

**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): February 4, 2025

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

Delaware
(State or other jurisdiction
of incorporation)

001-41455
(Commission
File Number)

83-1495913
(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.

On February 4, 2025, MAIA Biotechnology, Inc. (the “Company”) issued a press release announcing efficacy updates for its Phase 2 THIO-101 trial in advanced non-small cell lung cancer. Pursuant to Regulation FD, the press release is furnished with this Current Report (this “Report”) as Exhibit 99.1.

The information set forth in Item 7.01 of this Current Report on Form 8-K 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 Current Report on Form 8-K, 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

The Company has made available a presentation about the Company’s business and was posted to the Company’s website on February 5, 2025, a copy of which is filed as Exhibit 99.2 to this Report and is hereby incorporated by reference.

The information contained in the presentation 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. The presentation speaks as of the date of this Report. While the Company may elect to update the presentation 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.

The presentation contains 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 February 4, 2025 |
| 99.2 | Presentation Materials |
| 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: February 5, 2025

MAIA BIOTECHNOLOGY, INC.

By: /s/ Vlad Vitoc

Name: Vlad Vitoc

Title: Chief Executive Officer

MAIA Biotechnology Announces Positive Efficacy Updates for Phase 2 THIO-101 Trial in Advanced Non-Small Cell Lung Cancer

- **Median overall survival (OS) from THIO treatment extends to 16.9 months**
- **Newest data strengthens regulatory strategy**

CHICAGO – February 04, 2025 - MAIA Biotechnology, Inc., (NYSE American: MAIA) (“MAIA”, the “Company”), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced positive updated data from its THIO-101 pivotal Phase 2 clinical trial evaluating its lead clinical candidate, THIO, sequenced with Regeneron’s immune checkpoint inhibitor (CPI) cemiplimab (Libtayo[®]) in patients with advanced non-small cell lung cancer (NSCLC) who failed two or more standard-of-care therapy regimens.

As of January 15, 2025, third line (3L) data showed median overall survival (OS) of 16.9 months for the 22 NSCLC patients who received at least one dose of THIO (the intent-to-treat population) in parts A and B of the trial. The analysis demonstrated a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. The treatment has been generally well-tolerated to date in this heavily pre-treated population¹. Studies of standard-of-care (SOC) chemotherapy treatments for NSCLC in a similar setting have shown OS of 5 to 6 months.²

“Treatment with THIO now shows a 99% probability that overall survival will extend past chemotherapy’s measure by a wide margin,” said Vlad Vitoc, M.D., CEO of MAIA. “THIO’s efficacy in advanced stages of NSCLC continues to exceed our expectations, especially in third-line treatment where the cancer is typically even more resistant to therapy. Our findings suggest great benefits to patients with unmet medical needs who see little hope for the future.

“With our latest overall survival results, our outlook for potential FDA commercial approval of THIO is stronger than ever,” Dr. Vitoc concluded.

Based on its regulatory strategy, MAIA believes there could be an opportunity for accelerated FDA approval of THIO depending on final results from the ongoing expansion of the THIO-101 trial.

About THIO

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 (THIO) induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. THIO-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment with THIO 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. THIO 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.

¹ Details on safety can be found on the previously announced SITC 2024 presentation available on [MAIA's website](#).

² Girard N, et al. J Thorac Onc 2009;12:1544-1549.

About THIO-101, a 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 THIO's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO 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 THIO administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with THIO followed by cemiplimab (Libtayo[®]) has been generally well-tolerated 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 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.

Investor Relations Contact

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MAIA
BIOTECHNOLOGY

TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER
NYSE AMERICAN: MAIA

February 2025

FORWARD-LOOKING STATEMENTS

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.

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 expansion in 2025: THIO sequenced with CPI in NSCLC.

- Unprecedented disease control, response, post-therapy patient benefit
- Continued clinical supply agreement with Regeneron (Libtayo®)
- Potential accelerated approval in 2026

Phase 3 trial THIO-104: THIO + CPI vs. Investigator's Choice in NSCLC.

- Interim analysis can lead to early full approval in 2026
- Final analysis for commercial approval in 2027

Key targeted clinical milestones within reach.

- THIO-101 Part A and B long-term data
- 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)
- 1 FDA Rare Pediatric Disease Designation for pediatric diffuse high-grade gliomas

Multiple THIO trials planned for additional cancer indications.

