

MAIA Biotechnology Announces Positive Efficacy Update for Phase 2 THIO-101 Clinical Trial in Non-Small Cell Lung Cancer

Median overall survival (OS) from ateganosine (THIO) treatment extends to 17.8 months in latest data

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 updated data from its THIO-101 pivotal Phase 2 clinical trial evaluating its lead clinical candidate, ateganosine (THIO), sequenced with Regeneron's immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who are resistant to immune therapy and chemotherapy.

As of May 15, 2025, third line (3L) data showed median overall survival (OS) of 17.8 months for the 22 NSCLC patients who received at least one dose of ateganosine (the intent-to-treat population) in parts A and B of the trial. The updated analysis continues to demonstrate 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 to date in this heavily pre-treated population.¹ Studies of standard-of-care (SOC) chemotherapy treatments for NSCLC in a similar setting have shown OS of 5 to 6 months.²⁻³

"It is gratifying to see that our treatment further extends lives for these hard-to-treat patient populations, especially in third-line NSCLC treatment where patients are most resistant to therapy," said MAIA Chairman and CEO Vlad Vitoc, M.D. "This new benchmark of 17.8 months median OS is nearly triple the recognized SOC data for third-line NSCLC found in medical literature. We believe this is a substantial indicator of the potential ateganosine has to shift the NSCLC treatment landscape."

MAIA's multiple potential regulatory pathways for ateganosine could provide accelerated FDA approval and robust exclusivity in NSCLC, with a potential FDA decision as early as next year.

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 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 <u>www.maiabiotech.com</u>.

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.

¹Details on safety can be found on the previously announced ASCO 2025 poster available on <u>MAIA's website</u>.

²Girard N, et al. J Thorac Onc 2009;12:1544-1549.

³A.T. Freeman et al. Curr Oncol. 2020 May 1;27(2):76–82

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

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