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): November 8, 2024

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** **(Address of principal executive offices)**	**60606** **(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.

1. MAIA Biotechnology, Inc. (the "Company") has prepared a poster (the "Poster") detailing new efficacy data from its Phase 2 THIO-101 clinical trial evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who failed 2 or more standard-of-care therapy regimens, which includes: (i) as of September 16, 2024, 19 patients had survival follow-up surpassing 12 months, including 10 in third line treatment (3L); (ii) Interim median survival follow-up in 3L across all dose levels of THIO was 11.5 months; and (iii) Interim median survival follow-up in 3L in the THIO 180mg dose was 11.4 months. The Poster was selected as a "late-breaking abstract" and is being presented and displayed at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting on November 8, 2024. The Poster will also be posted to the Company's website on November 8, 2024, a copy of which is filed as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

2. The Company has made available a presentation (the "Presentation") about the Company's business which was posted to the Company's website on November 8, 2024, a copy of which is filed as Exhibit 99.2 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

3. The Company has made available a summary ("Summary") highlighting certain aspects of the Company's business, clinical programs and partnership with Regeneron which was posted to the Company's website on November 8,, 2024, a copy of which is filed as Exhibit 99.3 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

The information contained in each of the Poster, the Presentation and the Summary is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements the Company may make by press release or otherwise from time to time. Each of the Poster, the Presentation and the Summary speaks as of the date of this Report. While the Company may elect to update the Poster, the Presentation and/or the Summary in the future to reflect events and circumstances occurring or existing after the date of this Report, the Company specifically disclaims any obligation to do so.

Each of the Poster, the Presentation and the Summary contains forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

The information set forth in this Report, including, without limitation, the Poster, the Presentation and the Summary, is 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, nor shall it be incorporated by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such a filing. This Report (including the exhibits hereto) will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Forward-looking Statements

The Company cautions that all statements, other than statements of historical facts, contained in this Current Report on Form 8-K, or furnished herewith, 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. 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, including, but not limited to: (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. Any forward-looking statement speaks only as of the date on which it was made. The Company undertakes 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Poster
99.2	Presentation
99.3	Summary
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: November 8, 2024

MAIA BIOTECHNOLOGY, INC.

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

Abstract 1492

Telomere-Targeting Agent THIO in Sequential Combination with Cemiplimab Demonstrates Long Term Therapeutic Benefits Beyond Treatment Cessation. A Phase 2 Trial in Advanced Immune Checkpoint Inhibitor Resistant Non-Small Cell Lung Cancer Patients

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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).
- Biomarkers assessing telomere damage in cancer cells are becoming increasingly important for accurately determining efficacy following treatment.
- THIO (6-thio-2'-deoxyguanosine, also known as 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]
  - THIO 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 THIO induce sensitivity to ICIs when administered prior to an ICI in tumors which otherwise are resistant or do not respond to an ICI.
- Here we describe a phase 2 dose-optimization study (NCT05208944) for adult patients with advanced NSCLC who progressed or relapsed after 1–4 prior treatment lines including first-line ICI alone or in combination with platinum chemotherapy and new biomarker findings.

Methods

- Using a modified 3+3 design, the safety lead-in (Part A) enrolled 10 patients who received THIO 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.
- The trial completed enrollment for Parts A and B in February 2024. We report here data from the 79 patients enrolled on the study, who received at least one dose of the treatment.
- An expansion cohort is planned based on data from Part B (n=100).

Baseline characteristics

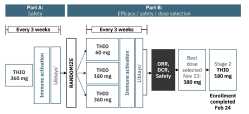
- At the time of data cut-off (16 September 2024), 79 patients with advanced NSCLC had received ≥1 dose of THIO.
- All patients had previously failed ≥1 prior line of ICI ± chemotherapy in the advanced setting and had documented disease progression at study entry.
- 34% of patients had ≥2 prior treatment lines at study entry.

Table 1. Baseline characteristics

Characteristic	60 mg (n=24)	180 mg (n=41)	360 mg (n=14)	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)

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 THIO in circulating tumor cells measured by specific biomarkers).

Safety findings

Table 2. Related TEAEs by dose level reported in ≥2 patients

Preferred Term	60mg (N=24)	180mg (N=41)	360mg (N=14)	Total (N=79)
Aspartate aminotransferase increased	6 (25%)	11 (26.8%)	4 (28.6%)	21 (26.6%)
Alanine aminotransferase increased	6 (25%)	9 (22%)	3 (21.4%)	18 (22.8%)
Nausea	2 (8.3%)	1 (2.4%)	7 (50%)	10 (12.7%)
Neutropenia	2 (8.3%)	2 (4.9%)	0(0.0%)	4 (5.1%)
Anemia	0(0.0%)	2 (4.9%)	1 (7.1%)	3 (3.8%)
Pyrexia	0(0.0%)	2 (4.9%)	1 (7.1%)	3 (3.8%)
Decreased appetite	0(0.0%)	1 (2.4%)	2 (14.3%)	3 (3.8%)
Blood alkaline phosphatase increased	1 (4.2%)	1 (2.4%)	0(0.0%)	2 (2.5%)
Blood bilirubin increased	0(0.0%)	1 (2.4%)	1 (7.1%)	2 (2.5%)
Gamma-glutamyltransferase increased	0(0.0%)	2 (4.9%)	0(0.0%)	2 (2.5%)
Leukopenia	1 (4.2%)	0(0.0%)	1 (7.1%)	2 (2.5%)
Asthenia	0(0.0%)	2 (4.9%)	0(0.0%)	2 (2.5%)
Erythema	0(0.0%)	2 (4.9%)	0(0.0%)	2 (2.5%)
Hypothyroidism	0(0.0%)	2 (4.9%)	0(0.0%)	2 (2.5%)
Infusion related reaction	0(0.0%)	2 (4.9%)	0(0.0%)	2 (2.5%)

Table 3. Related Grade ≥3 TEAEs

Preferred Term	60mg (N=24)	180mg (N=41)	360mg (N=14)	Total (N=79)
Alanine aminotransferase increased	3 (12.5%)	4 (9.8%)	2 (14.3%)	9 (11.4%)
Aspartate aminotransferase increased	5 (20.8%)	2 (4.9%)	2 (14.3%)	9 (11.4%)
Neutropenia	2 (8.3%)	1 (2.4%)	0(0.0%)	3 (3.8%)
Blood alkaline phosphatase increased	0(0.0%)	1 (2.4%)	0(0.0%)	1 (1.3%)
Gamma-glutamyltransferase increased	0(0.0%)	1 (2.4%)	0(0.0%)	1 (1.3%)
Lipase increased	1 (4.2%)	0(0.0%)	0(0.0%)	1 (1.3%)
Weight decreased	0(0.0%)	1 (2.4%)	0(0.0%)	1 (1.3%)
Nausea	0(0.0%)	0(0.0%)	1 (7.1%)	1 (1.3%)
Hyperkalaemia	1 (4.2%)	0(0.0%)	0(0.0%)	1 (1.3%)
Cerebellar stroke*	0(0.0%)	1 (2.4%)	0(0.0%)	1 (1.3%)
Ischaemic stroke*	0(0.0%)	1 (2.4%)	0(0.0%)	1 (1.3%)

*Cerebellar and ischaemic strokes reported refer to the same event. The medical monitor assessment was unrelated.

