UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report

Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 19. 2025

MAIA Biotechnology, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41455**	**83-1495913**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

444 West Lake Street, Suite 1700	
Chicago, IL	**60606**
(Address of principal executive offices)	**(Zip Code)**

(312) 416-8592
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	MAIA	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 23, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Biotechnology Details 30-Month Patient Survival in Ongoing Phase 2 Clinical Trial in Non-Small Cell Lung Cancer." Pursuant to Regulation FD, the press release is furnished with this Current Report on Form 8-K (this "Report") as Exhibit 99.1.

The information set forth in Item 7.01 of this Report and in the attached Exhibit 99.1 is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in Item 7.01 of this Report, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01 Other Events

1. The Company has prepared a poster (the "Poster") entitled "Presentation 1: A Phase 2 Study of Ateganosine (THIO; 6-thio-2'-deoxyguanosine) in Combination with Immune Checkpoint Inhibitor (ICI) in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Resistant to Prior ICI and Chemotherapy: THIO-101 Trial ("THIO-101 Trial Poster"). The THIO-101 Poster was presented at the European Society for Medical Oncology (ESMO) Congress 2025 held in Berlin, Germany starting on October 19, 2025 and posted to the Company's website on such date, a copy of which is filed as Exhibit 99.2 to this Report and is hereby incorporated by reference.

2. The Company has prepared a poster (the "Poster") entitled • Presentation 2: A Phase 3 Study of Ateganosine (THIO) Sequenced with Immune Checkpoint Inhibitor (ICI) versus Standard of Care Chemotherapy in ICI-Resistant Advanced NSCLC: THIO-104 Trial in Progress ("THIO-104Trial Poster"). The THIO-104 Poster was presented ESMO starting on October 19, 2025 and posted to the Company's website on such date, a copy of which is filed as Exhibit 99.3 to this Report and is hereby incorporated by reference.

Each of the THIO-101 Trial Poster and THIO-104 Trial Poster contain forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated October 23, 2025
99.2	THIO-101 Trial Poster
99.3	THIO-104 Trial Poster
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 23, 2025

MAIA BIOTECHNOLOGY, INC.

By: */s/ Vlad Vitoc*
Name: Vlad Vitoc
Title: Chief Executive Officer

Exhibit 99.1

MAIA Biotechnology Details 30-Month Patient Survival in Ongoing Phase 2 Clinical Trial in Non-Small Cell Lung Cancer

● Outstanding measure of efficacy relative to high-risk cancers with limited treatment options

CHICAGO – October 23, 2025 – MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced highlights from a recent presentation at the European Society for Medical Oncology (ESMO) Congress 2025 held in Berlin, Germany. Starting October 19, 2025, MAIA showcased two e-posters at ESMO detailing its ongoing Phase 2 and Phase 3 clinical trials of ateganosine in non-small cell lung cancer (NSCLC).

"The posters showcased at ESMO 2025 featured exceptional extended survival in third-line NSCLC patients. In addition, as of September 17, 2025, a patient that began therapy in March 2023 has shown survival of 30 months, or 912 days, an outstanding measure relative to many of the high-risk cancers," said MAIA CEO Vlad Vitoc, M.D. "Very few options exist for patients who are refractory or resistant to immune checkpoint inhibitors (ICI). We believe that a survival of over two years is a clear signal of ateganosine's role in effectively targeting and eliminating NSCLC tumor cells."

The THIO-101 patient with 30-month survival received therapy every three weeks, and concluded treatment upon reaching the maximum treatment duration of 2 years based on protocol requirements.

MAIA's newest posters featured at ESMO 205 are now available on MAIA's website at maiabiotech.com/publications.