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



ROBUST PIPELINE

THIO Telomere Targeting Agent

| Clinical Trial | Indication | Treatment | Status | Preclinical | Phase 1 | Phase 2 | Phase 3 | Rights |
|----------------|--------------------|-----------------|-------------------|---|---------|---------|---------|--------------------------------|
| THIO-104 | NSCLC 3L | THIO → CPI | Planned Phase 3 | [Progress bar spanning Preclinical, Phase 1, and Phase 2] | | | | Worldwide rights owned by MAIA |
| THIO-101 | NSCLC 2L+ | THIO → Libtayo® | Ongoing Phase 2 | [Progress bar spanning Preclinical, Phase 1, and Phase 2] | | | | |
| THIO-102 | CRC, HCC, SCLC, ST | THIO → CPI | Planned Phase 2 | [Progress bar spanning Preclinical and Phase 1] | | | | |
| THIO-103 | NSCLC-1, SCLC-1 | THIO → CPI | Planned Phase 2/3 | [Progress bar spanning Preclinical, Phase 1, and Phase 2] | | | | |

Clinical supply agreement with
REGENERON

2nd Generation Telomere Targeting Agents

| Agent | Indication | Status | Preclinical | Phase 1 | Phase 2 | Phase 3 | Rights |
|---------------|----------------------|--------------|----------------|---------|---------|---------|--|
| MAIA-2021-020 | Multiple Tumor Types | IND Enabling | [Progress bar] | | | | Developed in-house fully-owned by MAIA |
| MAIA-2022-012 | Multiple Tumor Types | IND Enabling | [Progress bar] | | | | |
| MAIA-2021-019 | Multiple Tumor Types | IND Enabling | [Progress bar] | | | | |

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**

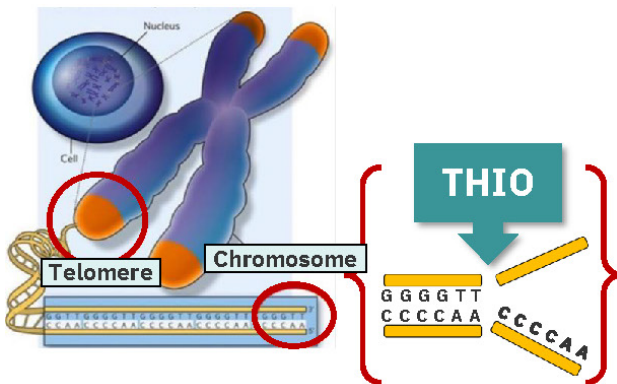
**THIO is the only direct
telomere targeting
anticancer agent in
clinical development**

THIO - NOVEL MECHANISM OF ACTION

THIO (6-thio-2'-deoxyguanosine)

THIO has a dual Mechanism of Action:

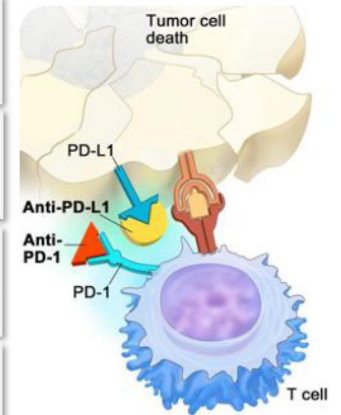
- 1 Telomere targeting
- 2 Immunogenic effect



- 3 FDA Orphan Drug Designations: HCC, SCLC, Malignant Gliomas
- 1 Rare Pediatric Disease Designation (RPDD): Pediatric Gliomas

Followed by Immune Checkpoint Inhibitor (CPI)

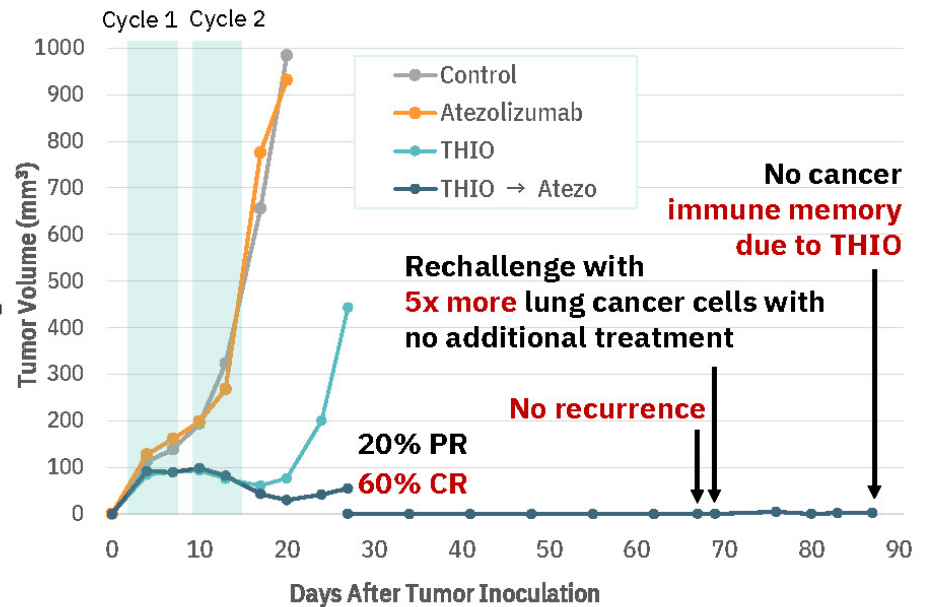
- Examples of commercially available CPIs:



