October 19, 2023

MAIA Biotechnology to Present Preliminary Safety and Efficacy Data from THIO-101 Phase 2 Clinical Trial at European Society for Medical Oncology Congress 2023

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc. (NYSE American: MAIA), a clinical stage company developing telomere-targeting immunotherapies for cancer, today announced that preliminary safety and efficacy data from its ongoing Phase 2 clinical trial, THIO-101, was accepted for poster presentation at the European Society for Medical Oncology (ESMO) Congress 2023, being held in Madrid, Spain, October 20-24, 2023. THIO-101 is evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC) in sequential combination with Regeneron's anti-PD-1 cemiplimab (Libtayo®).

"We look forward to presenting THIO data at the esteemed ESMO Congress, where we will have the opportunity to update global leaders in cancer research from around the world on the only direct telomere targeting agent currently in clinical development," said Vlad Vitoc, M.D., Chairman and Chief Executive Officer of MAIA Biotechnology.

The abstract is available online at the ESMO Congress website, and MAIA is scheduled for poster presentation on Monday, October 23. Details of the presentation are as follows:

Abstract title: A Phase 2, Multi-Center, Open-Label, Dose-Optimization Study Evaluating Telomere Targeting Agent THIO Sequenced with Cemiplimab in Patients with Advanced NSCLC - Preliminary Results

Presenter: Tomasz Jankowski, M.D.

Presentation Number: 1493P

Session title: NSCLC, metastatic

About ESMO and the ESPO Congress

The European Society for Medical Oncology is the leading professional organization for medical oncology. With more than 30,000 members representing oncology professionals from 168 countries worldwide, ESMO is the society of reference for oncology education and information.

The ESMO Congress is one of the most influential oncology platforms for clinicians,

researchers, patient advocates, journalists and healthcare industry representatives from all over the world. Only the highest quality studies are approved to be presented, supporting dissemination of the latest cutting-edge data, high quality education and unparalleled networking opportunities for oncologists and other stakeholders from all around the world.

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 vivo cancer models by induction of cancer type–specific immune memory. THIO is presently developed as a second or later line of treatment for patients with advanced NSCLC who progressed after first line treatment regimens containing an immune check point inhibitor.

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. 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/20231019027398/en/

Investor Inquiries
MAIA Biotechnology
Joseph McGuire
Chief Financial Officer
jmcguire@maiabiotech.com
904-228-2603

Investor Relations
ir@maiabiotech.com

Source: MAIA Biotechnology, Inc.