- Presentation 1: A Phase 2 Study of Ateganosine (THIO; 6-thio-2'-deoxyguanosine) in Combination with Immune Checkpoint Inhibitor (ICI) in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Resistant to Prior ICI and Chemotherapy: THIO-101 Trial in Progress

- Presentation 2: A Phase 3 Study of Ateganosine (THIO) Sequenced with Immune Checkpoint Inhibitor (ICI) versus Standard of Care Chemotherapy in ICI-Resistant Advanced NSCLC: THIO-104 Trial in Progress

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 THIO-101 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 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 (ORR) as the primary clinical endpoint. The expansion of the study will assess overall response rates (ORR) in advanced NSCLC patients receiving third line (3L) therapy who were resistant to previous checkpoint inhibitor treatments (CPI) and chemotherapy. Treatment with ateganosine followed by cemiplimab (Libtayo®) has shown an acceptable safety profile to date in a heavily pre-treated population. For more information on this Phase II trial, please visit 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 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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A Phase 2 Study of Ateganosine (THIO; 6-thio-2'-deoxyguanosine) in Combination with Immune Checkpoint Inhibitor (ICI) in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Resistant to Prior ICI and Chemotherapy: THIO-101 Trial in Progress

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Introduction

- Despite recent advances for the first-line treatment of advanced Non-Small Cell Lung Cancer (NSCLC), long-term prognosis remains poor with a 5-year survival rate of 28%[1] and limited options exist in patients' refractory or resistant to immune checkpoint inhibitors (ICI).
- Ateganosine (THIO, 6-thio-2'-deoxyguanosine, 6-thio-dG) is a small molecule, first-in-class direct cancer telomere targeting agent that selectively kills telomerase positive (TERT+) cancer cells:
  - Over 80% of all cancers and approx. 78-83% of all NSCLC types are TERT+.[2,3]
  - Ateganosine is incorporated into de novo synthesized telomeres leading to chromatin uncapping, generation of DNA damage signals, and rapid apoptosis.[4]
- In preclinical models, sequential treatment of THIO and ICIs overcame ICI resistance and showed a potent and durable antitumor activity.[5]
- Preliminary trial results in NSCLC indicates that low doses of Ateganosine induce sensitivity to ICIs when administered prior to an ICI in tumors which otherwise are resistant or do not respond to an ICI.
- Treatment options for immune checkpoint inhibitor (ICI)-resistant patients are limited. THIO, a telomere-targeting agent, modifies telomeres in cancer cells, including circulating tumor cells (CTCs), confirming its mechanism of action and demonstrating efficacy independent of PD-L1 expression.
- Biomarkers assessing telomere damage in cancer cells are becoming increasingly important for accurately determining efficacy following treatment.

Methods

- Using a modified 3+3 design, the safety lead-in (Part A) enrolled 10 patients who received Ateganosine 360 mg IV (120 mg QD, D1–3), followed by 350 mg cemiplimab on D5, Q3W. Following completion of Part A, enrollment was opened in the dose-finding portion of the study (Part B).
- Using a Simon 2-stage design, 79 patients were assigned to one of the THIO doses: 360, 180, or 60 mg followed by cemiplimab Q3W for up to 1 year in Part B.
- Disease status is assessed at Cycle 3 Day 1, Cycle 5 Day 1 and every 9 -12 weeks thereafter.
- An expansion cohort started based on data from Part B: up to 48 patients in Part C (one arm with the combination of Ateganosine + cemiplimab, one arm with Ateganosine as monotherapy) and up to 100 patients are planned in Part D.
- CTCs were labeled with TRF1 and γH2AX to detect telomere dysfunction-induced foci (TIFs). TIF fraction in CTCs were measured using flow cytometry and averaged for consistency.
- Interleukin-6 (IL-6) protein levels were measured in the blood, with concentrations expressed in picograms per milliliter (pg/mL).

