October 24, 2023

MAIA Biotechnology Announces 100% Disease Control in Second-Line Non-Small Cell Lung Cancer Demonstrating Impressive Positive Preliminary Efficacy Data for Ongoing THIO-101 Phase 2 Trial

- Unprecedented disease control rate (DCR) of 100% in second-line of treatment far surpasses standard of care (SoC) DCR of 53-64%
- DCR is far stronger than overall response rate (ORR) in predicting overall survival benefit, as shown in recent meta-analysis of 74 clinical trials worldwide[1]

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA), a clinical stage company developing telomere-targeting immunotherapies for cancer, today reported positive preliminary efficacy data from its ongoing Phase 2 clinical trial, THIO-101, evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC) in sequential combination with Regeneron's anti-PD-1 cemiplimab (Libtayo®).

Key findings:

- 100% Preliminary DCR observed in second-line and 88% in third-line, in highly difficult-to-treat patients who already progressed through previous lines of treatment.
- DCRs across all dose levels met the pre-determined statistical requirements earlier than expected to proceed to next stage of the trial.

"In NSCLC patients who received at least one line of therapy, DCRs have shown to be excellent predictors of overall survival.[1] Observing 100% DCR to date in second-line treatment is unprecedented compared to DCRs for the SoC ranging from 53-64%,[2]" said Vlad Vitoc, M.D., MAIA's Chief Executive Officer. "We have also observed unprecedented high DCRs in third-line, with an 88% control rate, with treatment of THIO followed by cemiplimab. The results are even more remarkable given patients in this population have previously failed treatment with a checkpoint inhibitor. Currently, there is no SoC for third-line, but previous studies have reported an approximate 30% DCR.[3] These exceptional preliminary results underscore our confidence in advancing the trial to bring our novel treatment to advanced stage NSCLC patients."

[1] Matsumoto H et al. Transl Lung Cancer Res. 2021 May; 10(5): 2278–2289

[2] REVEL https://www.cyramza.com/hcp/nsclc-treatment/revel-response-rate-efficacy

[3] Journal of Thoracic Oncology (VOLUME 16, ISSUE 10, OCTOBER 2021), T. Beninato et al.

Study Disease Control Rates by Line of Treatment

Treatment Line	Standard of Care Treatment	DCR
NSCLC-1	pembrolizumab (KEYNOTE-024)	71%
NSCLC-2	ramucirumab + docetaxel (REVEL)	64%
	docetaxel monotherapy (REVEL)	53%
NSCLC-3	chemotherapy (RWD)	25-35%

Treatment Line	THIO + Libtayo® (cemiplimab) DCR
NSCLC-1	TBD
NSCLC-2	100%
NSCLC-3	88%

The Company presented the data at the European Society for Medical Oncology (ESMO) Congress 2023 in Madrid, Spain, on October 23, 2023. Full preliminary data is detailed in the poster available here.

About THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a first-in-class 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. The modified nucleotide 6-thio-2'-deoxyguanosine (THIO) induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. THIO-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment with THIO followed by PD-(L)1 inhibitors resulted in profound and persistent tumor regression in advanced, in vivo cancer models by induction of cancer type–specific immune memory. THIO is presently 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, 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 anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO administered prior to Regeneron's anti-PD-1 cemiplimab (Libtayo®) 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 a checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety and tolerability of THIO administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with cemiplimab followed by THIO has been generally well-tolerated to date in a heavily pre-treated population. 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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