- MAIA has a clinical supply agreement with REGENERON for NSCLC on THIO-101

THIO-101 NSCLC TRIAL - RATIONALE

- 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

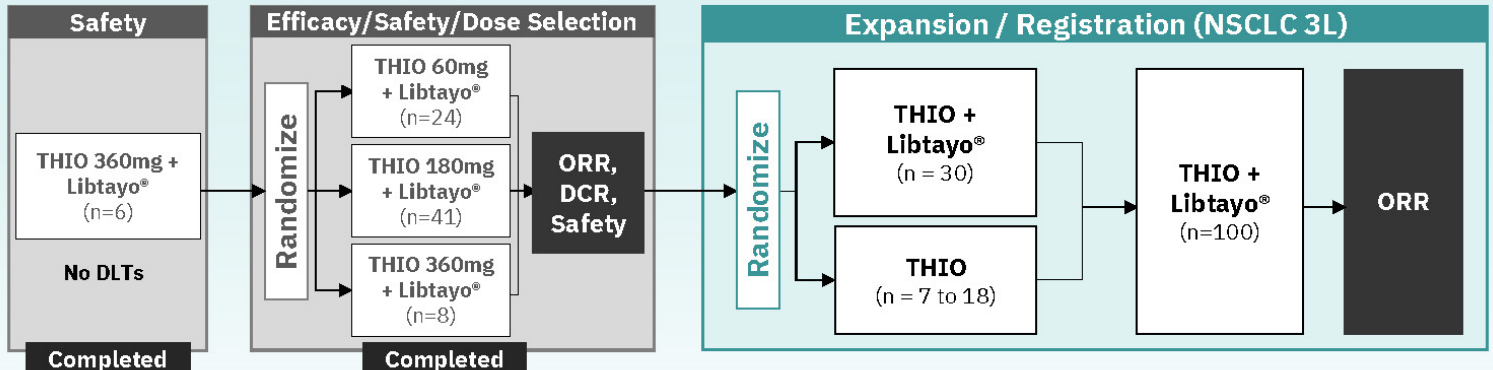


Note: Mender et al, Cancer Cell, 2020; THIO followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with THIO followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron). Data from preclinical results.

NSCLC CLINICAL TRIALS

THIO-101 PHASE 2 PIVOTAL TRIAL DESIGN (ONGOING)

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 Who Are Resistant to Checkpoint Inhibitors

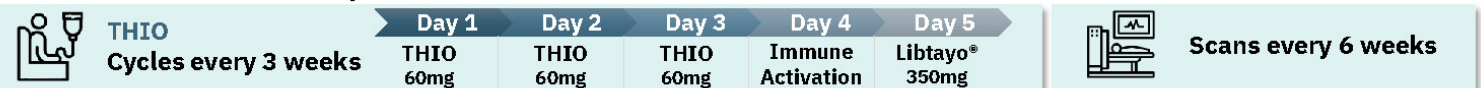


- Modified 3+3 design
- Completed

- Simon's 2-stage in each arm (N=41):
 - ✓ Stage 1 (n=19)
 - ✓ Stage 2 (n=22)
- Best dose THIO 180mg - selected on Nov'23
- Enrollment completed Feb'24

