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MAIA Biotechnology Holds Successful Pre-IND Meeting with FDA for Planned US Expansion of THIO-101 Phase 2 Trial for Non-Small Cell Lung Cancer

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA," "the Company") today announced that it completed a pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) for the planned U.S. expansion of the THIO-101 Phase 2 trial evaluating THIO, an investigational telomere-targeting agent, in patients with advanced non-small cell lung cancer (NSCLC). MAIA received positive feedback from the FDA regarding its manufacturing, preclinical and clinical development plan. MAIA also obtained guidance from the FDA on the assessment of its safety and efficacy in the THIO-101 Phase 2 trial that will be incorporated in the U.S. IND application. MAIA plans to file its U.S. IND in the first half of 2023 and commence enrolling patients in the U.S. in the second half of 2023.

A pre-IND meeting provides an opportunity for open communication between a drug development company and the FDA to discuss the IND proposed filing and plan to obtain the agency's guidance for the initial clinical studies of a novel drug candidate. The FDA reviewed the pre-IND package submitted by MAIA containing preclinical data, manufacturing and the Phase 2 clinical study protocol synopsis for THIO-101, provided guidance and recommendations, and addressed MAIA's questions on the initial development plan of THIO in the advanced NSCLC indication.

"We appreciate the FDA's guidance as we prepare to file the IND application for our Phase 2 trial and open enrollment of patients in the U.S.," said Mihail Obrocea, MD, MAIA's Chief Medical Officer. "The successful completion of this engagement with the FDA is an important milestone that has helped provide regulatory direction with our planned THIO clinical development program."

THIO-101 is a multicenter, open-label, dosing finding Phase 2 clinical trial designed to evaluate THIO's potential immune system activation effects in NSCLC patients by administering THIO in advance of Regeneron's anti-PD1 therapy, Libtayo® (cemiplimab), allowing for immune system activation and sensitivity to the PD-1 inhibitor 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 preliminary clinical efficacy of THIO in patients with advanced NSCLC who either progressed or relapsed through the initial treatment with an immune-check point inhibitor alone or in combination with chemotherapy. The clinical trial is currently enrolling patients in Australia and the European Union as regulatory approvals have been received.

About THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a telomere-targeting agent currently in clinical development to evaluate its activity in non-small cell lung cancer (NSCLC), in sequential administration with Regeneron's anti-PD1 therapy, Libtayo® (cemiplimab). Telomeres 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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