March 15, 2022

MAIA Biotechnology, Inc. Announces HREC Approval in Australia for its THIO-101 Phase 2 Trial for NSCLC

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 company's lead compound, THIO, has received approval by the Bellberry Human Research Ethics Committee (HREC) in Australia to initiate the THIO-101 Phase 2 clinical study evaluating the administration of THIO followed by cemiplimab in patients with advanced Non-Small Cell Lung Cancer (NSCLC). The primary objectives of the trial are to evaluate the safety of THIO administered as a direct anticancer and priming immune system agent prior to cemiplimab administration and to assess the clinical efficacy of THIO in patients.

"We are thrilled to receive the Ethics Committee approval to proceed with our Phase 2 clinical study, THIO-101, in Australia," said Mihail Obrocea, M.D., MAIA's Chief Medical Officer and Head of Clinical Development. "Our approach to treating NSCLC patients with THIO is unique – we look forward to exploring the utility of THIO as a lead-in agent for checkpoint inhibitors, which we believe will enhance and extend the immune system's response, allowing for a more effective and targeted therapeutic approach. In the near term, we look forward to dosing our first patient with THIO in this Phase 2 study."

About THIO-101, a Phase 2 Clinical Trial

This trial (THIO-101) will be the first to test THIO's potential immune system activation effects in NSCLC patients by administering THIO in advance of administration of the checkpoint inhibitor cemiplimab (co-developed by Regeneron and Sanofi), potentially allowing for immune activation and PD-1 sensitivity to take effect. The trial will test the hypothesis that low doses of THIO administered prior to checkpoint inhibitor treatment will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or progressed after first-line treatment regimen containing a checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety of THIO administered as an anticancer agent and a priming immune system agent prior to cemiplimab administration and (2) to assess the clinical efficacy of THIO followed by cemiplimab using Overall Response Rate (ORR) as the primary clinical endpoint. We expect the study to start initially in Australia and Europe followed by the United States.

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 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 Biotechnology, Inc. 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 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20220315005329/en/

Investor Relations, Media & General Inquiries:
Amy Conrad

ir@maiabiotech.com

Source: MAIA Biotechnology, Inc.