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# MAIA Biotechnology Announces Expansion of Clinical Supply Agreement with Regeneron for Phase 2 Trial in Non-Small Cell Lung Cancer

- Expansion of 2021 clinical supply agreement for Phase 2 clinical trial
- Next stage of trial to further assess efficacy of THIO in third line non-small cell lung cancer patients
- MAIA expects new patient enrollment to begin soon in the expansion of THIO-101

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 amended the 2021 clinical supply agreement with Regeneron for the expansion portion of THIO-101, its Phase 2 clinical trial evaluating THIO in sequential administration with cemiplimab (Libtayo®). The new expansion will further assess the efficacy of MAIA's lead asset, THIO, sequenced with immune checkpoint inhibitor (CPI) Libtayo® (cemiplimab) for advanced non-small cell lung cancer (NSCLC) patients receiving third-line therapy who were resistant to previous checkpoint inhibitor treatments and chemotherapy.

The original 2021 agreement between MAIA and Regeneron was designed to supply the original THIO-101 trial through the dose selection and safety evaluation process. The THIO-101 trial has been amended and expanded to further evaluate efficacy at the target dose and target third line patient population.

"In keeping with our clinical strategy for THIO, we look forward to continuing our collaboration with Regeneron to evaluate THIO's anti-tumor activity when followed by PD-(L)1 inhibition. So far, THIO-101 has demonstrated favorable disease control, progression free survival, overall response rates, and we remain on track to achieve our overall survival goals," said MAIA Chairman and Chief Executive Officer Vlad Vitoc, M.D.

Under terms of the amended clinical supply agreement, MAIA continues to sponsor THIO-101 and Regeneron will provide Libtayo® for the treatment of all patients in the trial including the additional patients in the THIO 101 expansion. MAIA holds an exclusive worldwide patent license to develop and commercialize THIO.

MAIA expects to start enrolling new patients in the expansion of THIO-101 in the near future.

The company continues to evaluate its regulatory strategy and believes that there could be an opportunity for an accelerated approval in the United States based on the ultimate

outcome of the ongoing THIO 101 trial.

## **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 THIO-101, a Phase 2 Clinical Trial**

THIO-101 is a multicenter, open-label, dose finding Phase 2 clinical trial. It is the first trial designed to evaluate THIO's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO administered prior to cemiplimab (Libtayo®) will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or developed resistance and progressed after first-line treatment regimen containing another checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety and tolerability of THIO administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with THIO followed by cemiplimab (Libtayo®) has been generally well-tolerated to date in a heavily pre-treated population. For more information on this Phase II trial, please visit [ClinicalTrials.gov](https://ClinicalTrials.gov) using the identifier NCT05208944.

## **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](http://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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