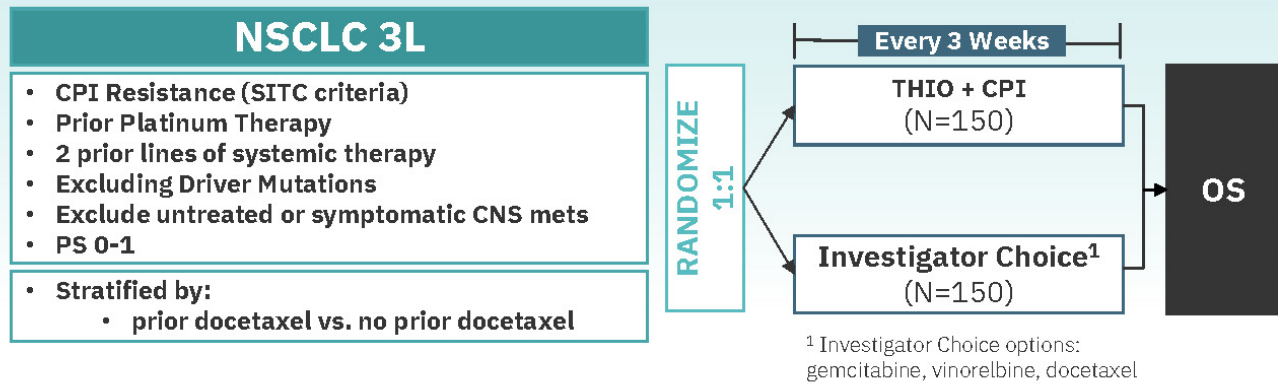
- Up to 148 patients – Enrollment to start Q1'25
- Patient population:
 - CPI Resistance (SITC)
 - Chemotherapy Resistance

Treatment with THIO + Libtayo®



ClinicalTrials.gov: <https://clinicaltrials.gov/study/NCT05208944>

A Multicenter, Open-label, Pivotal Phase 3 Trial Evaluating the Efficacy of THIO Administered in Sequence with a Checkpoint Inhibitor in NSCLC Patients Who Are Resistant to Checkpoint Inhibitors Compared to Chemotherapy



| | |
|------------------------------|---|
| 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 THIO in circulating tumor cells measured by specific biomarkers) |

BEST RESULTS IN THIRD-LINE WITH THE 180MG DOSE

THIO-101 (Pivotal Phase 2, ongoing):

- Current data in third-line indicates that as of 15-Jan-2024, estimated Median Overall Survival (OS) is at 16.9 months with a 95% CI lower bound of 12.5 months and 99% CI lower bound of 10.8 months
- The treatment has been generally well-tolerated to date in this heavily pre-treated population¹

3L NSCLC is an excellent market entry segment for THIO:

- Best results observed in THIO-101
- Highly unmet medical need in this CPI and chemo-resistant population
- Large population
- No current standard of care for this setting
- Limited competition for clinical trials patients

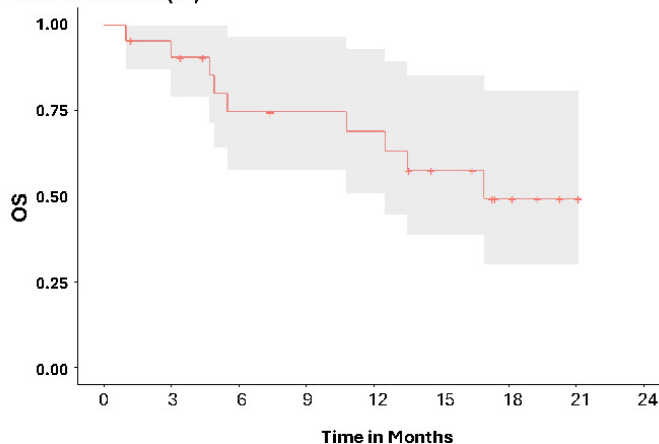
THIO-104 (Phase 3, planned):

- Full approval trial planned to start in H1 2025

Focus on execution:

- Probability of OS to be > 7.8 months (HR 0.74 vs. chemo) is >99%

Overall Survival (3L)



Number at risk

| Strata | 0 | 3 | 6 | 9 | 12 | 15 | 18 | 21 | 24 |
|--------|----|----|----|----|----|----|----|----|----|
| All | 22 | 20 | 14 | 13 | 12 | 8 | 4 | 1 | 0 |

Note: Clinical data presented from 15Jan2025 data cut and includes all patients who received at least one dose of THIO (intent to treat population). This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data is subject to change.

