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MAIA Biotechnology Announces Updates in Enrollment in Phase II Clinical Trial: THIO-101 Has Enrolled 29 Patients

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA) announced today that 29 patients have been dosed in MAIA's Phase 2 clinical trial, THIO-101, evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC). With the addition of sites in Hungary, Poland, and Bulgaria in March 2023, THIO-101 has rapidly increased the number of patients enrolled and dosed with THIO. Thirteen sites were activated with another two new additional sites ready to open in the coming weeks.

THIO is a first-in-class cancer telomere targeting agent administered in sequence with a checkpoint inhibitor (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.

"We are very pleased with the progress of enrollment in Europe. Since our last update, we have more than doubled the number of patients dosed to 29, bringing us closer to our target of 184 patients planned to be treated in the trial. With a large number of lung cancer cases in Europe, we anticipate a robust rate of enrollment in the upcoming weeks," stated Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer.

"With rapid enrollment in the trial, we project a substantial number of patients completing 3-6 months of treatment by the fall which will allow us a preliminary evaluation of the treatment efficacy," added Mihail Obrocea, MD, MAIA's Chief Medical Officer.

About THIO-101, a Phase 2 Clinical Trial

THIO-101 is a multicenter, open-label, dose selection Phase 2 clinical trial. It is the first trial designed to evaluate THIO's potential immune system activation effects in NSCLC patients by administering THIO in advance of administration of an immune checkpoint inhibitor allowing for immune activation and PD-1 sensitivity to take effect. The trial is testing the hypothesis that low doses of THIO administered prior to a checkpoint inhibitor 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 agent and a priming immune system agent and (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 THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is an 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. THIO is being 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 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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