MAIA Biotechnology enrolls first patient in expansion of phase 2 clinical trial for ateganosine in advanced non-small cell lung cancer

MAIA Biotechnology, Inc, a targeted therapy and 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, announced dosing of the first patient in Taiwan in the expansion phase of its THIO-101 phase 2 trial for advanced non-small cell lung cancer. The trial's entry into another continent marks a key milestone for MAIA, opening a significantly larger patient pool for its evaluations of ateganosine (THIO). Screening for the trial is ongoing in Europe and Asia.

Trial Design: The expansion study evaluates ateganosine in heavily pre-treated patients in third-line (3L) Non-small cell lung cancer who have previously failed treatment with checkpoint inhibitors (CPIs) and chemotherapy. Two treatment arms are being studied: ateganosine sequenced with cemiplimab (Libtayo) and ateganosine monotherapy. Regeneron is supplying Libtayo for the combination cohort.

Strategic opportunity: Non-small cell lung cancer represents one of the largest global oncology indications. The market was valued at $34.1 billion in 2024, and is projected to reach $68.8 billion by 2033 with a projected CAGR of 8.1 per cent.

Current data: As of May 15, 2025, the median overall survival for the 22 patients in the third-line treatment was 17.8 months, with a 95 per cent confidence interval lower bound of 12.5 months and a 99 per cent confidence interval lower bound of 10.8 months. The treatment has been generally well-tolerated in the trial's heavily pre-treated population.

Other studies of chemotherapy for non-small cell lung cancer in a similar setting have shown overall survival of 5 to 6 months.

"We are excited to have the expansion of the trial officially started. Ateganosine's observed overall survival in third-line non-small cell lung cancer exceeds all known benchmarks," said MAIA's CEO Vlad Vitoc. "This potentially positions us for first-mover advantage in a multibillion-dollar space with no currently approved standard of care."

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. 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 with 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 non-small cell lung cancer for patients that have progressed beyond the standard-of-care regimen of existing checkpoint inhibitors.

THIO-101 is a multicenter, open-label, dose finding phase 2 clinical trial. It is the first trial designed to evaluate ateganosine's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of ateganosine 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 ateganosine administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of ateganosine using overall response rate as the primary clinical endpoint. The expansion of the study will assess overall response rates in advanced non-small cell lung cancer patients receiving third line therapy who were resistant to previous checkpoint inhibitor treatments and chemotherapy. Treatment with ateganosine followed by cemiplimab (Libtayo) has been generally well-tolerated to date in a heavily pre-treated population.

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