- THIO + cemiplimab has been generally well tolerated in a heavily pre-treated population, with most events being Grade 1–2 in severity.
- Most TEAEs were laboratory value elevations, except nausea (12.7% overall and 2.4% at the 180 mg dose) and decreased appetite (3.8% overall and 2.4% at the 180 mg dose).
- No DLTs have been reported in the Part A safety lead-in.
- A related Grade ≥3 ALT increase was reported in 9 patients (11.4%), including 2 patients receiving 360 mg, 4 at 180 mg, and 3 at 60 mg. No clinical symptoms were associated with the elevated laboratory values, and all returned to baseline or normal without sequelae.
- All other related Grade ≥3 events occurred in <5% of patients.
- Following an event of Grade 4 LFT elevation in a patient receiving 360 mg in Part B, enrollment into the 360 mg arm was paused.
- Enrollment was completed in Part B at the selected dose of 180 mg/cycle in February 2024.
- THIO mechanism of action allows for more selective targeting of cancer cells, potentially reducing the frequency of adverse events relative to non-targeted therapies.[6,7]

Efficacy findings

Figure 2. Patients receiving THIO as 3L treatment, 180 mg dose (n=8)*

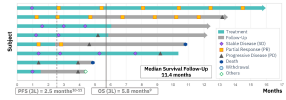


Figure 3. Patients receiving THIO as 3L treatment, all dose levels (n=20)*

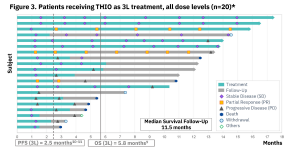
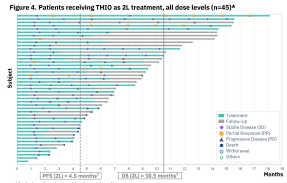


Figure 4. Patients receiving THIO as 2L treatment, all dose levels (n=45)*



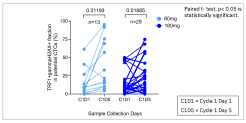
*Includes all patients with ≥1 post-baseline response assessment.

- 69 evaluable patients had completed ≥1 post-baseline assessment at the time of data cut-off (45 in 2L, 20 in 3L, 4 in 4L+).
- Partial Responses (PRs) RECIST 1.1 were reported for 9 subjects (6 in 2L, 3 in 3L), with 7 PRs confirmed by a 2nd scan per Investigators' assessment (4 in 2L, 3 in 3L).
- 19 patients with survival follow-up above 12 months:
  - 9 in 2L, 9 ongoing follow-up
    - 10 in 3L, 8 ongoing follow-up
    - 1 patient has received 25 cycles of therapy
- In the 3L setting (n=20):
  - DCR was 85% for THIO vs. standard of care 25–35% for chemotherapy.[8]
  - 14/20 (70%) patients crossed the 5.8-month OS threshold.[9]
  - 17/20 (85%) patients crossed the 2.5-month PFS threshold.[10-11]
  - The median survival follow-up time is currently 11.5 months (n=20).
- In the 3L setting with THIO at 180 mg (n=8):
  - Median PFS: 5.5 months (24.1 weeks); OS rate at 6 months: 75%.
  - ORR 38% (3/8) vs. standard of care 6–10% for chemotherapy.[9]
  - 6/8 (75%) patients crossed the 5.8-month OS threshold.[9]
  - 7/8 (88%) patients crossed the 2.5-month PFS threshold.[10-11]
  - The median survival follow-up time is currently 11.4 months (n=8).

Biomarker findings

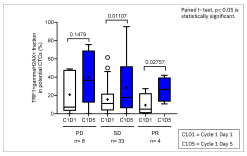
- Telomere dysfunction-Induced foci (TIF)-positive CTCs were characterized as TRF1+/gammaH2AX+fraction in CD326+/PanKRT+ CTCs.
- TIF (Telomere dysfunction-Induced Foci) analysis demonstrated the intended on-target mechanism of action: modification of telomeres in circulating tumor cells (CTCs) by THIO (Figure 5).
- On average, patients in the Stable Disease (SD) and Partial Response (PR) groups showed increased levels of TIF biomarker, whereas the Progressive Disease (PD) group did not demonstrate a statistically significant increase in the TIF biomarker (Figure 6).
- Additionally, TIF formation in CTCs was shown to be a good biomarker of on-target activity.

Figure 5. TIFs fraction in CTCs (paired samples at each dose level)



- 42 paired samples are represented in the graph.
  - 5 patients excluded (>85% TIFs at baseline)

Figure 6. TIFs fraction in CTCs (Patient Status)



- 45 patients' status represented in the graph.
  - 4 patients excluded (>85% TIFs at baseline)
  - 4 patients' status not available (1/4 baseline TIFs>85%).

References

1. https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics
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8. Matsumoto H, et al. Transl Lung Cancer Res 2021;10:2278–89.
9. Girard N, et al. J Thorac Onc 2009;12:1544-1549.
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Conclusions

- **The combination of THIO + cemiplimab has durable activity in this hard-to-treat patient population (CPI resistant and chemotherapy resistant progressors).**
- **The ORR in the 3L setting with the 180 mg dose is 38% (3/8), which compares favorably with response rates reported of ~6% for other currently available treatments for heavily pre-treated patients.**
- **Median survival follow-up in the 3L setting has surpassed 11.5 months.**
- **Induction of TIFs in CTCs from patients treated with THIO + cemiplimab shows on-target effect. These findings suggest a potential link between biomarker TIF positivity and more favorable clinical outcomes.**
- **THIO + cemiplimab has so far been generally well-tolerated in a heavily pre-treated population.**
- **Treatment has the potential to be given for longer, which usually translates into longer survival.**
- **The ongoing Phase 2 study selected the best dose of THIO in November 2023. The 180 mg dose has shown better safety and superior efficacy compared with other doses: to date, 9.8% of patients receiving the 180 mg dose reported related Grade ≥3 AEs.**

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.

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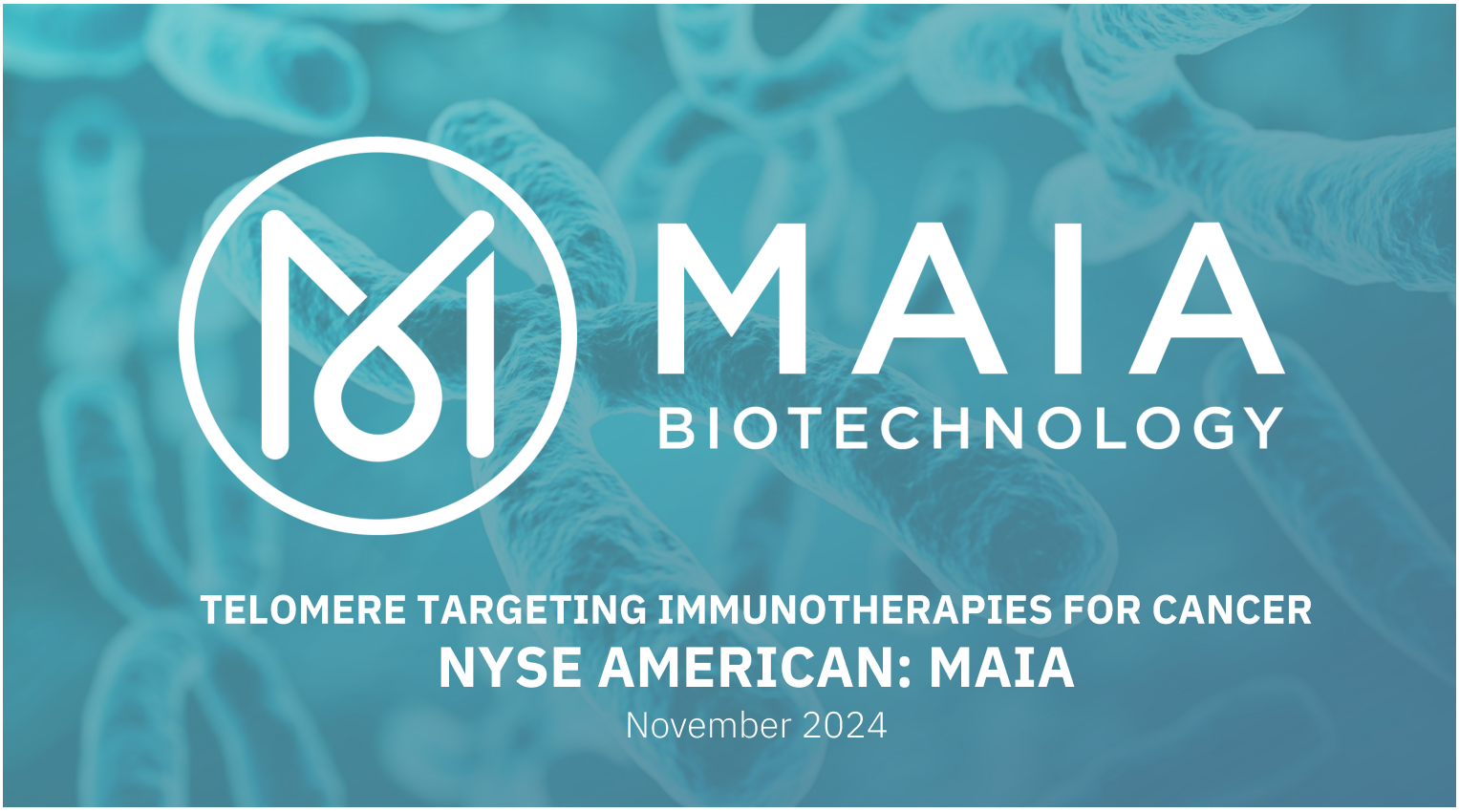
Exhibit 99.2


