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MAIA Biotechnology Receives FDA Orphan Drug Designation for THIO for the Treatment of Small-Cell Lung Cancer (SCLC)

CHICAGO--(BUSINESS WIRE)-- [MAIA Biotechnology, Inc.](#), (NYSE American: MAIA) (“MAIA”, the “Company”), a targeted therapy, immuno-oncology company focused on developing potential first-in-class oncology drugs, announced today that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to THIO, a telomere-targeting agent currently in development to evaluate its activity in multiple cancer indications, for the treatment of small-cell lung cancer (SCLC). This is the second orphan drug designation granted to THIO, following receipt of orphan designation for hepatocellular carcinoma (HCC).

“Receiving our second Orphan Drug Designation is an impressive regulatory milestone that highlights the FDA’s recognition of THIO’s potential to improve outcomes for patients with SCLC and HCC,” said Vlad Vitoc, M.D., MAIA’s Chairman and Chief Executive Officer. “We believe there is a significant, multi-billion-dollar opportunity for THIO across many difficult-to-treat cancers and we look forward to advancing THIO towards the market and to patients in need for more effective therapies.”

“Patients with SCLC have exceptionally poor prognosis, with only 6% of patients remaining alive five years after diagnosis,” said Mihail Obrocea, MD, Chief Medical Officer of MAIA. “While clinical progress in SCLC treatment has been incredibly slow to evolve, an increased understanding of the disease biology has demonstrated that targeted therapies, like THIO, may offer a novel therapeutic option for SCLC.”

Sergei Gryaznov, Ph.D., Chief Scientific Officer of MAIA, added, “There is significant room for improvement in the treatment landscape for SCLC, with the currently available standard-of-care therapies providing incremental benefit to patients. We are optimistic about our telomere-targeting approach to provide clinical benefit in patients with SCLC, CRC and HCC who have failed first-line therapies and we look forward to evaluating our approach in a future trial.”

Lung cancer is the leading cause of cancer death among both men and women and accounts for about one-fifth of all cancer deaths. Lung cancer is broadly split into NSCLC and SCLC, with about 15% classified as SCLC. About two-thirds of SCLC patients are diagnosed with extensive-stage disease, in which the cancer has spread widely through the lung or to other parts of the body. SCLC is an aggressive, fast-growing cancer that recurs and progresses rapidly despite initial response to platinum-based chemotherapy.

The FDA's Office of Orphan Products Development grants orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain benefits, including financial incentives, to support clinical development and the potential for up to seven years of market exclusivity for the drug for the designated orphan indication in the U.S. if the drug is ultimately approved for its designated indication.

About THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a 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. THIO is being 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.

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