June 4, 2024

MAIA Biotechnology Reveals New Clinical Data Showing THIO's Strong Efficacy in Non-Small Cell Lung Cancer

THIO's favorable disease control and overall response rates exceed reported standard-of-care data in third line treatment

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced new efficacy data from its Phase 2 THIO-101 clinical trial evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who failed 2 or more standard-of-care therapy regimens. Updated results show a favorable overall response rate (ORR) of 38% and a disease control rate (DCR) of 85% from THIO + CPI in third-line treatment. The new data was presented in a poster session at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting on June 3, 2024.

The primary objectives of THIO-101 Phase 2 trial are to examine the safety and tolerability of THIO as an anticancer drug and as an immune system primer, and to examine the clinical efficacy of THIO in the form of ORR. At the time of the most recent data cut-off (April 30, 2024), all evaluable patients had completed ≥1 post-baseline assessment.

Results from third-line treatment:

- Disease control rate (DCR) was 85% for THIO vs. standard of care DCR of 25–35% for chemotherapy[1]
- 65% of patients crossed the 5.8-month overall survival (OS) threshold[2]
- 85% of patients crossed the 2.5-month progression-free survival (PFS) threshold[3-4]
- Median survival follow-up time is currently 9.1 months (n=20)

Results from third-line treatment with THIO 180mg (optimal dose selection)

- Median PFS of 5.5 months (24.1 weeks)
- 78% OS rate at 6 months
- 38% ORR vs. standard of care 6–10% for chemotherapy[2]
- 75% of patients crossed the 5.8-month OS threshold[2]
- 88% of patients crossed the 2.5-month PFS threshold[3-4]
- Median survival follow-up time is currently 9.1 months (n=8)

[1] Matsumoto H, et al. Transl Lung Cancer Res 2021;10:2278–89.
[2] Girard N, et al. J Thorac Onc 2009;12:1544-1549.

[3] Shepherd F, et al. N Engl J Med 2005;353:123-132.
[4] Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.

“All exceptional measures of efficacy in our trial to date have exceeded our own expectations and outperformed standard of care treatments,” said Vlad Vitoc, M.D., MAIA’s Chairman and Chief Executive Officer. “The data presented at ASCO advances THIO’s excellent clinical profile as a strong, safe, and highly effective alternative for patients who progressed following chemotherapy and other available treatments. We eagerly anticipate full efficacy data from THIO-101 in the second half of this year.”

To date, treatment with THIO + cemiplimab has been generally well tolerated in a heavily pre-treated patient population. Full enrollment in THIO-101 was completed on February 19, 2024, earlier than expected as per trial design. The Company expects that THIO-101 will be the first completed clinical study of a telomere targeting agent in the field of cancer drug discovery and treatment.

The poster and updated Company presentations can be accessed on the company’s website.

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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20240604727806/en/

Investor Relations Contact
+1 (872) 270-3518
ir@maiabiotech.com

Source: MAIA Biotechnology, Inc.