MAIA
BIOTECHNOLOGY
TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER
NYSE AMERICAN: MAIA
November 2024

FORWARD-LOOKING STATEMENTS

MAIA BIOTECHNOLOGY
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All statements in this presentation, other than those relating to historical facts, are "forward-looking statements." These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans, and strategies; statements that contain projections of results of operations or of financial condition; statements relating to the industry and government policies and regulations relating to our industry; and all statements (other than statements of historical facts) that address activities, events, or developments that we intend, expect, project, believe, or anticipate will or may occur in the future. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments, and other factors they believe to be appropriate. Important factors that could cause actual results, developments, and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things: the overall global economic environment; general market, political, and economic conditions in the countries in which we operate: projected capital expenditures and liquidity; changes in our strategy; government regulations and approvals; the application of certain service license; and litigation and regulatory proceedings. Factors that may cause such differences also include, but are not limited to, those discussed under Risk Factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2023 and other periodic reports filed by the Company from time to time with the Securities and Exchange Commission. You may get these documents for free by visiting EDGAR on the Commission's website at www.sec.gov. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. This presentation shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any of our securities nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Any offering of securities can only be made in compliance with applicable securities laws. You should read carefully the factors described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023 to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from those anticipated by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus. These forward-looking statements speak only as of the date of this presentation, and we assume no obligation to update or revise these forward-looking statements for any reason.

INVESTMENT PROFILE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

New science for cancer therapy: dual MOA telomere targeting and immunogenicity.

- Lead molecule THIO in clinic; 2nd generation compounds in R&D

Phase 2 trial THIO-101 nearing completion: THIO sequenced with CPI in NSCLC.

- Unprecedented disease control, response, post-therapy patient benefit
- Clinical supply agreement with Regeneron (Libtayo®)

Key targeted clinical milestones within reach.

- THIO-101 long-term data in 2nd half of 2024
- Multiple potential pathways to FDA commercial approval

Significant market opportunity in hard-to-treat cancers with unmet need.

- NSCLC: largest tumor type globally, $34B annual sales
- 3 FDA Orphan Drug Designations: liver (HCC), lung (SCLC) and brain (malignant gliomas)

Multiple THIO trials planned for additional cancer indications.

- Expansion for NSCLC
- Colorectal cancer (CRC), Liver (HCC), SCLC, solid tumors

ROBUST PIPELINE

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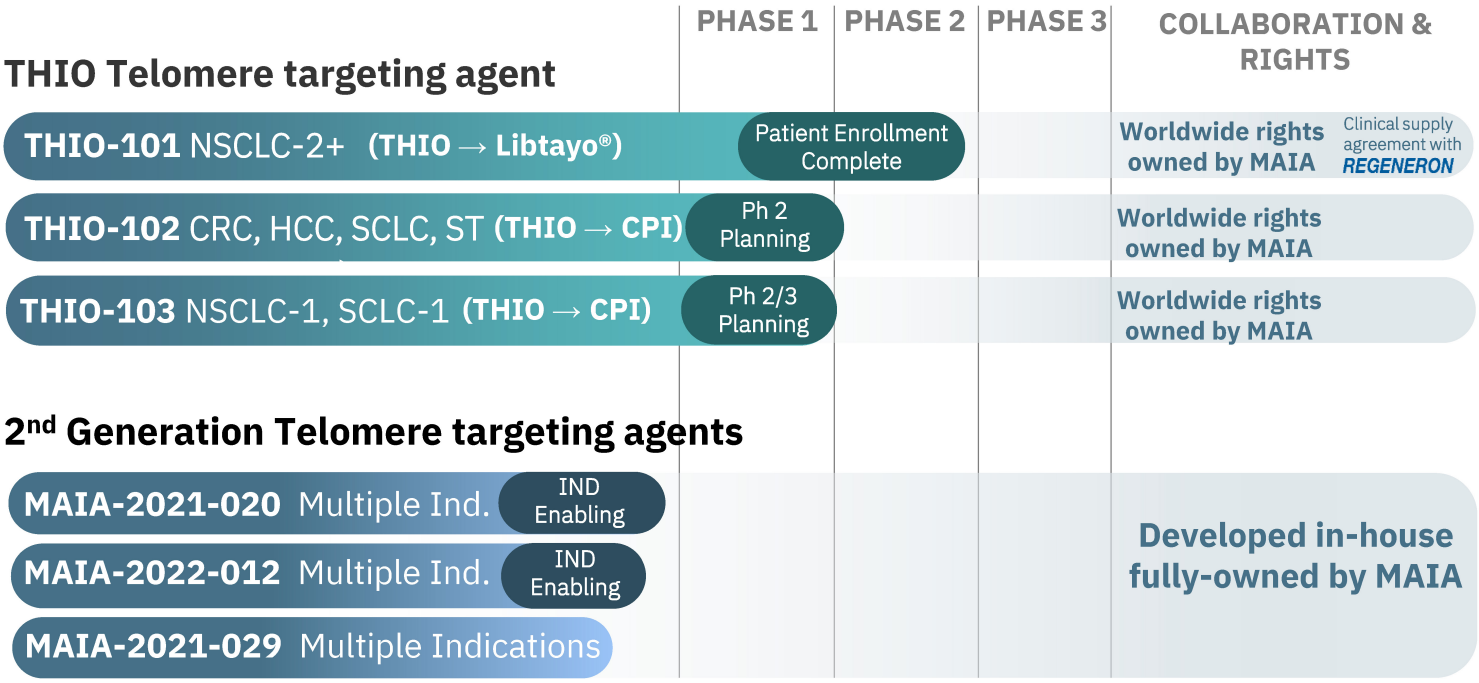

MISSION AND APPROACH

Cancer is the most dominant age-related disease

Population aged >80 expected to triple by 2050

142 million
2020

426 million
2050

At age 90:
40% will be diagnosed
20% will die of it

THIO is the only direct telomere targeting anticancer agent in clinical development

THIO – NOVEL MECHANISMS OF ACTION

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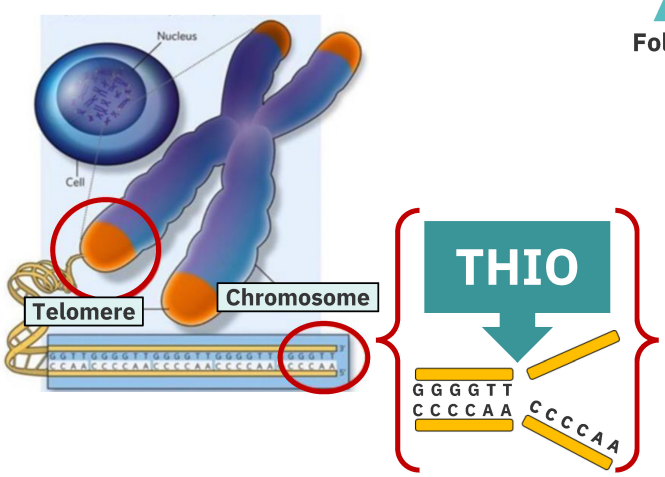
NYSE American: MAIA

