July 23, 2024

# MAIA Biotechnology Announces New Updates from Phase 2 Trial of Novel Cancer Treatment Agent

- ***THIO followed by cemiplimab shown to be well tolerated throughout trial, with far lower toxicity compared to standard of care treatments***
- ***6 patients on trial regimen for more than 12 months have completed up to 21 cycles, with treatment ongoing***

CHICAGO--(BUSINESS WIRE)-- **MAIA Biotechnology, Inc., (NYSE American: MAIA)** ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announces positive treatment updates from its Phase 2 clinical trial, THIO-101, evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who failed two or more standard-of-care therapy regimens.

The trial's therapeutic regimen is cycled every 3 weeks, with THIO 180mg administered in 60mg incremental doses on days 1, 2 and 3, followed by immune activation on day 4 (no dosing), and cemiplimab 350mg administered on day 5. As of the latest clinical cutoff date, June 12, 2024:

- 6 patients remain on treatment following at least 12 months of therapy.
- Treatment with THIO followed by cemiplimab has been well tolerated throughout the trial, with much lower toxicity compared to standard-of care treatments.
- Continuing treatment past 12 months demonstrates safety, efficacy and ongoing benefit from MAIA's novel telomere targeting NSCLC therapy.

"Our longest treated patient so far has completed 21 cycles of THIO sequenced with a CPI, and 6 patients who have crossed the 12-month survival follow-up are continuing the treatment," said Vlad Vitoc, M.D., Chairman and Chief Executive Officer of MAIA. "With current therapies, second-line patients' treatment duration is usually around 3-4 months[1] and third-line is even lower than that. It is very encouraging to see that our patients can remain on treatment for much longer. The ongoing benefits of THIO in longer-term patients are particularly notable, signifying THIO's potential as a durable and efficacious treatment for advanced NSCLC patients faced with limited options."

1. https://www.sciencedirect.com/science/article/pii/S0169500217304373

**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, 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 anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO administered prior to 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 another 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 (Libtayo®) 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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