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MAIA Biotechnology Reports Updates on Preliminary Survival Data for THIO-101 Phase 2 Trial for Advanced Non-Small Cell Lung Cancer

- First 2 patients dosed with THIO continue to be without documented progression for 12.2 and 11.5 months and remarkably without any new anti-cancer treatment 10.2 and 8.5 months after concluding treatment with THIO.

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA) today announced updates on preliminary survival data in the Part A safety lead-in of its ongoing THIO-101 phase 2 trial, evaluating THIO in sequential combination with cemiplimab in patients with advanced Non-Small Cell Lung Cancer (NSCLC).

The first 2 patients enrolled in the study continue to be alive, approximately 12.2 and 11.5 months respectively, from treatment initiation. Both patients have advanced Stage IV metastatic disease and failed 2 prior lines of therapy, including one line with an immune checkpoint inhibitor (CPI), and platinum-based chemotherapy. Following the conclusion of study treatment, they have remained free of disease progression for 10.2 and 8.5 months, respectively, without requiring any additional therapy. No new safety analysis was conducted.

“We are excited by the observed continued progression free survival of the first 2 patients following treatment discontinuation, and these results align with our hypothesis that THIO, followed by an immune CPI, can re-sensitize tumors to the CPI and stimulate a potent and long-lasting anti-cancer immune response. This is particularly encouraging given that patients with advanced NSCLC who failed two or more therapy regimens in real-world scenarios have an expected survival of only 3 to 4 months. With therapy, third-line patients generally survive about 6 months; without therapy, survival is only weeks,” said Vlad Vitoc, MAIA’s Chief Executive Officer.

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 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 potential immune system activation effects in NSCLC patients by administering THIO in sequential combination with Regeneron's anti-PD1 therapy, Libtayo® (cemiplimab), 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 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 (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. 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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