and Phase 3 THIO-104 clinical trials of its first-in-class small molecule telomere targeting agent, ateganosine, as a treatment for non-small cell lung cancer (NSCLC). The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ateganosine for the treatment of NSCLC.

MAIA's Sr. Medical Director, Victor Zaporojan, M.D., presenter at SITC 2025 commented, "It was a privilege to return to SITC for its 40th anniversary. This event was an ideal forum to highlight the continued success of our Phase 2 clinical trial. We are making steady progress in the expansion phase of this trial, with patient enrollment now underway in European Medicines Agency (EMA) countries. Sites in Hungary and Poland, which were instrumental in Parts A and B of the trial, are actively screening patients along Turkey and Taiwan, and we have 12 patients enrolled in the expansion to date. We expect further momentum in identifying and enrolling patients for THIO-101 Part C in the near term".

"We also began screening patients in our Phase 3 trial, THIO-104, and noticed great excitement from physicians in the sites we're bringing our trial to," added MAIA CEO Vlad Vitoc, M.D. "In this population, third-line NSCLC patients resistant to chemo and immunotherapy, current treatments show overall survival (OS) of around 6 months, and based on the 17.8 months OS observed in THIO-101 to date, we believe that our Phase 3 trial could lead to an early commercial approval of ateganosine by the FDA. It's only a matter of successful execution to bring our novel NSCLC treatment to this large patient population with significant unmet medical need."

The posters presented at SITC 2025 feature trial designs for the Phase 2 and Phase 3 studies in advanced NSCLC patients receiving ateganosine followed by a checkpoint inhibitor, cemiplimab (Libtayo®). As of September 17, 2025, a patient that began therapy in

March 2023 in the THIO-101 Phase 2 trial has shown survival of 30 months, or 912 days.

“A novel therapy with proven efficacy, such as ateganosine, could strengthen existing treatment strategies and further advance the principles of precision oncology in lung cancer care worldwide,” said Tomasz Jankowski, M.D., Ph.D., key investigator for THIO-101 in Poland and co-author of many of MAIA’s scientific posters. “In Poland, where improving outcomes in advanced NSCLC remains a central focus, ateganosine has the potential to become an important addition to the therapeutic landscape, offering new hope for patients and clinicians alike.”

The posters presented at SITC 2025 were attached as exhibits to a Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission (the “Commission”) on November 7, 2025 and available on the Commission’s website at www.sec.gov. In addition, the posters were made available on MAIA’s website at maiabiotech.com/publications on November 7, 2025.

- Presentation 1: A Phase 3 Study of Ateganosine (THIO) Sequenced with Immune Checkpoint Inhibitor (ICI) versus Standard of Care Chemotherapy in ICI-Resistant Advanced NSCLC: THIO-104 Trial in Progress
- Presentation 2: A Phase 2 Study of Ateganosine (THIO; 6-thio-2'-deoxyguanosine) in Combination with Immune Checkpoint Inhibitor (ICI) in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Resistant to Prior ICI and Chemotherapy: THIO-101 Trial in Progress

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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