Baseline characteristics from Parts A and B

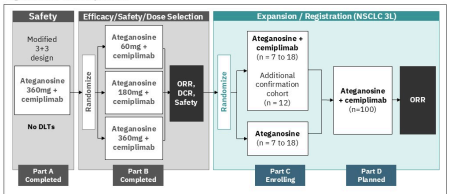
Table 1. Baseline characteristics

Characteristic	60 mg (n=24)	180 mg (n=41)	360 mg (n=54)	Total (N=79)
Median age (range), years	67 (52–85)	68 (45–81)	68 (50–75)	67 (45–85)
Sex, n (%)				
Female	10 (42)	11 (27)	7 (50)	28 (35)
Male	14 (58)	30 (73)	7 (50)	51 (65)
Number of prior lines, n (%)				
1	17 (71)	30 (73)	5 (36)	52 (66)
2	6 (25)	10 (25)	6 (43)	22 (28)
3	1 (4)	0 (0)	2 (14)	3 (4)
4	0 (0)	1 (2)	1 (7)	2 (3)
ECOG PS, n (%)				
0	6 (25)	8 (20)	7 (50)	21 (27)
1	18 (75)	33 (80)	7 (50)	58 (73)
Histology, n (%)				
Non-Squamous cell carcinoma	15 (63)	25 (61)	8 (57)	48 (60)
Squamous cell carcinoma	9 (37)	16 (39)	6 (43)	31 (40)
Brain metastases, n (%)	1 (4)	1 (2)	2 (14)	4 (5)
Liver metastases, n(%)	4 (17)	5 (12)	3 (21)	12 (15)

- At the time of data cut-off (June 30, 2025), 79 patients with advanced NSCLC had received ≥1 dose of Ateganosine in Parts A and B.
- All patients had previously failed ≥1 prior line of ICI ± chemotherapy in the advanced setting and had documented disease progression at study entry.
- 34% of patients had ≥2 prior treatment lines at study entry.

Study design

Figure 1. THIO-101 study schema



- **Primary endpoints:** Safety, ORR, DCR (CR, PR and SD).
- **Secondary endpoints:** DoR; PFS; OS.
- **Exploratory endpoints:** PK and PD (activity of Ateganosine in circulating tumor cells measured by specific biomarkers).

THIO-101 Part A (Completed enrollment, N=10)
- Modified 3+3 design
- Safety lead-in study of Ateganosine 360 mg per cycle (120 mg on Days 1-3, sequenced with cemiplimab).

THIO-101 Part B (Completed enrollment, N= 69)
- Randomized, dose-finding, Simon's 2-stage design
- 3-arm study (Ateganosine 60 mg, Ateganosine 180 mg, or Ateganosine 360 mg per cycle; all dose levels sequenced with cemiplimab).

- Enrollment for parts A and B of the study completed in Feb'24
- Optimal dose of Ateganosine 180mg selected in Nov'23 based on evaluations of safety, tolerability, and efficacy
- At the time of data cut-off (June 30, 2025), in third-line NSCLC patients that are resistant to chemotherapy and ICI, the observed Median Overall Survival (OS) is at 17.8 months and observed Overall Response Rate (ORR) is at 30% in the intent-to-treat population (3/10).

THIO-101 Part C (Enrollment initiated, up to N = 48)
- Randomized, Simon's 2-stage in each arm
- Arm 1: Ateganosine 180 mg/cycle (60 mg IV on D1-3) sequenced with cemiplimab
- Arm 2: Ateganosine 180 mg/cycle (60 mg IV on D1-3)
- Objective: To evaluate the efficacy and safety of Ateganosine 180 mg per cycle sequenced with cemiplimab compared with single-agent Ateganosine 180 mg per cycle as third-line treatment in advanced/metastatic NSCLC patients that are resistant to chemotherapy and ICI.

THIO-101 Part D (Planned, N = 100)
- Single-Arm Efficacy Cohort
- Ateganosine 180 mg/cycle (60 mg IV on D1-3) sequenced with cemiplimab.
- Objective: To evaluate the efficacy and safety of Ateganosine 180 mg per cycle sequenced with cemiplimab as third-line treatment in advanced/metastatic NSCLC patients that are resistant to chemotherapy and ICI.

Pharmacodynamics (Parts A, B, C and D) and Pharmacokinetics (Parts C and D) analysis for THIO-101

Pharmacokinetic parameters (PK):
- Ateganosine concentration levels and PK parameters (Full PK collection for Part C and limited PK collection for Parts C and D)

Pharmacodynamic parameters and Biomarkers (PD):
- TIF (Telomere dysfunction-induced foci) formation in CTCs
- CTCs evaluation of PDL1 expression
- Tumor telomerase TERT (+) status (via expression of telomerase mRNA), by ISH-TERT (in situ hybridization for TERT) of paraffin-embedded tumor samples.