THIO

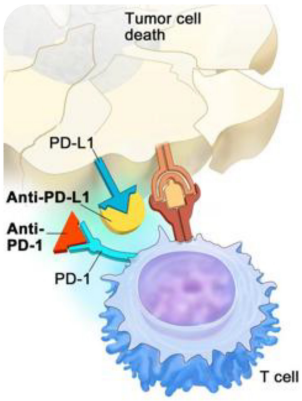
THIO has a dual MoA:

1. Telomere targeting
2. Immunogenic effect



Followed by

Immune Checkpoint Inhibitor



★ LIBTAYO® (cemiplimab) REGENERON

IMFINZI® (durvalumab) AstraZeneca

KEYTRUDA® (pembrolizumab) MERCK

TEVIMBRA® (tislelizumab) BeiGene

TECENTRIQ® (atezolizumab) Genentech

Jemperli® (dostarlimab-gxly) GSK

OPDIVO® (nivolumab) Bristol Myers Squibb

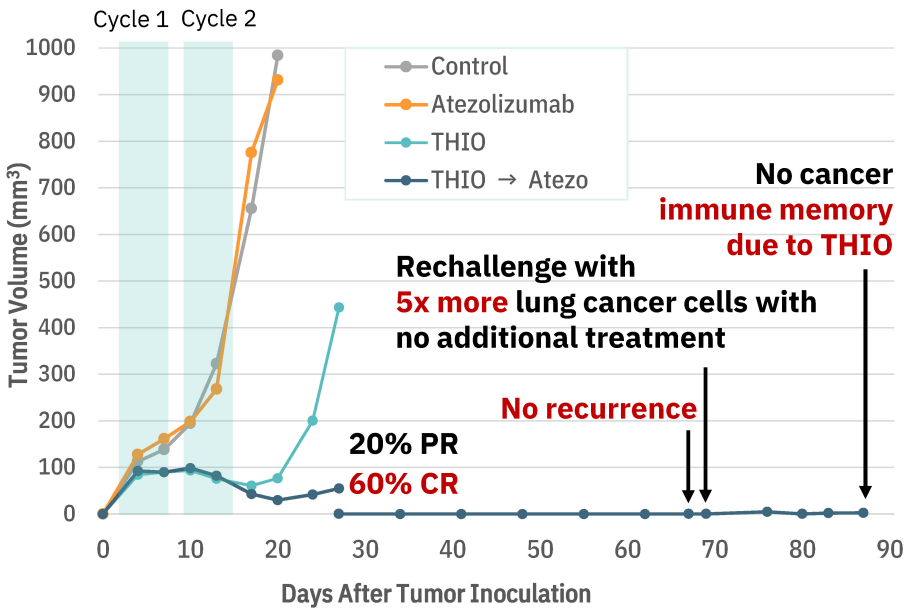
BAVENCIO® (avelumab) EMD SERONO

★ Clinical supply agreement with REGENERON for NSCLC

THIO-101 NSCLC TRIALS - RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- THIO followed by CPI results in 60% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 5x more lung cancer (LLC) cells with no additional therapy



Note: Mender et al, Cancer Cell, 2020; THIO followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with THIO followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron).

THIO-101 TRIAL

NON-SMALL CELL LUNG CANCER

REGENERON CLINICAL SUPPLY AGREEMENT

MAIA BIOTECHNOLOGY
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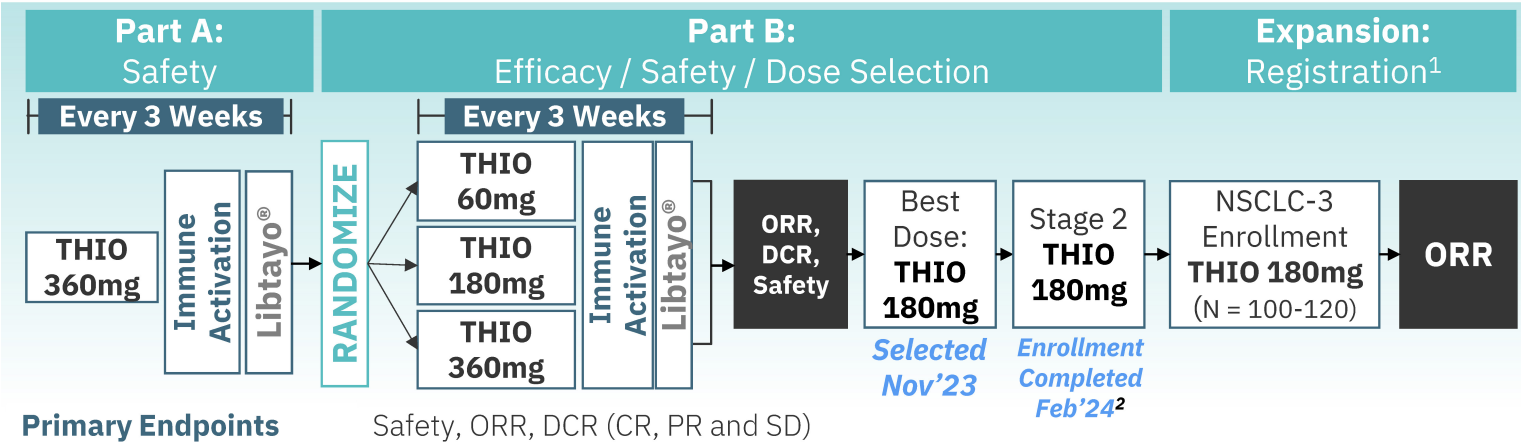
MAIA BIOTECHNOLOGY & REGENERON

MAIA Biotechnology, Inc. Announces Clinical Supply Agreement with Regeneron for Phase 1/2 Clinical Trial Evaluating THIO in Sequential Administration with Libtayo® (cemiplimab) in Advanced Non-Small Cell Lung Cancer

THIO-101 – TRIAL DESIGN

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-Label, Dose-Finding Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with LIBTAYO® (*cemiplimab*) in NSCLC patients RESISTANT TO CHECKPOINT INHIBITORS



Primary Endpoints	Safety, ORR, DCR (CR, PR and SD)
Secondary Endpoints	DoR; PFS; OS
Exploratory Endpoints	PK and PD (activity of THIO in circulating tumor cells measured by specific biomarkers)

ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05208944?term=05208944&draw=2&rank=1
1. Would require FDA agreement.
2. https://ir.maiabiotech.com/news-events/press-releases/detail/91/maia-biotechnology-completes-enrollment-in-thio-101-phase-2

PATIENTS' SURVIVAL BY LINE OF THERAPY

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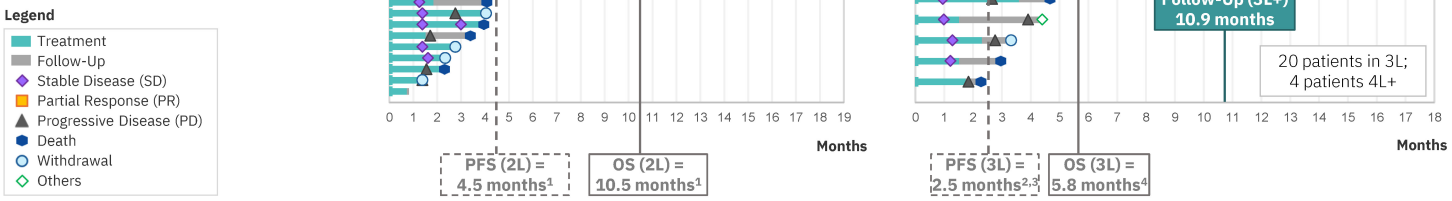
- As of September 16, 2024, 19 patients had survival follow-up above 12 months:
  - ✓ 9 in 2L, 9 ongoing
  - ✓ 10 in 3L, 8 ongoing
  - ✓ 1 patient 25 cycles of therapy



Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change. Clinical data presented from 16Sep2024 data cut. Includes all patients with ≥1 post-baseline response assessment. Overall, THIO + cemiplimab been generally well tolerated in a heavily pre-treated population.

