July 9, 2025

MAIA Biotechnology Announces First Patient Dosed in Expansion of Phase 2 Trial for Ateganosine in Advanced Non-Small Cell Lung Cancer

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced dosing of the first patient in Taiwan in the expansion phase of its THIO-101 Phase 2 trial for advanced non-small cell lung cancer (NSCLC). The trial's entry into another continent marks a key milestone for MAIA, opening a significantly larger patient pool for its evaluations of ateganosine (THIO). Screening for the trial is ongoing in Europe and Asia.

Trial Design: The expansion study evaluates ateganosine in heavily pre-treated patients in third-line (3L) NSCLC who have previously failed treatment with checkpoint inhibitors (CPIs) and chemotherapy. Two treatment arms are being studied: ateganosine sequenced with cemiplimab (Libtayo®) and ateganosine monotherapy. Regeneron is supplying Libtayo for the combination cohort.

Strategic Opportunity: NSCLC represents one of the largest global oncology indications. The market was valued at $34.1B in 2024, and is projected to reach $68.8B by 2033 with a projected CAGR of 8.1%.[1]

Current Data: As of May 15, 2025, the median overall survival (OS) for the 22 patients in the third-line treatment was 17.8 months, with a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. The treatment has been generally well-tolerated in the trial's heavily pre-treated population.[2]

Other studies of chemotherapy for NSCLC in a similar setting have shown overall survival of 5-6 months.[3]

"We are excited to have the expansion of the trial officially started. Ateganosine's observed OS in third-line NSCLC exceeds all known benchmarks," said MAIA's Chief Executive Officer Vlad Vitoc, M.D. "This potentially positions us for first-mover advantage in a multibillion-dollar space with no currently approved standard of care."

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 with 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, a 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 been generally well-tolerated 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 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.

[1] Custom Market Insights, Global NSCLC Drug Market Size Likely to Surpass at a CAGR of 8.1% By 2033, Apr. 2024

[2] Details on safety can be found on the previously announced SITC 2024 presentation available on MAIA’s website.

3 Girard N, et al. J Thorac Onc 2009;12:1544-1549.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20250709705403/en/

Investor Relations Contact
+1 (872) 270-3518
ir@maiabiotech.com

Source: MAIA Biotechnology, Inc.