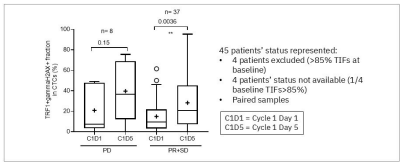
Hematology and Clinical Chemistry:
- Interleukin- 6 (IL-6)
- C-Reactive Protein (CRP)
- Carcinoembryonic Antigen (CEA)
- Lactate dehydrogenase (LDH)
- Neutrophil-lymphocyte ratio (NLR)
- Platelet-lymphocyte ratio (PLR)

References

1. https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics
2. Shay JW, Bacchetti S. Eur J Cancer 1997;33:787–91.
3. Tahara H, et al. Cancer Res 1995;55:2734–6.
4. Mender I, et al. Cancer Disc 2015 Jan;5(1):82-95.
5. Mender I, et al. Cancer Cell 2020;38:400–11.

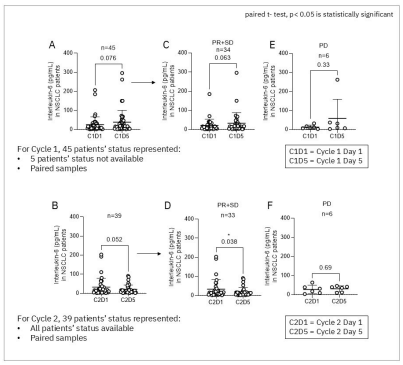
Biomarker findings from Parts A and B

Figure 2. Telomere dysfunction-Induced foci (TIFs) fraction in circulating tumor cells (CTCs) (Patient Status) - including all patients doses with 60, 180, 360 mg Ateganosine (Parts A and B)



- TIFs are a key biomarker of on-target activity for Ateganosine.
- TIF-positive CTCs were characterized as TRF1+/gammaH2AX+ fraction in CD326+/PanKRT+ CTCs.
- TIF analysis demonstrated the intended on-target mechanism of action: modification of telomeres in CTCs by Ateganosine.
- As of June 30, 2025, patients in the Stable Disease (SD) and Partial Response (PR) groups together showed increased levels of biomarker TIF, whereas the Progressive Disease (PD) group did not demonstrate a statistically significant increase in the TIF biomarker (Figure 2).
- TIF formation in CTCs was shown to be a good biomarker of on-target activity and we plan to continue the analysis as the trial continues.

Figure 3. Interleukin-6 levels-including all patients doses with 60, 180, 360 mg Ateganosine (Parts A and B)



- Interleukin-6 (IL-6) was evaluated to assess the specific transient activation of the immune system by Ateganosine in NSCLC patients receiving 60, 180 or 360 mg doses (Figure 3).
- The trend shows an increase in IL-6 after Ateganosine treatment in cycle 1 day 5 (Figure 3A) and a decrease in cycle 2 day 5 (Figure 3B).
- In patients responding to Ateganosine and cemiplimab treatment (partial response (PR) and stable disease (SD)), the trend also shows an increase in IL-6 in cycle 1 day 5 after THIO treatment (Figure 3C) and a statistically significant decrease of IL-6 in cycle 2 day 5 (Figure 3D), but not in non-responsive group (progressive disease (PD)) (Figure 3E and F).
- This indicates that the initial elevation of IL-6 appears to be associated with immune response to Ateganosine and cemiplimab treatment, suggesting its potential as a biomarker to predict treatment response.

Conclusions

- **The expansion of the study was warranted by the completion of Parts A and B of THIO-101.**
- **As of the data cut-off (June 30, 2025), the selected dose of Ateganosine 180mg, has shown a median observed Overall Survival (OS) of 17.8 months in advanced third-line NSCLC patients who were resistant to prior treatment with ICI and chemotherapy.**
- **For all subjects enrolled in Parts C and D of the study, pharmacokinetic samples will be collected for longitudinal exposure-response assessments. The levels of Ateganosine and 6-TG in human plasma will be determined using a GLP-validated Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) method.**
- **Treatment with Ateganosine alone leads to a significant induction in TIF formation in CTCs among the responsive group (Parts A and B). This highlights the utility of telomere DNA damage as a biomarker for monitoring the pharmacodynamic (PD) effects of Ateganosine treatment.**
- **An initial elevation of IL-6 may be associated with the immune response to Ateganosine and cemiplimab, indicating its potential as a predictive biomarker for the treatment efficacy.**
- **Additional biomarker studies (PK) from Parts C and D will be conducted as the trial continues.**

Acknowledgements

- This study is sponsored by MAIA Biotechnology, Inc.
- The authors would like to thank the patients and research staff who contributed to this study.
- The sponsor would like to send a special thanks to REGENERON, CROMOS and NOVA-CLIN for their exceptional contribution to this study.