1. Details on safety can be found on the previously announced SITC 2024 presentation available on [MAIA's website](#).

THIO-101 Pivotal Phase 2

THIO-104 Pivotal Phase 3

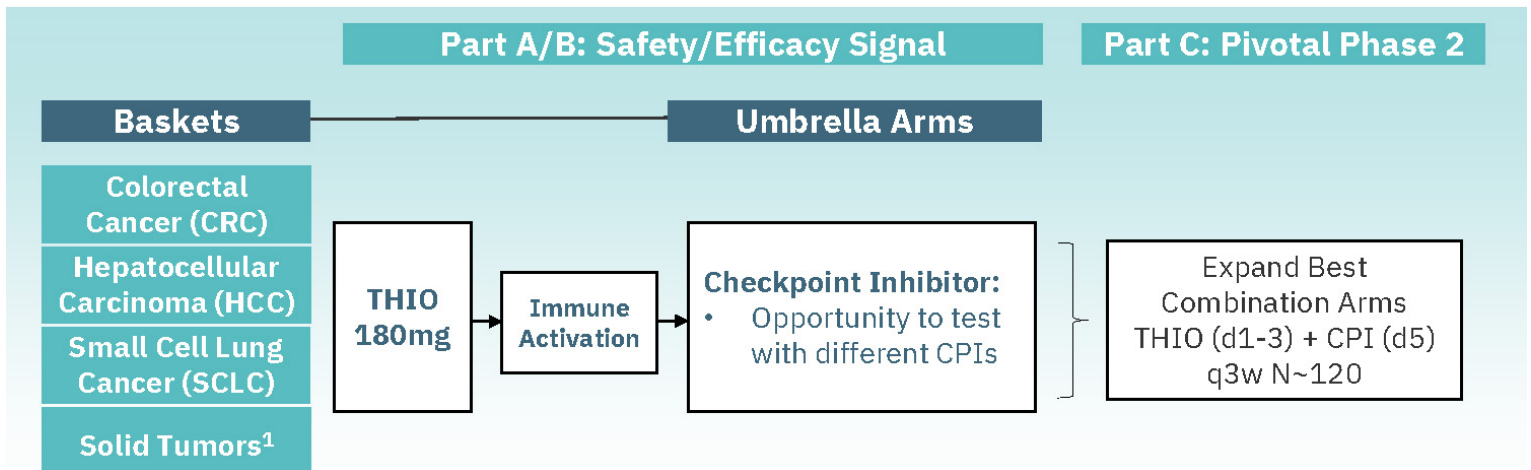
| | THIO + Libtayo® (n = 137-148) | THIO + CPI (n = 150) | Chemotherapy (n = 150) |
|-------------------|--|--|---------------------------|
| Target Population | <ul style="list-style-type: none"> CPI + Platinum Resistant Prior treatment with docetaxel | <ul style="list-style-type: none"> CPI + Platinum Resistant Stratified: prior docetaxel vs. no prior docetaxel | |
| DCR | 88% | >80% | 30% |
| ORR | 38% | >30% | 6% |
| PFS | 5.5 months | 5.5 months | 2 months |
| OS | Not reached at 12.2 months median follow-up ¹ | Projected: >12 months Needed: 7.8 months | 5.8 months |

1. Based on the lower bound of the 95% confidence interval of the median OS (November 15 data cut off). Final estimates may differ as follow-up continues.

OTHER TUMOR TYPES PLANNED TRIALS

THIO-102 TRIAL (PLANNED)

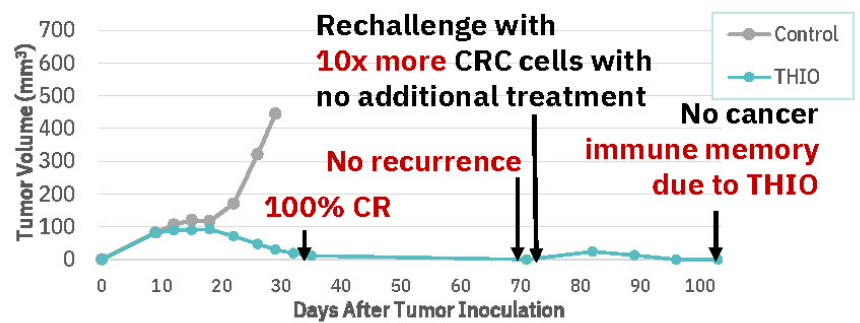
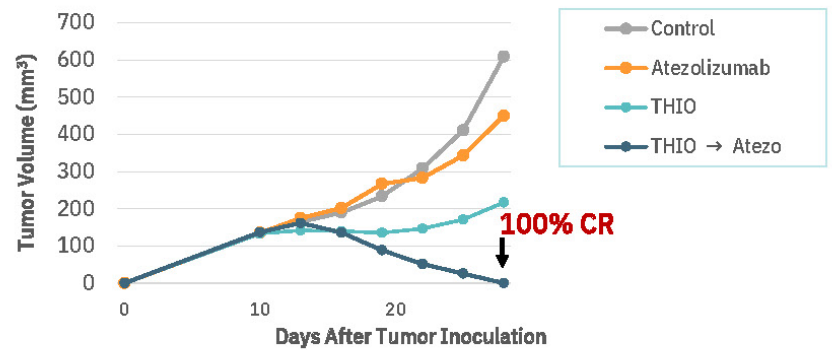
A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with a Checkpoint Inhibitor (CPI)



