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MAIA Biotechnology, Inc. Announces Clinical Supply Agreement with Regeneron for Phase 1/2 Clinical Trial Evaluating THIO in Sequential Administration with Libtayo® (cemiplimab) in Advanced Non-Small Cell Lung Cancer

CHICAGO--(BUSINESS WIRE)-- MAIA Biotechnology, Inc., a targeted therapy, immuno-oncology company focused on development of first-in-class oncology drugs, today announced a clinical supply agreement with Regeneron Pharmaceuticals, Inc. (REGN) to evaluate THIO (aka 6-thio-dG) followed by the PD-1 inhibitor Libtayo® (cemiplimab), in a Phase 1/2 clinical trial in second-line or later advanced non-small cell lung cancer (NSCLC) patients who have progressed following treatment with standard-of-care regimen that includes a checkpoint inhibitor. This clinical trial will evaluate the safety and efficacy of four dose levels of THIO, the only telomere-by-telomerase targeting agent in development for the treatment of cancer, followed by Libtayo. The lead-in portion of the study will initially assess the safety and immunogenic effects of each of the THIO doses and overall response rate (ORR) as the basis for potentially expanding individual patient cohorts and evaluation in other cancer types. The Phase 1/2 clinical trial is expected to begin enrolling patients in 2021.

“We are excited for the opportunity to partner with Regeneron on our planned clinical trial of THIO and believe this collaboration to be validating of the program’s potential to transform both the immuno-oncology landscape and the cancer treatment paradigm,” stated Vlad Vitoc, MD, MAIA’s Chief Executive Officer and President. “Notably, THIO has a well-demonstrated clinical safety profile at varying dosage levels and in preclinical results, low-dose THIO followed by immunotherapy has shown complete elimination of advanced tumors with no indication of treatment limiting toxicity. The efficacy results of this trial are expected to support the continued development of THIO in NSCLC and potentially its expansion to treat a vast array of other cancers. Based on our extensive preclinical experience, we believe that THIO may transform immunologically ‘cold’ tumors into ‘hot’, rendering them responsive to standard-of-care immuno-oncology therapies, and potentially improving their effectiveness.”

Under the terms of the collaboration, MAIA will sponsor and fund the planned clinical trial and Regeneron will provide Libtayo. MAIA maintains global development and commercial rights to THIO and is free to develop the program in combination with other agents outside of NSCLC.

“At Regeneron, we seek opportunities to explore cutting-edge approaches to cancer treatment with other healthcare innovators who have complementary expertise,” said Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology, at Regeneron. “Priming tumors with THIO before Libtayo treatment is a novel approach that may enhance and extend the potential benefits of immunotherapy for patients with advanced non-small cell lung cancer, and we look forward to seeing if the positive pre-clinical results that MAIA has published will translate to the clinic.”

THIO followed by Libtayo for the treatment of advanced non-small cell lung cancer is currently under clinical development, and the safety and efficacy of THIO or its administration with Libtayo have not be reviewed by any regulatory authorities. Libtayo is being jointly developed by Regeneron and Sanofi. MM Dillon & Co. acted as advisors to MAIA Biotechnology, Inc.

About the Phase 1/2 Clinical Trial

This trial will be the first to test THIO’s immune system activation followed by administration of the checkpoint inhibitor Libtayo, allowing for the immune activation and PD-1 sensitivity to take effect. The trial will test the hypothesis that lower doses of THIO administered prior to Libtayo treatment would enhance and prolong responses in subjects with advanced NSCLC who did not respond or progressed after first-line treatment with a checkpoint inhibitor.

The initial part of the trial will assess both the safety, mechanistic activity and immune system activation of four THIO dose levels, each in separate arms. Each dosing arm will then be evaluated further for efficacy based on Overall Response Rate (ORR), Duration of Response (DoR), Progression Free Survival (PFS) and Overall Survival (OS). Additional patients may be recruited for further clinical evaluation in any of the THIO arm(s) based on safety and clinical benefit. A total of up to 40 evaluable patients will be enrolled in each of the arms of the trial.

About Non-small Cell Lung Cancer

Lung cancer is the leading cause of cancer death worldwide, In 2020, more than 2.2 million and 228,000 new cases were estimated to have been diagnosed globally and in the U.S., respectively. Approximately 85% of all lung cancers are NSCLC, and an estimated 80% of these cases are telomerase positive [TERT(+)]. While immunotherapies have transformed advanced NSCLC treatment in recent years, there remains a significant unmet need to optimize treatment of patients and offer additional clinical options.

About THIO

THIO (aka 6-thio-dG, 6-thio-2’-deoxyguanosine) is a first-in-class small molecule that is the only telomere-by-telomerase targeting agent currently in development. THIO selectively kills cancer cells by modifying telomeric DNA structure and function utilizing *telomerase.* Telomerase is present in >85% of human cancers and contributes significantly to the proliferation and reproductive immortality of cancer cells. THIO’s activity was shown to be cancer-specific in tumor types with active telomerase. THIO is recognized by telomerase and incorporated into telomeres selectively in cancer cells. Once incorporated, it compromises the telomere structure and function, leading to ‘uncapping’ of the chromosome ends and thus resulting in rapid tumor cell death. Low doses of THIO, followed by anti-PD-L1 or anti-

PD1 therapy, completely eliminated advanced tumors in preclinical models and produced cancer cell specific immune memory, where the immune system continued to be active against the cancer cells after extended periods of time, with no additional treatment. These results demonstrate how the THIO-produced telomere stress increases innate sensing and adaptive anti-tumor immunity, which provides a strong rationale for sequentially combining telomere-targeted therapy with immunotherapy. THIO is investigational and has not been approved for any use by regulatory authorities.

About MAIA Biotechnology, Inc.

MAIA Biotechnology, Inc. is a targeted therapy, immuno-oncology company focused on development and commercialization of first-in-class drugs with novel mechanisms of action that are intended to meaningfully improve and extend the lives of people with cancer. Drug candidates include (i) THIO, a first-in-class telomere-by-telomerase targeting agent in clinical development for the treatment of telomerase positive cancer cells; (ii) The FKBP52 preclinical program is evaluating the FKBP52 co-chaperone as a therapeutic target for prostate cancer and breast cancer; two compound families have been identified with a potentially novel mode of action targeting androgen receptor (AR) and direct FKBP52 co-chaperone inhibition, that are important in prostate and breast cancers. 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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