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MAIA Biotechnology Doses First Patient With THIO in Phase 2 Trial (THIO-101) for Non-Small Cell Lung Cancer

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc., a targeted therapy, immuno-oncology company focused on developing potential first-in-class oncology drugs ("MAIA"), announced today that the first patient has been dosed in MAIA's Phase 2 clinical trial, THIO-101, evaluating the administration of THIO, in sequence with cemiplimab, in patients with advanced Non-Small Cell Lung Cancer (NSCLC).

The THIO-101 Phase 2 trial is designed to evaluate THIO's potential immune system activation effects in NSCLC patients by administering THIO in advance of administration of the checkpoint inhibitor cemiplimab (developed by Regeneron), allowing for immune activation and PD-1 sensitivity to take effect. The primary objectives of the trial are to evaluate the safety and tolerability of THIO administered as a direct anticancer and priming immune system agent prior to cemiplimab administration, as well as the clinical efficacy of THIO in patients with advanced NSCLC who either progressed or relapsed through treatment with an immune-check point inhibitor alone or in combination with chemotherapy. The first patient in THIO-101 was dosed in Australia in July 2022 after the Company's application received regulatory approval in March 2022. The Company also plans to submit a similar application in the second quarter of 2022, to conduct the same Phase 2 study in Europe.

"Dosing our first patient in this Phase 2 trial with THIO is an important milestone for MAIA, marking the continued development of our telomere-targeting approach," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer. "Despite the advancements made in the field with checkpoint inhibitors, monoclonal antibodies and newer immunotherapies, very limited treatment options exist for patients that have progressed beyond the standard-of-care regimens. We believe THIO has the potential to hold a significant place in the NSCLC treatment paradigm."

Sergei Gryaznov, Ph.D., Chief Scientific Officer of MAIA, added, "Lung cancer is the second most diagnosed cancer worldwide and NSCLC is the most common form of lung cancer, accounting for more than eighty percent of all lung cancer diagnoses. This represents a significant unmet medical need across the globe, and we remain enthusiastic about THIO's observed mechanism of action."

About THIO-101, a Phase 2 Clinical Trial

THIO-101 is a multicenter, open-label, dosing finding 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 the checkpoint inhibitor cemiplimab

(developed by Regeneron), potentially allowing for immune activation and PD-1 sensitivity to take effect. The trial will test the hypothesis that low doses of THIO administered prior to checkpoint inhibitor treatment will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or progressed after first-line treatment regimen containing a checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety of THIO administered as an anticancer agent and a priming immune system agent prior to cemiplimab administration and (2) to assess the clinical efficacy of THIO followed by cemiplimab 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 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 for patients with NSCLC 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 development for the treatment of patients with telomerase-positive cancers. 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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