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MAIA Biotechnology Announces Design for Expansion of THIO-101 Phase 2 Trial in Advanced Non-Small Cell Lung Cancer

- **Expansion study to enroll patients in the U.S. and select countries in Europe and Asia**
- **Multiple milestones attainable for 2025**

CHICAGO--(BUSINESS WIRE)-- **MAIA Biotechnology, Inc., (NYSE American: MAIA)** ("MAIA," the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced the trial design for the expansion of its THIO-101 pivotal Phase 2 trial in non-small cell lung cancer (NSCLC). Following successful outcomes to date in THIO-101, 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.

The THIO-101 study in 3L will enroll up to 48 patients with two arms: Arm 1, continuing the evaluation of THIO sequenced with Libtayo® (cemiplimab); and Arm 2, evaluating THIO as a monotherapy, to further gain experience of THIO in the contribution of components. Treatment cycles for patients in both arms will administer THIO on 3 consecutive days, followed by immune activation on day 4. Arm 1 will administer Libtayo on day 5. The Company plans to enroll an additional 100 patients for the registration phase of the trial. MAIA expects to conduct the trials in the U.S. and select countries in Europe and Asia.

MAIA recently announced an amended clinical supply agreement with Regeneron to include the expansion portion of THIO-101. Under terms of the amended agreement, MAIA continues to sponsor THIO-101 and Regeneron will provide Libtayo for the treatment of all patients including the additional patients in the expansion and potentially, the registration studies.

"We are excited to start the expansion arm of our THIO-101 trial which is designed to determine overall response rates in third line NSCLC. We expect to have new patients enrolled in the coming weeks," said Vlad Vitoc, M.D., CEO of MAIA. "Through THIO-101 to date, THIO has delivered unprecedented disease control, response, and survival results. Continued efficacy and safety data generated by our study could support an FDA NDA submission directly, particularly as we plan to seek an accelerated approval of THIO in the U.S.

"We have multiple milestones that we believe are attainable for 2025 and we look forward to keeping our shareholders and investors well informed of our progress on value creation," Dr. Vitoc added.

As of January 15, 2025, data indicated that Median Overall Survival (OS) in third-line treatment was reached at 16.9 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 to date in this heavily pre-treated population[1].

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

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 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 THIO's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO 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 THIO administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with THIO 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.

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