

December 16, 2024



MAIA Biotechnology Granted FDA Rare Pediatric Disease Designation for THIO as a Treatment for Pediatric High-Grade Gliomas

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 the FDA has designated THIO for the treatment of pediatric-type diffuse high-grade gliomas (PDHGG) as a drug for a "rare pediatric disease."

"THIO is a versatile anti-cancer agent that has demonstrated positive results in multiple difficult to treat cancer types, including pediatric high-grade glioma, which is among the most treatment-resistant cancers in children. THIO is shown to activate the immune system while evading tumor immunosuppression, a novel therapeutic approach for this devastating childhood disease," said MAIA Chairman and Chief Executive Officer Vlad Vitoc, M.D. "We are proud to receive the FDA's Rare Pediatric Disease designation for THIO, which significantly bolsters our plans for continuing research in the PDHGG indication."

MAIA's Vice President and Head of Regulatory and Quality K. Robinson Lewis added, "Rare pediatric disease designation also offers a highly valuable incentive for MAIA. Upon FDA approval of a future new drug application in PDHGG, MAIA would be eligible to receive a priority review voucher that can be redeemed or sold as an asset at a very high valuation."

Rare pediatric disease priority review vouchers (PRVs) can be redeemed by drug developers for FDA priority review of a different product or transferred or sold to another sponsor. Since 2015, FDA priority review vouchers have sold as assets at an average amount of \$100 million.¹

Previous research showcased THIO's potency as a treatment for a PDHGG subtype known as diffuse intrinsic pontine glioma (DIPG). A research collaboration between MAIA and Nationwide Children's Hospital found that THIO combined with ionizing radiation (IR) resulted in significantly decreased cell proliferation and produced potent anticancer effects in highly aggressive DIPG. The data was presented in April 2024 at the American Association for Cancer Research (AACR) Annual Meeting.

MAIA collaborated with Only Orphans Cote for THIO's designation request. Only Orphans Cote is a foremost provider of regulatory services and strategies for FDA orphan drug designations and marketing authorization.

In addition to its rare pediatric disease designation in PDHGG, THIO holds orphan drug

designations (ODD) in three cancer types: hepatocellular carcinoma (HCC), small cell lung cancer (SCLC) and glioblastoma. MAIA believes that THIO is the only direct telomere-targeting agent currently in clinical development.

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 [Pharmaceutical Technology](#), GlobalData Pharma Intelligence Centre, January 2024

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Investor Relations Contact

+1 (872) 270-3518

ir@maiabiotech.com

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