

January 7, 2025



MAIA Biotechnology Announces Clinical Supply Agreement with BeiGene for Upcoming Phase 2 Trials in Three Cancer Indications

- *Phase 2 pivotal trials to evaluate efficacy of THIO in combination with BeiGene's checkpoint inhibitor (CPI) tislelizumab*

CHICAGO--(BUSINESS WIRE)-- **MAIA Biotechnology, Inc., (NYSE American: MAIA)** ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced that it has entered into a clinical supply agreement with global oncology company BeiGene to assess the efficacy of THIO, its small molecule telomere-targeting anticancer agent, in combination with BeiGene's immune checkpoint inhibitor (CPI) tislelizumab in three cancer indications. The single arm pivotal Phase 2 trials will study the drug combination in hepatocellular carcinoma (HCC), small cell lung cancer (SCLC) and colorectal cancer (CRC).

MAIA's preclinical results in HCC, with THIO in combination with a CPI, showed complete, durable and highly potent anti-tumor immune response. Preclinical results of THIO treatment in SCLC showed profound activation of innate and adaptive anti-tumor responses. In CRC pre-clinical studies, THIO administered in sequence with a CPI resulted in 100% complete response and anticancer immune memory was induced, resulting in no recurrence after rechallenge with 10x more CRC cells and no additional therapy. In all preclinical studies, THIO converted immunologically cold and non-responsive tumors into hot tumors that are responsive to a CPI.

"Based on excellent pre-clinical results, THIO was awarded orphan drug designation (ODD) for the treatment of both HCC and SCLC. Along with a third ODD in glioblastoma, the FDA has clearly recognized THIO's potential as an effective treatment for multiple cancer indications. Comparatively, most oncology compounds at this stage of development have only one indication," said MAIA Chairman and Chief Executive Officer Vlad Vitoc, M.D. "BeiGene's tislelizumab has also demonstrated its potential to deliver clinically meaningful outcomes across a range of tumor types. We are pleased to partner with BeiGene for these important studies, two of which address the top three most lethal cancers worldwide."

Under the terms of the collaboration, MAIA will sponsor and fund the planned clinical trials and BeiGene will provide tislelizumab. MAIA maintains global development and commercial rights to THIO and is free to develop the programs in combination with other agents and in other indications.

MAIA is targeting accelerated FDA approvals in each of the three indications to be studied

along with non-small cell lung cancer (NSCLC), the focus of a current Phase 2 clinical trial of THIO with a CPI.

Market Trends

Hepatocellular carcinoma is the third most common cause of cancer-related deaths globally. The market for HCC was valued at \$780 million in 2023 and is expected to increase to grow at a CAGR of 6.3% to \$1.5 billion by 2034.¹

Small cell lung cancer accounts for an estimated 15% of all lung cancer globally. The global SCLC therapeutics market is valued at approximately \$6.5 billion in 2024 and is expanding at an estimated CAGR of 12.3% from 2024 to 2034.²

Colorectal cancer is the second leading cause of cancer-related deaths globally.³ Approximately 85% of all CRC cases are classified as microsatellite stable. MSS tumors are “cold tumors” that typically do not trigger the body’s immune system. The global CRC therapeutics market size was \$9.26 billion in 2018 and is projected to reach \$26.49 billion by 2032.⁴

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 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 *IMARC, Hepatocellular Carcinoma Market: Epidemiology, Industry Trends...*, 2023.

² *Precedence Research, Small Cell Lung Cancer Therapeutics Market Size... 2024 to 2034, October 2024.*

³ *World Health Organization, Fact Sheet: Colorectal Cancer, July 2023.*

⁴ *Fortune Business Insights, Colorectal Cancer Therapeutics Market...*, August 2024.

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Source: MAIA Biotechnology, Inc.