1. https://clinicaltrials.gov/study/NCT01168973?tab=results
2. Shepherd F, et al. N Engl J Med 2005;353:123-132.
3. Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.
4. Girard N, et al. J Thorac Onc 2009;12:1544-1549.

TREATMENT IN THIRD-LINE

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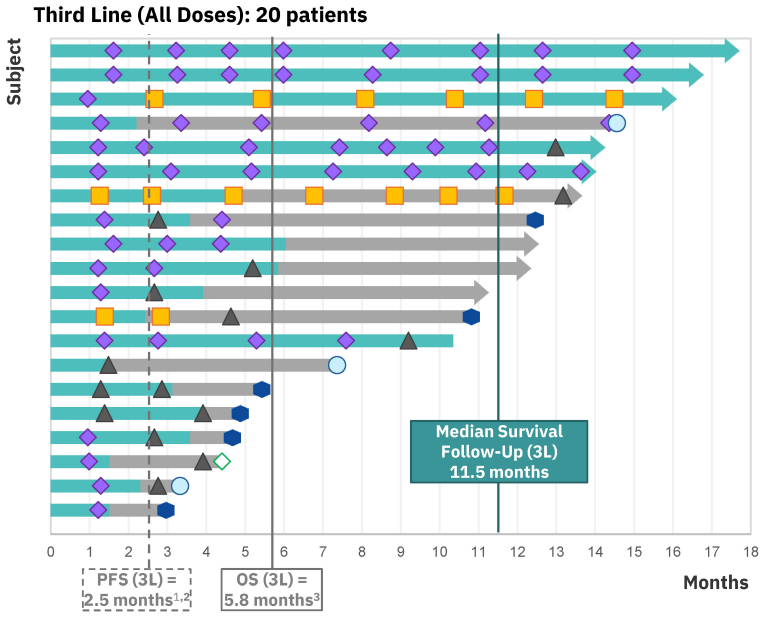
NYSE American: MAIA

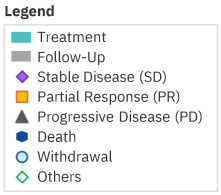
Extended Survival

- 20 subjects in 3L completed at least 1 post baseline assessment at time of cut-off
- 14/20 (70%) patients crossed 5.8 months OS threshold
- 17/20 (85%) crossed 2.5 months PFS threshold

Unprecedented Efficacy

- DCR 85% vs 25-35% chemotherapy





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3. Girard N, et al. J Thorac Onc 2009;12:1544-1549.

BEST 3L RESULTS IN THE 180MG DOSE

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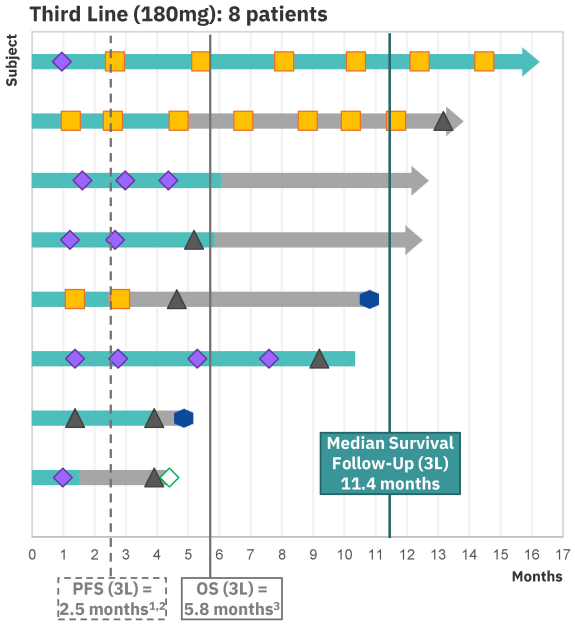
NYSE American: MAIA

NSCLC-3 – 180mg:

- 6/8 (75%) patients crossed 5.8 months OS threshold
- 7/8 (88%) crossed 2.5 months PFS threshold
- ORR (180mg dose) 38% vs 6-10% chemotherapy[4]
- DCR 88% vs 25-35% chemotherapy



Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change. Clinical data presented from 16Sep2024 data cut. Includes all patients with ≥1 post-baseline response assessment. Overall, THIO + cemiplimab been generally well tolerated in a heavily pre-treated population.

1. Shepherd F, et al. N Engl J Med 2005;353:123-132.
2. Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.
3. Girard N, et al. J Thorac Onc 2009;12:1544-1549.
4. https://ir.maiabiotech.com/news-events/press-releases/detail/94/maia-biotechnology-announces-strong-efficacy-of-thio-as

EXPECTED EFFICACY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

	THIO-101
	THIO + Libtayo®
Target Population	**NSCLC-3:** • CPI+Platinum Resistant • Prior treatment with Docetaxel
DCR	88%
ORR	38%
PFS (median)	5.5 months
OS (median)	Not reached at 11.4 months median follow-up[1]

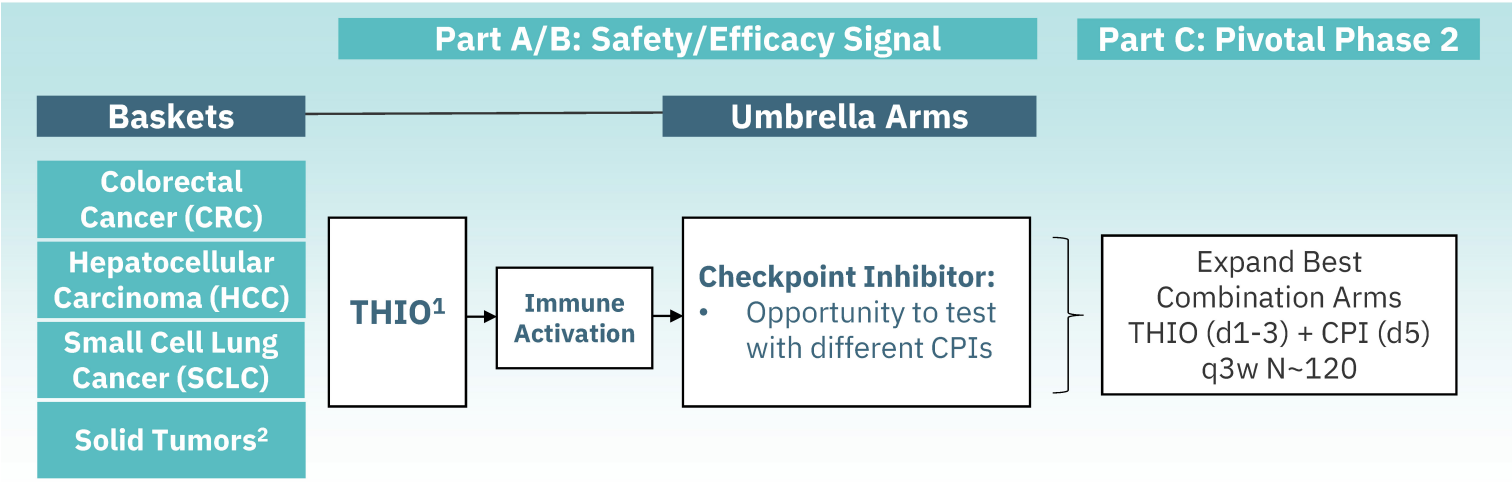
1. Based on the lower bound of the 95% confidence interval of the median OS (September 16 data cut off). Final estimates may differ as follow-up continues.

