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MAIA Biotechnology Accelerates Enrollment in THIO-101 Phase II Clinical Trial as Efficacy Is Observed in Dosed Patients

- 49 patients dosed to date; 37 have completed at least 1 post baseline assessment
- THIO-101 enrollment pace currently exceeds average for similar NSCLC trials

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA), a clinical stage company developing telomere-targeting immunotherapies for cancer, announced today that 49 patients have been dosed in MAIA's Phase 2 clinical trial, THIO-101, evaluating THIO in sequential combination with an immune checkpoint inhibitor (CPI) in patients with advanced Non-Small Cell Lung Cancer (NSCLC).

"In feedback received from the clinical trial investigators, the encouraging efficacy observed in dosed patients is prompting physicians to speed up trial enrollment even further. Following [U.S. Food and Drug Administration \(FDA\) clearance of the Investigational New Drug \(IND\) application](#), we expect to more than double the number of sites in the near future," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer. "We are pleased with the pace of enrollment for THIO-101, our go-to-market trial, which is currently exceeding the average enrollment pace in similar NSCLC trials. We look forward to sharing preliminary safety and efficacy data in the coming weeks."

"Out of the 49 patients dosed, 37 already completed at least 1 post baseline assessment, providing key data for our preliminary readings on the safety and efficacy of the treatment with THIO in NSCLC," said Mihail Obrocea, MD, MAIA's Chief Medical Officer.

THIO is a first-in-class cancer telomere targeting agent administered in sequence with a CPI. The main objectives of the THIO-101 trial are to evaluate the safety, tolerability, and preliminary clinical efficacy of THIO in patients with advanced NSCLC who have experienced disease progression or relapse after initial treatments with an immune CPI alone or in combination with chemotherapy. The trial dosed its first patient in Australia in July 2022 and expanded to include European patients in March 2023.

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, 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 an anti-PD-1 agent 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. 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. 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. These forward-looking statements are only predictions and may differ materially from actual results due to a variety of factors including: (i) lower than anticipated rate of patient enrollment, (ii) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (iii) our ability to advance product candidates into, and successfully complete, clinical studies, (iv) the timing or likelihood of regulatory filings and approvals, (v)

our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (vi) the rate and degree of market acceptance of our product candidates, (vii) the size and growth potential of the markets for our product candidates and our ability to serve those markets, (viii) our ability to obtain and maintain intellectual property protection for our product candidates and (ix) other risks and uncertainties detailed from time to time in our filings with the Securities and Exchange Commission, including without limitation our periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time. 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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