Author disclosures

- Veronika Müller has no conflict of interest.

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17-21 OCTOBER 2025

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A Phase 3 Study of Ateganosine (THIO) Sequenced with Immune Checkpoint Inhibitor (ICI) versus Standard of Care Chemotherapy in ICI-Resistant Advanced NSCLC: THIO-104 Trial in Progress

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Introduction

- Despite progress in the treatment of advanced non-small cell lung cancer (NSCLC), therapeutic options remain scarce for patients who have developed resistance to immune checkpoint inhibitors (ICIs).
- Long-term prognosis remains poor with a 5-year survival rate of 28%[1] and limited options exist in patients' refractory or resistant to ICIs.
- Ateganosine (THIO, 6-thio-2'-deoxyguanosine), a telomere-targeting agent, is selectively recognized by telomerase and integrated into the telomeres of cancer cells. Once incorporated, Ateganosine compromises the telomere structure and function, leading to 'uncapping' of the chromosome ends and thus resulting in rapid tumor cell apoptosis.
- Preliminary trial results in NSCLC from THIO-101 (NCT05208944) indicates that low doses of Ateganosine induce sensitivity to ICIs when administered prior to an ICI in tumors which otherwise are resistant or do not respond to an ICI.

Methods

- THIO-104 is a multicenter, open-label, randomized Phase 3 study enrolling approximately 300 subjects with histologically confirmed advanced/metastatic NSCLC (NCT06908304).
- Eligible participants must have received two prior lines of systemic treatment, including at least one line of ICIs and platinum-based chemotherapy
- Participants will be randomized 1:1 to receive either Ateganosine 180 mg per cycle (60 mg IV on Days 1-3 of a 3-week cycle) followed by cemiplimab 350 mg IV on Day 5, or single-agent chemotherapy (vinorelbine, gemcitabine, or docetaxel).
- The primary endpoint is overall survival (OS). Secondary endpoints include objective response rate (ORR), progression-free survival (PFS) and duration of response (DoR).
- Preliminary safety data and efficacy outcomes will be assessed through scheduled interim analysis as the study develops.
- The trial is planned to enroll patients globally, including the USA and countries in Europe and Asia. Final list of sites may vary depending on regulatory approvals.

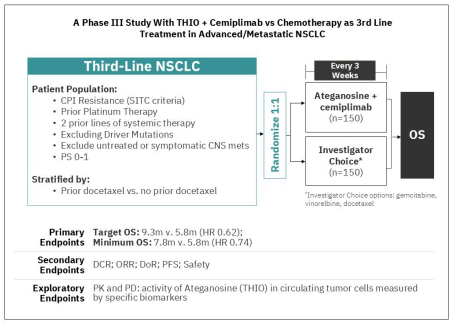
Figure 1. THIO-104 planned enrollment geographies

References

1. https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics
2. Mender I, et al. Cancer Disc 2015 Jan;5(1):82-95.

Study design

Figure 2. THIO-104 study schema



Primary Endpoints	**Target OS:** 9.3m v. 5.8m (HR 0.62); **Minimum OS:** 7.8m v. 5.8m (HR 0.74)
Secondary Endpoints	DCR; ORR; DoR; PFS; Safety
Exploratory Endpoints	PK and PD: activity of Ateganosine (THIO) in circulating tumor cells measured by specific biomarkers

Objective: To evaluate the efficacy and safety of Ateganosine (180 mg per cycle) sequenced with fixed dose cemiplimab (350 mg per cycle) compared to Investigator's choice of single-agent chemotherapy as third-line treatment in subjects with advanced/metastatic NSCLC.