PLANNED UPCOMING TRIALS

THIO-102 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with Anti-PD-1 or Anti-PD-L1

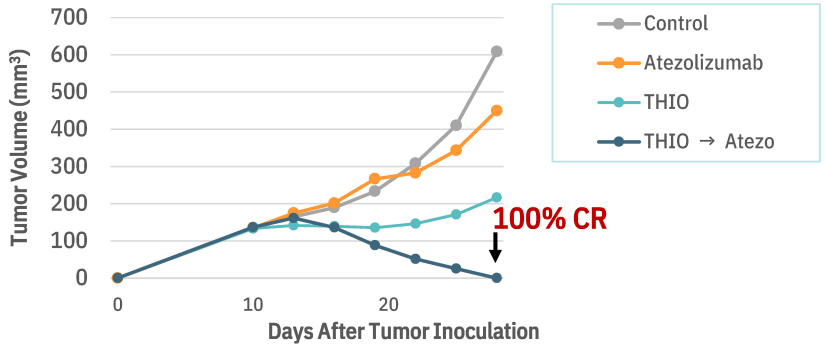


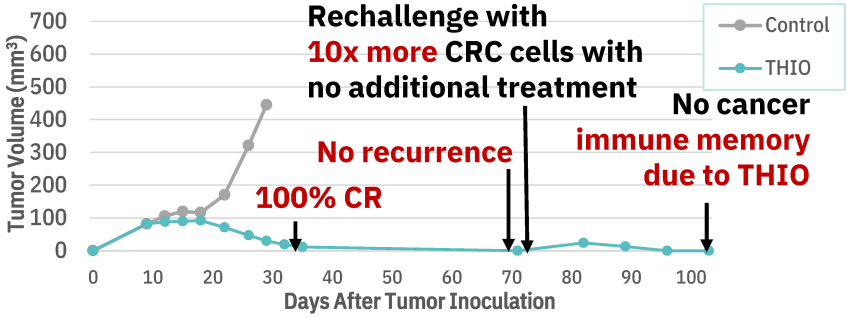
[1] Dose to be selected from THIO-101 study results.
[2] E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc.

THIO-102 – COLORECTAL RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- THIO followed by CPI results in 100% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 10x more CRC cells with no additional therapy

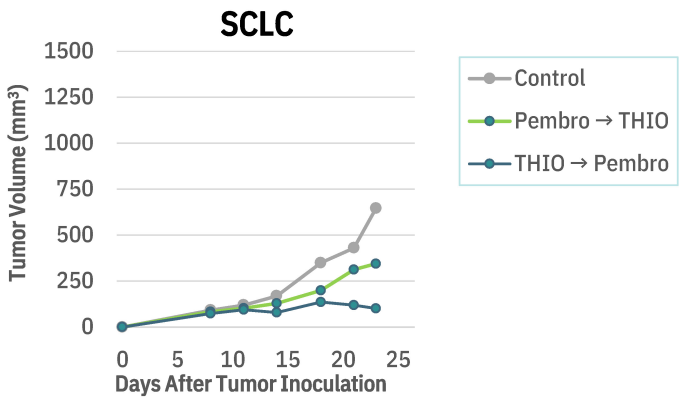


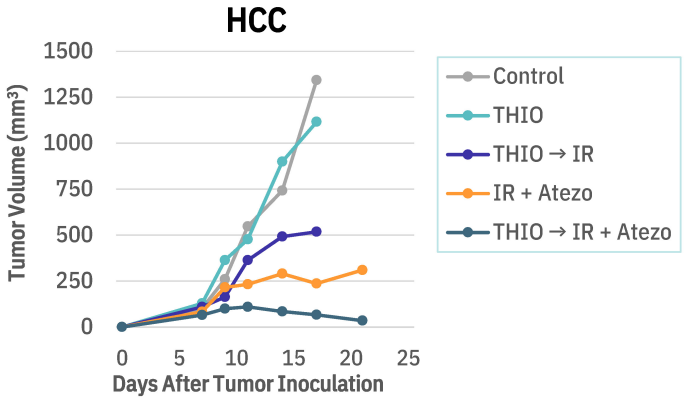


Mender et al, Cancer Cell, 2020

SCLC & HCC – ORPHAN DRUG DESIGNATION

MAIA BIOTECHNOLOGY
NYSE American: MAIA





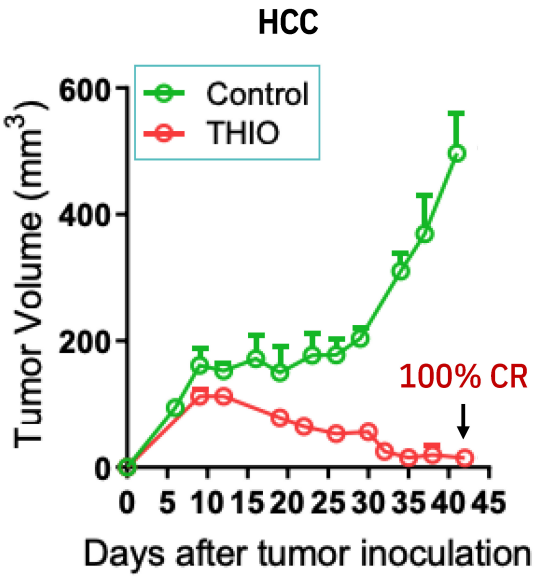
- THIO is synergistic with anti-PD-1 agent Pembrolizumab in Small Cell Lung Carcinoma (H2081) *in vivo* in humanized murine cancer model
- Treatment with THIO followed by Pembrolizumab results in highly potent anticancer effect, as compared to Pembrolizumab alone
- THIO converts immunologically "cold non-responsive" SCLC tumor into "hot and responsive" to Pembrolizumab

- THIO is highly synergistic and effective in combination with anti-PD-L1 agent Atezolizumab and Ionizing Radiation (IR 10Gy) in HCC53N Hepatocellular Carcinoma
- Treatment with THIO in combination with IR and Atezolizumab results in a complete regression of aggressive HCC tumors. The combination of IR and Atezolizumab is just partially efficacious

EXCELLENT EFFICACY IN HCC MODELS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- THIO achieved complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology in primary liver cancer (90%), in *in vivo* models



HCC ANTI-CANCER IMMUNE MEMORY

MAIA BIOTECHNOLOGY
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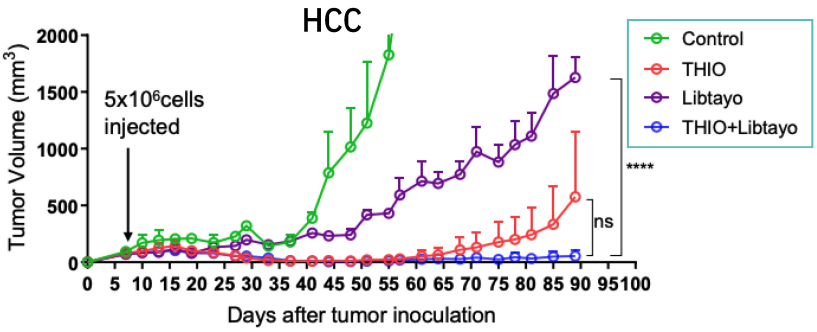
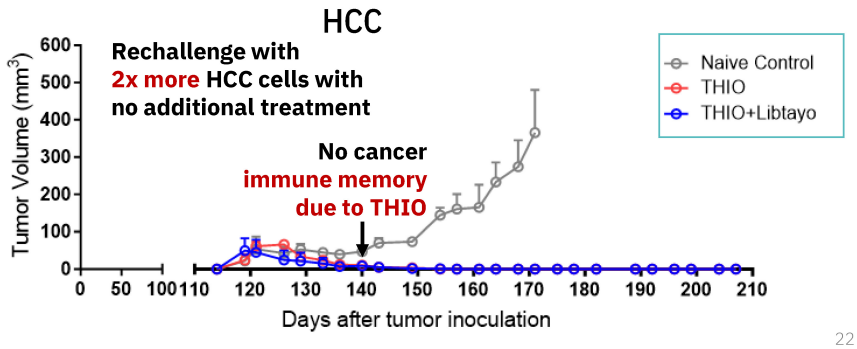
- When combined with immunotherapy checkpoint inhibitor Libtayo®, duration of response was further potentiated
- Upon rechallenge with two times more cancer cells and no additional treatment, tumor growth was completely prevented
- Administration of THIO alone and in combination with Libtayo® generated anti-cancer immune memory

