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MAIA Biotechnology, Inc. Announces FDA Orphan Drug Designation for THIO for the Treatment of Hepatocellular Carcinoma (HCC)

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc., a targeted therapy, immuno-oncology company focused on developing potential first-in-class oncology drugs ("MAIA"), 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 hepatocellular carcinoma (HCC).

"Receipt of Orphan Drug Designation for THIO is an important milestone for MAIA," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer. "The designation provides further momentum for the THIO program, which we are committed to advancing as quickly as possible for patients in need, like those living with HCC."

"Patients living with HCC currently have limited treatment options that are often ineffective. After completing standard-of-care therapy, patients with HCC tend to have poor outcomes with little to no improvement from treatment," said Mihail Obrocea, M.D., Chief Medical Officer of MAIA. "The FDA's decision to grant ODD to THIO is an important recognition of MAIA's unique scientific approach of telomere-targeting and the potential we have with THIO to deliver a first-in-class oncology drug to patients."

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.

Sergei Gryaznov, Ph.D., Chief Scientific Officer of MAIA, added, "We are pleased to have received ODD from the FDA for THIO since we have been preparing for clinical studies to evaluate the ability of THIO to enhance and extend the immune system's response to fight cancer. We look forward to continuing to advance THIO and to dosing our first patient in the upcoming Phase 2 studies."

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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