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MAIA Biotechnology Receives FDA's Fast Track Designation for Ateganosine as a Treatment for Non-Small Cell Lung Cancer

Potential first-to-market small molecule telomere targeting agent targets a $34 billion NSCLC treatment market

Latest data in pivotal Phase 2 THIO-101 clinical trial shows median overall survival of 17.8 months

CHICAGO--(BUSINESS WIRE)-- 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 granted Fast Track designation for ateganosine (THIO, 6-thio-dG or 6-thio-2'-deoxyguanosine) for the treatment of non-small cell lung cancer (NSCLC). Ateganosine is currently being evaluated in a pivotal Phase 2 THIO-101 clinical trial evaluating its anti-tumor activity when followed by a checkpoint inhibitor.

Ateganosine is a first-in-class small molecule that compromises telomere structure and function in cancer cells, leading to rapid tumor cell elimination and specific immune memory. Through telomerase-mediated action, ateganosine reverses intrinsic or acquired resistance to immune checkpoint inhibitors (ICIs).

"FDA's Fast Track Designation recognizes ateganosine's potential as a new therapeutic paradigm in cancer treatment science. Ateganosine is the first and only anticancer treatment of its kind that we are aware of in clinical development," stated MAIA Chairman and CEO Vlad Vitoc, M.D. "If we are successful in the Fast Track regulatory pathway, ateganosine could qualify for accelerated FDA approval and robust exclusivity in NSCLC, with a potential FDA decision as early as next year. If approved, ateganosine would have a first-to-market competitive position within a $34 billion NSCLC treatment market with significant unmet medical need."

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]

"This is an important milestone for MAIA's clinical development program. Ateganosine has demonstrated robust preclinical efficacy and superior clinical median overall survival compared to other FDA-approved treatments for NSCLC patients with prior disease progression on platinum-based chemotherapy and anti-PD-(L)1 antibody. Additionally, advanced NSCLC is a devastating disease that clearly meets the criteria for a serious condition with unmet medical need. Both are key criteria for the Fast Track designation," said K. Robinson Lewis, Vice President, Head of Regulatory and Quality at MAIA. "We intend to

utilize the incentives of the Fast Track Program to expedite the development and review of ateganosine and bring patient access sooner."

The FDA Fast Track is a process designed to facilitate development and expedite the review of drugs for treating serious conditions and filling an unmet medical need, as in providing a therapy where none exists or which may be potentially better than available therapy. If relevant criteria are met during the Fast Track process, a drug will be eligible for FDA Accelerated Approval and Priority Review (FDA decision within six months).

MAIA's most recent data from the pivotal Phase 2 THIO-101 clinical trial of ateganosine as of May 15, 2025 showed median overall survival (OS) of 17.8 months in a heavily pre-treated population. As of the data cut-off date, the patient with the longest survival in the trial had completed 32 cycles of therapy and had 24.3 months survival. Studies of standard-of-care chemotherapy treatments for NSCLC in a similar setting have shown overall survival of 5 to 6 months.

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

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