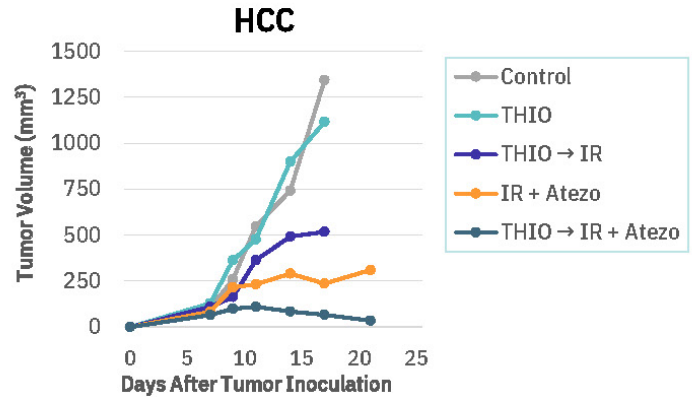
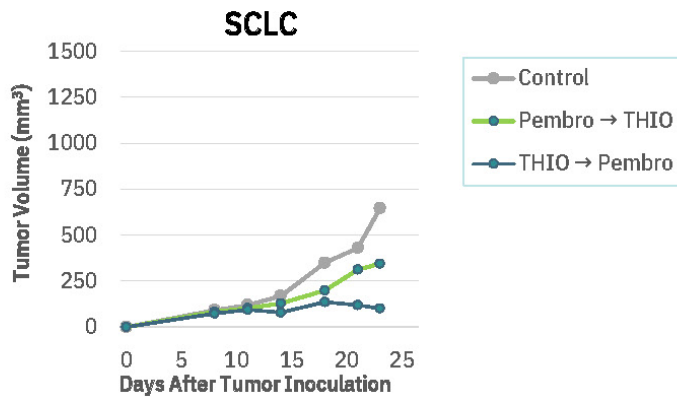
¹ E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc.

COLORECTAL RATIONALE

- 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



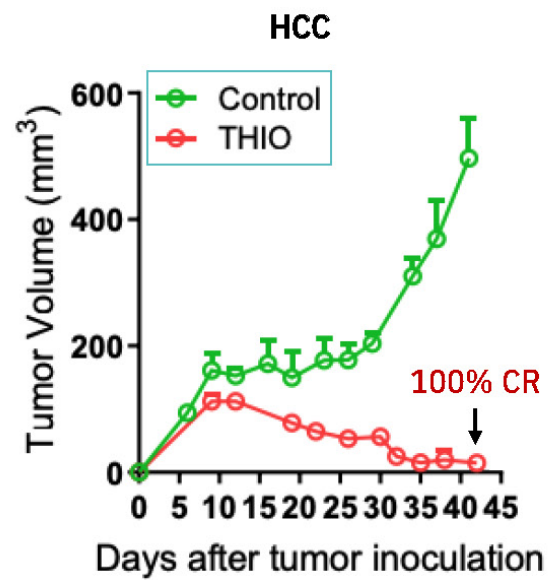
Note: Mender et al, Cancer Cell, 2020.