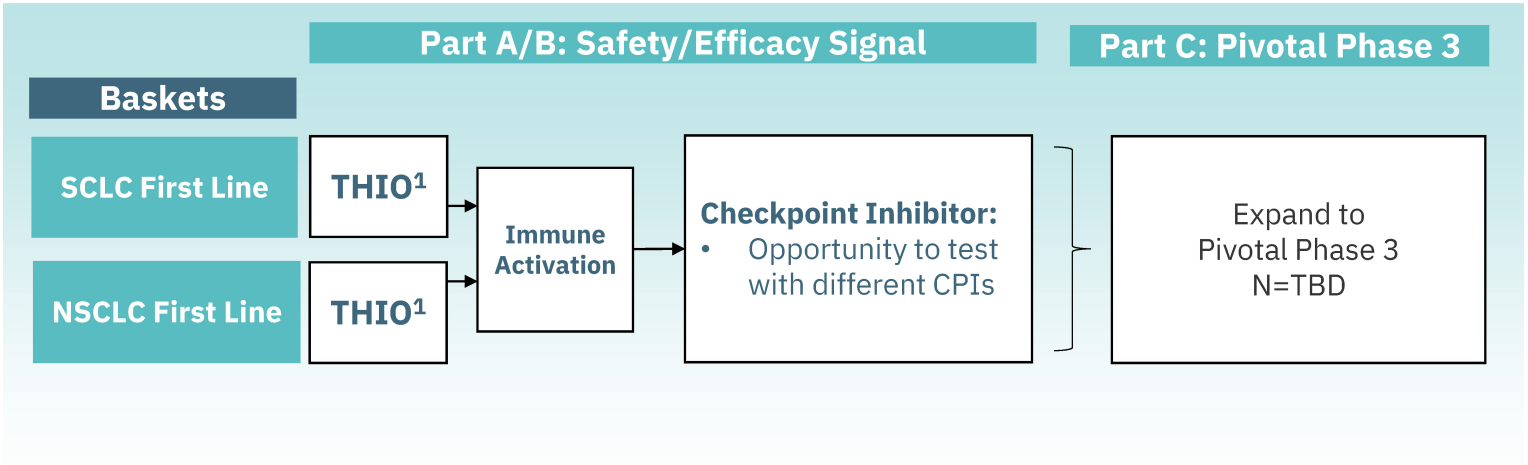




THIO-103 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with Anti-PD-1 or Anti-PD-L1



[1] Dose to be selected from THIO-101 study results.

INVESTMENT OPPORTUNITY

EXCLUSIVITY AND INTELLECTUAL PROPERTY

MAIA BIOTECHNOLOGY
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Goal: New Chemical Entity (NCE) Marketing Exclusivity

- THIO has never been previously approved by the FDA for commercialization
- Robust exclusivity
- US: 7 years; EU, Japan, other markets: 10 years

Robust and Growing Patent Portfolio for THIO

- 5 issued patents
- 29 pending patent applications

Current patents/provisional applications broadly cover the following key areas:

- Telomere targeting compounds (2034+)
- THIO's immunogenic treatment strategy: sequential combination with CPIs (2041)

EXPERIENCED MANAGEMENT TEAM

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Vlad Vitoc, MD, MBA

Founder and CEO

- 24+ years in Oncology Pharma/ Biotech: Commercial, Medical
- 12 compounds launched across 20+ tumor types
- Leadership roles at Bayer (Nexavar), Astellas (Tarceva, Xtandi), Cephalon (Treanda), Novartis (Zometa), Incyte (Jakafi)

Sergei Gryaznov, PhD

Chief Scientific Officer

- 25+ years as Scientist
- Expert Drug Discovery and Development, Oncology with 120+ publications
- Head of the J&J Oligonucleotide Center of Excellence Worldwide
- Expert of telomeres and telomerase in cancer, co-inventor of THIO

Jeffrey Himmelreich, MBA

Head of Finance

- 20+ years of financial expertise
- CFO for privately held and publicly traded companies in the healthcare and manufacturing industries
- Active CPA licensed in the state of Pennsylvania and is a Chartered Global Management Accountant

NOVARTIS astellas Pfizer BAYER janssen Incyte Cephalon Oncology geron PHARMACIA exicure

SIGNIFICANT MARKET OPPORTUNITY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

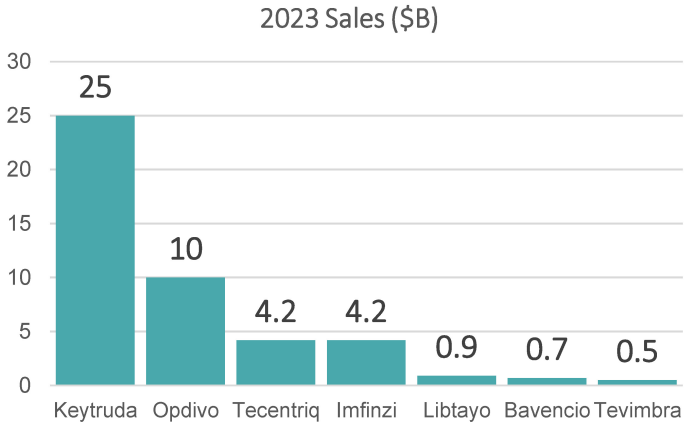
Developing agents for the top tumor types markets globally

NSCLC (#1 WW) **Mortality:** 1.7M / **Sales:** $34B	**HCC** **Mortality:** 0.8M / **Sales:** $3B
CRC (#2 WW) **Mortality:** 1.0M / **Sales:** $20B	**SCLC** **Mortality:** 0.3M / **Sales:** $2B

$46B CPIs Group (2023 Sales)

- 5 CPIs approved for NSCLC:
  - > 30% of NSCLC drug sales
  - > 40% of total CPI sales
- Keytruda®: $9B in NSCLC of $25B total

Checkpoint Inhibitors Market



- Keytruda® expected to hit $30B in 2026, biosimilars expected by 2028

COMPARABLE COMPANIES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- On June 3, 2022, Bristol Myers Squibb (BMS) announced the acquisition of Turning Point Therapeutics in an all-cash transaction for **$4.1B** in equity value
- On October 9, 2023, BMS acquired Mirati for **$4.8B** in cash, plus up to $1B in contingent value right
- **Commercial stage companies:** Mirati (on acquisition)
- **Phase 2 companies:** Arcus, Bicycle Therapeutics and Turning Point (on acquisition)

MAIA BIOTECHNOLOGY	Turning Point Therapeutics	MIRATI THERAPEUTICS	ARRIVENT	ARCUS	Bicycle
$66M	$3.8B	$4.1B	$1.0B	$1.4B	$1.6B
Market Cap[1]	Market Cap[2]	Market Cap[2]	Market Cap[1]	Market Cap[1]	Market Cap[1]
$2.75/share	$76/share	$58/share	$30.8/share	$15.5/share	$22.7/share

1. Market caps as of November 01, 2024 (source: Citadel Securities)
2. Last known market cap before acquisition (source: companiesmarketcap.com)

MULTIPLE VALUE-DRIVING MILESTONES

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NYSE American: MAIA

★ **Major inflection points**

	2024			2025			2026	
THIO-101 Ph2 NSCLC-2+	**Early Efficacy Update** (Biotech Showcase)	**Part B Efficacy** (ASCO) ★	**Part B Long-term Efficacy** ★	**Part B Full Efficacy** ★	**Part C Efficacy Update**	**Part C Enrollment Complete**	Filing for US approval	**Potential Accelerated Approval in US** ★
THIO-102 Ph2 CRC, SCLC, HCC, ST				**Enrollment** First Patient In ★		**Early Safety Report** ★		**Early Efficacy Report**
THIO-103 Ph2/3 SCLC-1, NSCLC-1				**Enrollment** First Patient In ★				**Early Safety Report** ★

Note: Estimated timelines. Trial names, targeted indications and projected dates may be subject to changes.

