February 27, 2025

MAIA Biotechnology to Initiate Phase 3 Pivotal Trial of THIO Sequenced with Checkpoint Inhibitor Compared with Chemotherapy Treatment in Advanced Non-Small Cell Lung Cancer Patients

CHICAGO--(BUSINESS WIRE)-- **MAIA Biotechnology, Inc., (NYSE American: MAIA)** ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced plans to initiate a Phase 3 pivotal trial in 2025, named THIO-104, to evaluate the efficacy of THIO administered in sequence with a checkpoint inhibitor (CPI) in third-line non-small cell lung cancer (NSCLC) patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients.

"THIO has consistently and substantially outperformed standard treatment options in our THIO-101 Phase 2 trial to date. THIO-104 will give us direct comparative data from a randomized study in patients in third line of treatment," said Vlad Vitoc, M.D., CEO of MAIA. "We expect that the results from this study will further illuminate THIO's unmatched benefits for advanced stage NSCLC patients.

"Our initiation of THIO-104 will mark an important milestone along our goal for THIO's FDA commercial approval," Dr. Vitoc added.

MAIA expects to begin enrolling patients in THIO-104 in the second half of 2025 in select countries in Asia, Europe and in the U.S.

The primary endpoint of the clinical trial is overall survival for THIO sequenced with a CPI compared to investigator's choice of chemotherapy in a third line setting. The secondary endpoints include disease control rate, overall response rate, duration of response, progression-free survival and safety.

About THIO

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 (THIO) induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. THIO-damaged

telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment with THIO 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. THIO is presently developed as a third line of treatment for NSCLC for patients that are resistant to checkpoint inhibitors and chemotherapy.

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.

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Source: MAIA Biotechnology, Inc.