March 6, 2024

MAIA Biotechnology Announces Strong Efficacy of THIO as Third-Line Treatment for Non-Small Cell Lung Cancer Patients

- Combination THIO 180mg + cemiplimab achieved 38% overall response rate (ORR) in difficult-to-treat, third-line non-small cell lung cancer (NSCLC)
- ORR of 38% significantly exceeds standard of care ORR in NSCLC third-line in patients without a targetable mutation who progressed on checkpoint inhibitors and chemotherapy

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc., (NYSE American: MAIA) (“MAIA”, the “Company”), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced positive efficacy data for third-line treatment in its Phase 2 THIO-101 clinical trial evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in advanced non-small cell lung cancer (NSCLC).

As of January 8, 2024, overall response rate (ORR), characterized as partial or complete response to therapy, was 38% (3 out of 8 patients) in the efficacy evaluable population for combination THIO 180mg + cemiplimab in third-line treatment for NSCLC patients who failed treatment with immune checkpoint inhibitors in prior lines of therapy, with or without chemotherapy.

“As an impressive measure of efficacy, the strong response rate of 38% in third-line treatment supports our premise that THIO administration prior to cemiplimab can improve tumor responses to immunotherapy in advanced NSCLC patients resistant to CPIs and other standard treatments,” said Vlad Vitoc, M.D., MAIA’s Chairman and Chief Executive Officer. “Around 60-70% of NSCLC patients do not have a targetable mutation and cannot benefit from a biomarker-targeted therapy, making it the greatest unmet medical need population in lung cancer. In currently available treatments for these patients in third-line, response rates range around 6%.[1] We are encouraged by the excellent efficacy findings in THIO-101 to date, adding impressive ORR to unprecented disease control rates (DCR), and further demonstrating the potential of our first-in-class treatment to redefine the standard of care for NSCLC patients.”

The efficacy evaluable population defined in the THIO-101 protocol considers all subjects who received at least one dose of THIO treatment and have at least one postbaseline tumor assessment (scans). Two third-line patients in the 180mg dose cohort did not have recorded scans at the data cutoff. Safety remained consistent with previous reports.

The Company recently announced early completion of enrollment in the THIO-101 trial.

THIO-101 is expected to be the first completed clinical study of a telomere-targeting agent in the field of cancer drug discovery and treatment.

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.

[1] Journal of Thoracic Oncology, Volume 4, Number 12, December 2009. *Note: no updated 3rd line NSCLC data in recent years.

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