- 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

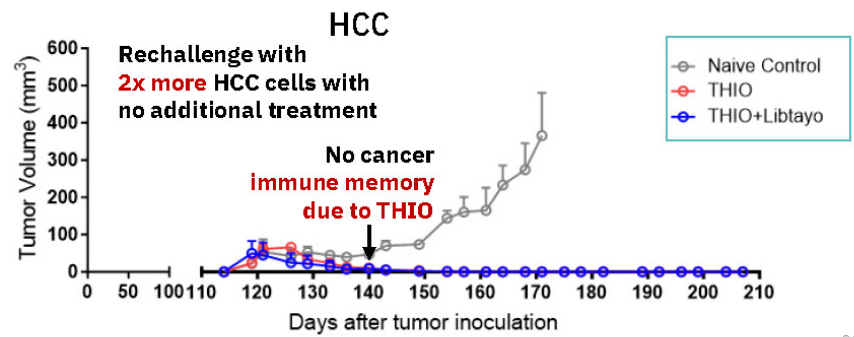
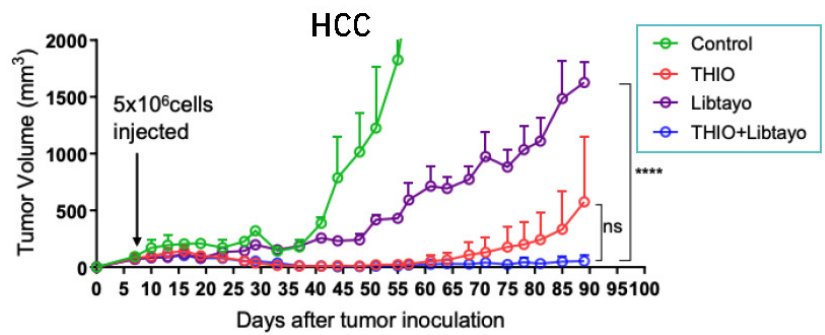
- THIO is highly synergistic and effective in combination with anti-PD-L1 agent Atezolizumab and Ionizing Radiation (IR 10Gy) in HCC53N Hepatocellular Carcinoma
- Treatment with THIO in combination with IR and Atezolizumab results in a complete regression of aggressive HCC tumors. The combination of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

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

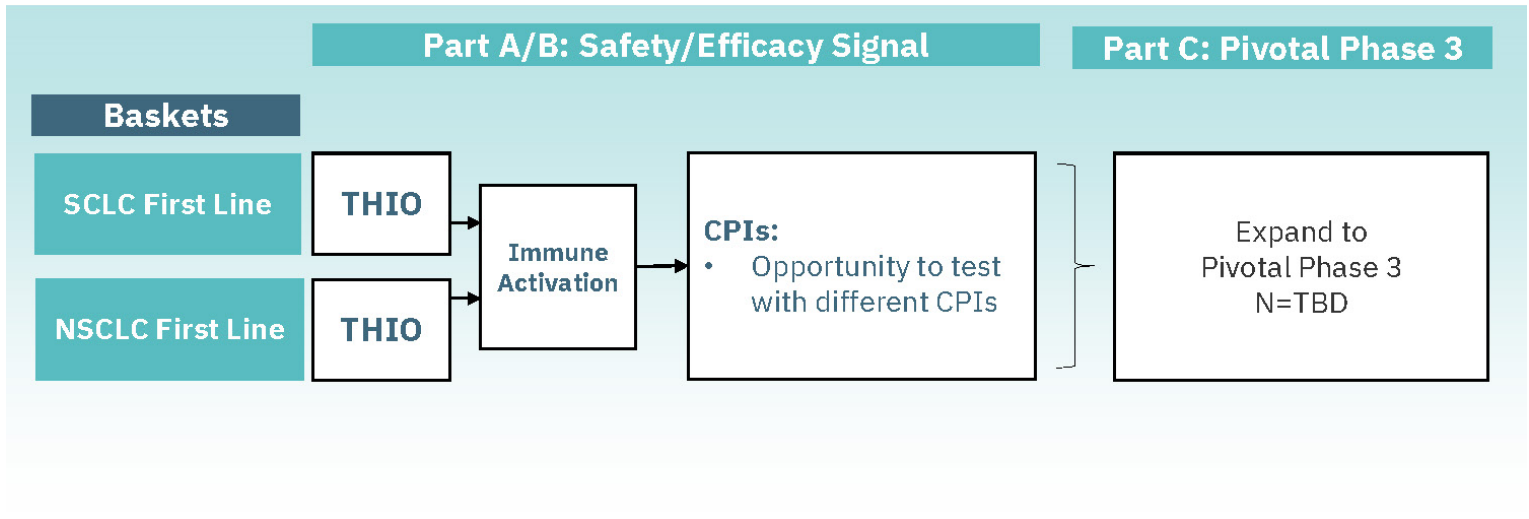


HCC ANTI-CANCER IMMUNE MEMORY

- 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



A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with a Checkpoint Inhibitor (CPI)