MAIA BIOTECHNOLOGY

THANK YOU

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ir@maiabiotech.com

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444 West Lake Street, Suite 1700
Chicago, IL 60606

APPENDIX

U.S. FDA GRANTED 3 ORPHAN DRUG DESIGNATIONS TO THIO

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- The FDA's Orphan Drug Act of 1983 is designed to <u>incentivize the development of therapies that demonstrate promise for the treatment of rare (orphan) diseases or conditions</u>
- **Rare disease -** affects fewer than 200,000 people total in the U.S, or if the cost of developing a drug and making it available in the U.S. will exceed any potential profits from its sale due to the small target population size
- **Multiple incentives -** to make development more financially possible for companies to pursue:
  - ✓ up to 7 years of market exclusivity
  - ✓ up to 20 years of 25% federal tax credit for expenses the U.S.
  - ✓ waiver of Prescription Drug User Fee Act (PDUFA) fees, a value of ~$2.9 million in 2021
- **Only highest quality data is considered for ODD -** a testament to the potential of THIO in the treatment of multiple indications
- **THIO has been granted 3 ODDs:**
  - ✓ Hepatocellular Carcinoma (HCC, 90% of primary liver cancers)
  - ✓ Small Cell Lung Cancer (SCLC, deadliest lung cancer)
  - ✓ Glioblastoma (brain cancer)

3x FDA Orphan Drug Designation

MAIA Biotechnology, Inc. Announces FDA Orphan Drug Designation for THIO for the Treatment of Hepatocellular Carcinoma (HCC)

April 26, 2022 08:37 AM Eastern Daylight Time

https://ir.maiabiotech.com/news-events/press-releases/detail/35/maia-biotechnology-inc-announces-fda-orphan-drug

MAIA Biotechnology Receives FDA Orphan Drug Designation for THIO for the Treatment of Small-Cell Lung Cancer (SCLC)

August 02, 2022 08:00 AM Eastern Daylight Time

https://ir.maiabiotech.com/news-events/press-releases/detail/41/maia-biotechnology-receives-fda-orphan-drug-designation-for

FDA Grants Orphan Drug Designation to MAIA Biotechnology for THIO as a Treatment for Glioblastoma

- Third orphan drug designation (ODD) granted to THIO by the FDA; drug also holds ODDs for hepatocellular carcinoma and small cell lung cancer
- Benefits include 7 years of U.S. market exclusivity after drug approval and tax credits for qualified clinical testing
- Expected glioblastoma market growth from $2.2 billion to $3.2 billion globally in the next three years

November 10, 2023 07:01 AM Eastern Standard Time

https://ir.maiabiotech.com/news-events/press-releases/detail/83/fda-grants-orphan-drug-designation-to-maia-biotechnology

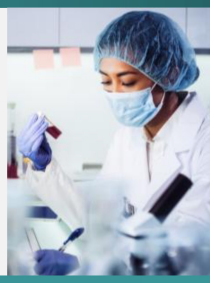
Exhibit 99.3

MAIA BIOTECHNOLOGY

Telomere Targeting Immunotherapies for Cancer

Vlad Vitoc, MD, MBA
Chief Executive Officer
444 West Lake Street, Suite 1700 - Chicago, IL 60606
(312) 416-8592 vvitoc@maiabiotech.com
(215) 971-5488 maiabiotech.com

MAIA is an immuno-oncology company focused on the development and commercialization of first-in-class drugs intended to meaningfully improve and extend the lives of people with hard-to-treat cancers. We are exploring new science for cancer therapy utilizing a novel dual mechanism of action: telomere targeting and immunogenicity. Our lead program is THIO, a first-in-class anticancer agent in clinical development for the treatment of Non-Small Cell Lung Cancer (NSCLC) in patients.



Company Highlights

Clinical Programs

THIO-101
Ph 2 trial of THIO + Libtayo® (cemiplimab)

- Go-to-market trial in second-line+ NSCLC
- Objectives: select most efficacious dose and expand into pivotal trial
- Enrollment completed earlier than expected in Feb 2024; trial nearing completion
- Long-term data on second half of 2024
- Unprecedented efficacy in third-line treatment with 180mg dose:
  - ✓ 38% overall response rate (ORR) vs. 6-10% with chemotherapy
  - ✓ 75% of patients crossed 5.8 months OS threshold
- Preliminary Disease Control Rate (DCR), best predictor for overall survival benefit (meta-analysis of 74 trials worldwide):
  - ✓ 85% DCR in third-line vs. 25-35% with chemotherapy

THIO-102 (planning)
Ph 2 trial of THIO + checkpoint inhibitors

- Go-to-market trial in late line of therapy in multiple tumor types: Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC, 90% of primary type of liver cancers), Small Cell Lung Cancer (SCLC) and Solid Tumors of any type (ST)
- Objectives: select most efficacious combination by tumor type and expand into pivotal trials (12+ possible market entry indications)
- File for accelerated approvals in 2026 and beyond

THIO-103 (planning)
Ph 2/3 trial of THIO + checkpoint inhibitors

- First-line NSCLC and SCLC
- Expand to Breast, Prostate, Pancreatic, Ovarian, Gastric Cancer, etc.
- Objectives: confirmatory for accelerated approvals from THIO-101 and THIO-102

THIO is a Unique Direct Telomere Targeting Agent

- Potential to be used in combination with other anticancer and immune therapies
- Novel dual mechanism of action: telomere targeting + immunogenic
- 3 FDA Orphan Drug Designations: HCC, SCLC, and Glioblastoma
- Excellent efficacy: achieved complete and durable responses in HCC *in vivo* models (peer-reviewed published study)
- Featured in multiple renowned scientific publications including Cancer Cell and Nature

Partnerships and Collaborations

- THIO-101: clinical supply agreement with Regeneron, provides Libtayo® for all patients in the trial
- Broad potential for partnerships with different companies and checkpoint inhibitors in upcoming clinical trials

Cap Table

NYSE American: MAIA

Share Price[1]	$2.75	Float[2]	19.7M
Market Cap[1]	$66M	Insider Holdings[2]	17%
FD Shares Outstanding[2]	39M	Cash[2]	$11.6M

1. As of Nov 01, 2024
2. As of Jun 30, 2024

MAIA Biotechnology's goal is to bring revolutionary cancer treatments to the market, with the only direct telomere targeting agent in clinical development. MAIA is developing agents for the top tumor types markets globally.

Significant Market Opportunity

- Cancer is the most dominant of the age-related disease categories and has life altering impacts in the lives of patients and their close ones
- The number of people aged 80 years or older is expected to triple between 2020 and 2050 to reach 426 million
- Approximately 40% of people alive today are projected to be diagnosed with a cancer type in their lifetime, and 20% will die of it
- NSCLC is the leading tumor type: Mortality 1.7M / Sales $32B (2022)
- CRC is second: Mortality 1M / Sales $20B (2022)

Strong and Growing IP Portfolio

- Potential for receiving NCE marketing exclusivity
- 5 patents issued, 29 patent applications pending

Next Generation Potential Telomere Targeting Therapeutics in R&D

- 84 new molecules engineered; same mechanism of action as THIO
- Following THIO to commercial stage within 4-5 years

Robust Pipeline

	PHASE 1	PHASE 2	PHASE 3	COLLABORATION & RIGHTS
THIO Telomere targeting agent				
THIO-101 NSCLC-2+ (THIO → Libtayo®)	Patient Enrollment Complete			Worldwide rights owned by MAIA; Clinical supply agreement with REGENERON
THIO-102 CRC, HCC, SCLC, ST (THIO → CPI)	Ph 2 Planning			Worldwide rights owned by MAIA
THIO-103 NSCLC-1, SCLC-1 (THIO → CPI)	Ph 2/3 Planning			Worldwide rights owned by MAIA
2nd Generation Telomere targeting agents				
MAIA-2021-020 Multiple Ind.	IND Enabling			Developed in-house fully-owned by MAIA
MAIA-2022-012 Multiple Ind.	IND Enabling			
MAIA-2021-029 Multiple Indications				

Vlad Vitoc, MD, MBA

Founder, Chairman, and Chief Executive Officer

- 24+ years in Pharma/Biotech: Commercial, Medical,
- 12 compounds launched across 20+ tumor types
- Leadership roles at Bayer (Nexavar), Astellas (Tarceva, Xtandi), Cephalon (Treanda), Novartis (Zometa), and Incyte (Jakafi)

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