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MAIA Biotechnology Expands Phase 2 THIO-101 Trial to Europe

Clinical trial evaluating MAIA Biotechnology's lead therapeutic candidate in non-small cell lung cancer patients

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA," "the Company"), announced today that regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, have approved the implementation of THIO-101, MAIA's Phase 2 clinical trial evaluating its lead therapeutic candidate, THIO, in patients with Non-Small Cell Lung Cancer (NSCLC). The first patients in THIO-101 were dosed in Australia earlier this year.

THIO-101 is designed to evaluate THIO's potential immune system activation effects in NSCLC patients by administering THIO in advance of administration 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 to evaluate 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.

"Adding EU sites to the THIO-101 study increases patient access to THIO on a global scale. Lung cancer is the second most common cancer indication, so addressing it requires worldwide research efforts," said MAIA Chief Medical Officer Mihail Obrocea, M.D. "Adding EU sites to THIO-101 officially makes it a global trial. We believe the data that THIO-101 generates will further validate THIO and be a major step towards bringing effective therapies to lung cancer patients."

"THIO-101 is a critical component of THIO's clinical development process and it is of the utmost importance that we collaborate with leading cancer institutes in Australia and now in Europe, for a target total of 30 clinical trial sites in six countries," said MAIA Chairman and Chief Executive Officer Vlad Vitoc, M.D. "European sites will be excellent additions to this clinical trial. We look forward to the role they will play in the evolution and expansion of this trial, which will continue validating our telomere-targeting approach."

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 a telomere-targeting agent currently in clinical development to evaluate its activity in non-small cell lung cancer (NSCLC), in sequential administration with LIBTAYO® (cemiplimab) an anti-PD1 therapy, developed and commercialized by Regeneron. 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 higher 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 clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer. The Company's lead program is THIO, a potential first-in-class cancer telomere targeting agent in clinical development for the treatment of patients with telomerase-positive cancers. For more information, please visit www.maiabiotech.com.

Forward Looking Statements

This press release includes forward-looking statements including, but not limited to, statements related to the closing of the offering and the expected use of proceeds, development of drug candidates, our operations and business strategy, our expected financial results, and corporate updates. The forward-looking statements contained in this press release are based on management's current expectations and are subject to substantial risks, uncertainty and changes in circumstances. Actual results may differ materially from those expressed by these expectations due to risks and uncertainties, including, among others, those related to our ability to obtain additional capital on favorable terms to us, or at all, including, without limitation, to fund our current and future preclinical studies and clinical trials and the success, timing and cost of our drug development program and our ongoing or future preclinical studies and clinical trials, including, without limitation, the possibility of unfavorable new clinical and preclinical data and additional analyses of existing data, that the risks that prior clinical and preclinical results may not be replicated, and risks associated with the current coronavirus pandemic. Forward-looking statements speak only as of the date of this press release, and we undertake no obligation to review or update any forward-looking statement except as may be required by applicable law.

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