Experimental Arm: THIO/Cemiplimab
- THIO 60 mg administered by 30-minute intravenous (IV) infusions once daily on Days 1-3 of every 3-week cycle (for a total of 180 mg per cycle), followed by a fixed dose of cemiplimab (350 mg IV) on Day 5 every 3 weeks (Q3W)

Control Arm: Single-Agent Chemotherapy
- Standard of Care (for example vinorelbine, gemcitabine, or docetaxel chemotherapy, if not previously exposed, per Investigator's Choice) in 3-week cycles
  - ❑ Option 1: Vinorelbine (30 mg/m2 IV on D1, D8, and D15 Q3W)
  - ❑ Option 2: Gemcitabine (1250 mg/m2 IV on D1 and D8 Q3W)
  - ❑ Option 3: Docetaxel (75 mg/m2 IV on D1 Q3W) (Docetaxel 60-65 mg/m2 permitted based on country-specific approvals).

*D = day (within a 21-day cycle); IV= intravenous; Q3W=every 3 weeks (21-day cycles)

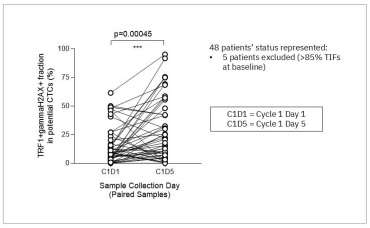
Pharmacokinetics and Pharmacodynamics analysis

Pharmacokinetic parameters (PK):
- Ateganosine concentration levels and PK parameters (Limited PK collection)

Pharmacodynamic parameters and Biomarkers (PD):
- TIF (Telomere dysfunction-induced foci) formation in CTCs
- CTCs evaluation of PDL1 expression
- Tumor telomerase TERT (+) status (via expression of telomerase mRNA), by ISH-TERT (in situ hybridization for TERT) of paraffin-embedded tumor samples.
- Hematology and Clinical Chemistry:
- Interleukin- 6 (IL-6)
- C-Reactive Protein (CRP)
- Carcinoembryonic Antigen (CEA)
- Lactate dehydrogenase (LDH)
- Neutrophil-lymphocyte ratio (NLR)
- Platelet-lymphocyte ratio (PLR)

Biomarker findings from THIO-101 ongoing Phase 2 study

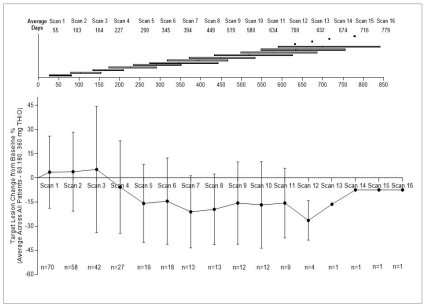
Figure 3. TIFs fraction in circulating tumor cells (CTCs) from THIO-101 patients (60, 180, 360 mg dosed patients)



- Telomere dysfunction-Induced foci (TIF)-positive CTCs were characterized as TRF1+/gammaH2AX+fraction in CD326+/PanKRT+ CTCs.
- TIF analysis demonstrated the intended on-target mechanism of action: modification of telomeres in CTCs by THIO (Figure 3).

Efficacy findings from THIO-101 ongoing Phase 2 study

Figure 4. Average response across patients in THIO-101 Parts A and B



- Figure 4 illustrates the average response across all patient cohorts to Ateganosine and cemiplimab in NSCLC patients receiving 60, 180 or 360 mg doses based on data from THIO-101 Parts A and B (August 13, 2025).
- At the data cut-off, 15 patients had observed survival greater than 12 months, 4 patients observed survival greater than 24 months. The longest observed survival was 842 days.
- The trend indicates a consistent response pattern to Ateganosine plus cemiplimab among patients to date.

Conclusions

- **THIO-104 is expected to provide critical insights into the potential role of telomere-targeting agents in improving survival in NSCLC patients resistant to immunotherapy and platinum agents.**
- **In the Phase 2 THIO-101 trial, as of the data cut-off (June 30, 2025), the selected dose of Ateganosine 180mg, has shown a median observed Overall Survival (OS) of 17.8 months in advanced third-line NSCLC patients who were resistant to prior treatment with ICI and chemotherapy.**
- **Based on the previously conducted studies[2], Ateganosine has been found to lead to a significant induction in TIF formation in CTCs, which is considered a primary biomarker for Ateganosine. The study will also explore key biomarkers to further characterize Ateganosine's mechanism of action and it's potential to predict patient response to therapy.**
- **The current response trend observed in the THIO-101 trial is expected to persist as the study progresses, paving the way for further exploration in THIO-104.**

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Author disclosures

- Veronika Müller has no conflict of interest.

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