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MAIA Biotechnology Expands Pivotal Phase 3 THIO-104 Non-Small Cell Lung Cancer Trial into Spain and Portugal

THIO-104 advances toward key 2027 interim survival analysis

CHICAGO, Sept. 23, 2026 (GLOBE NEWSWIRE) -- MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing immunotherapies for cancer, today announced that it has received regulatory approval by the Spanish Agency for Medicines and Medical Devices (AEMPS) and Portugal's National Authority of Medicines and Health Products (INFARMED) to begin screening patients for its ongoing pivotal Phase 3 THIO-104 clinical trial in non-small cell lung cancer (NSCLC).

Spain and Portugal represent important European markets for NSCLC, with an estimated 30,000 new cases annually across the two countries. Spain has a substantial lung cancer burden associated with historical tobacco exposure, with lung cancer incidence among women continuing to rise. In Portugal, NSCLC accounts for approximately 82% of lung cancer cases, the highest proportion reported among five European populations evaluated in a comparative study.

"Expanding THIO-104 into Spain and Portugal represents another important step in the execution of our pivotal Phase 3 program," said Vlad Vitoc, M.D., Chairman and Chief Executive Officer of MAIA. "Clinical trial participation can provide patients with access to investigational therapies in markets where access to newly approved lung cancer treatments has historically lagged. By establishing THIO-104 sites in Spain and Portugal, we are broadening access to a potentially important new treatment option for patients with advanced NSCLC who have progressed following standard of care treatments."

To date, THIO-104 has enrolled 65 NSCLC patients resistant to chemotherapy and checkpoint inhibitor treatments at 28 clinical sites in 6 European countries and 10 sites in Taiwan. Among the six European countries, sites in Hungary, Poland, and Turkey are actively enrolling and dosing patients from populations with the highest lung cancer incidence and mortality rates in Europe and globally.[1]

MAIA targets 100 patients dosed in THIO-104 by year-end 2026 and expects to have sufficient survival data to conduct an interim data analysis in 2027.

About Ateganosine

Ateganosine (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 induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. Ateganosine-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment of ateganosine 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. Ateganosine 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 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 ateganosine (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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[1] Sources: Global Cancer Observatory (GLOBOCAN), European Cancer Information System (ECIS), World Cancer Research Fund

Source: MAIA Biotechnology, Inc.