INVESTMENT OPPORTUNITY



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



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



SIGNIFICANT MARKET OPPORTUNITY



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

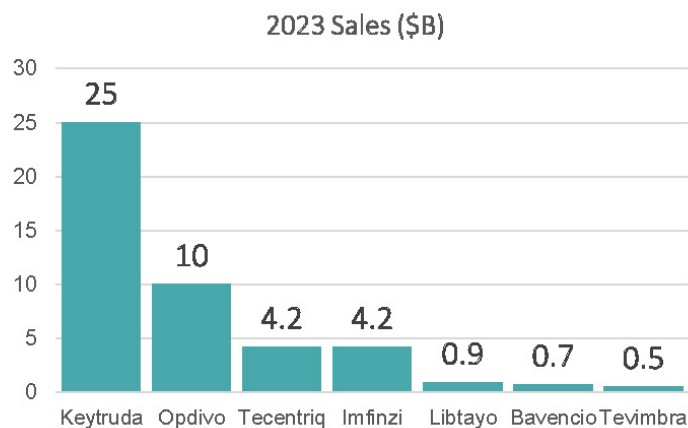
SCLC
Mortality: 0.3M / Sales: \$2B



\$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

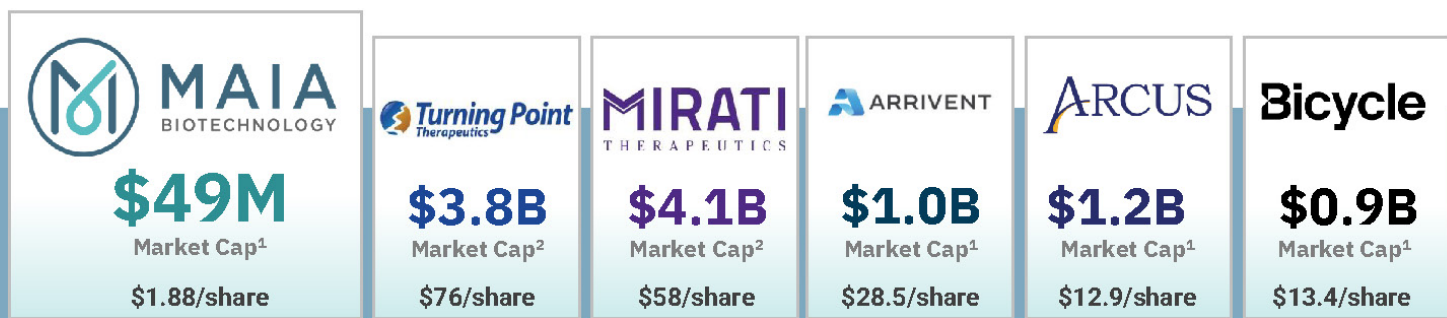
Checkpoint Inhibitors Market



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

COMPARABLE COMPANIES

- 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)



1. Market caps as of January 31, 2025 (Source: Citadel Securities)
2. Last known market cap before acquisition (Source: companiesmarketcap.com)

MULTIPLE VALUE-DRIVING MILESTONES

| | 2025 | | | | 2026 | |
|--|--|--|----------------------------------|-------------------------------|--|---|
| THIO-104 Ph3 NSCLC 3L | Enrollment First Patient In ★ | | | | Potential Early Full Approval in US (from interim analysis) ★ | |
| THIO-101 Ph2 NSCLC 2L+ | Part C First Patient In ★ | Part B Full Efficacy ★ | Part C Efficacy Update | 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 1L, NSCLC 1L | | | | | Enrollment First Patient In ★ | Early Safety Report ★ |

★ Major inflection points

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



THANK YOU

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APPENDIX

U.S. FDA GRANTED 3 ORPHAN DRUG DESIGNATIONS AND 1 RARE PEDIATRIC DISEASE DESIGNATION TO THIO



THIO has been granted 3 Orphan Drug Designations (ODD):

- ✓ Hepatocellular Carcinoma (HCC, 90% of primary liver cancers)
 - ✓ Small Cell Lung Cancer (SCLC, deadliest lung cancer)
 - ✓ Glioblastoma (brain cancer)
- The FDA's Orphan Drug Act of 1983 is designed to incentivize the development of therapies that demonstrate promise for the treatment of rare (orphan) diseases or conditions
 - **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 1 Rare Pediatric Disease Designation (RPDD):

- ✓ Pediatric-type diffuse high-grade gliomas
- The rare pediatric disease program aims to incentivize drug development for rare pediatric diseases. A sponsor who receives an approval for a drug or biological product for a rare pediatric disease may qualify for a voucher that can be redeemed to receive priority review for a different product.