



**MAIA**  
BIOTECHNOLOGY

**TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER**  
**NYSE AMERICAN: MAIA**

April 2024

# 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. The Company has filed a registration statement on Form S-1, as may be amended (Registration No.: 333-269606). Before you invest, you should carefully read the registration statement, including the factors described in the "RISK FACTORS" section of the Registration Statement and other documents that we have filed, and will subsequently file, with the Securities and Exchange Commission to better understand the risks and uncertainties inherent in our business and industry and for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the Commission's website at [www.sec.gov](http://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 the Registration Statement. 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 the Registration Statement 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 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 topline data in mid-2024; 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)

## **THIO trials planned for additional cancer indications.**

- THIO-102 — colorectal cancer (CRC), HCC, SCLC, solid tumors
- THIO-103 — SCLC, NSCLC

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

# 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 - MECHANISMS OF ACTION

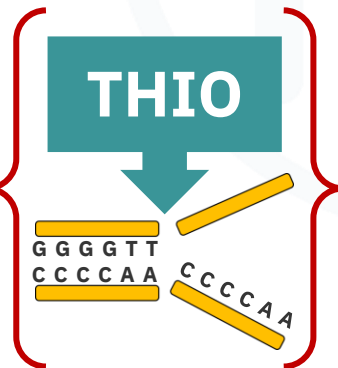
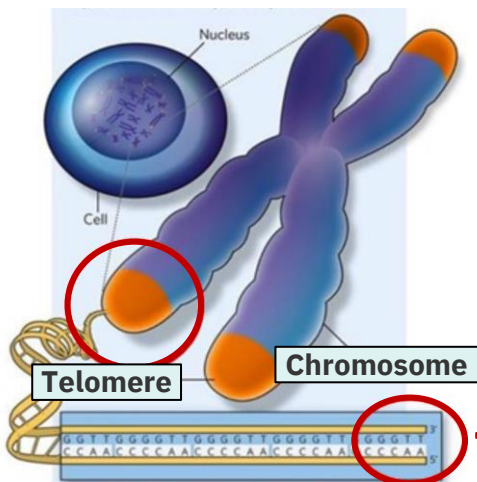
## THIO



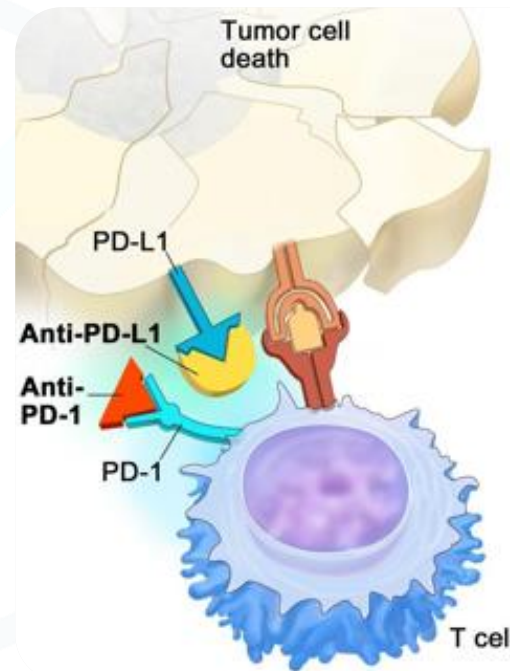
## Immune Checkpoint Inhibitor (CPI)

THIO has a dual MoA:

- 1 Telomere targeting
- 2 Immunogenic effect



Followed by



- LIBTAYO**<sup>®</sup>  
(cemiplimab)  
**REGENERON**
- KEYTRUDA**  
(pembrolizumab)  
**MERCK**
- TECENTRIQ**<sup>®</sup>  
(atezolizumab)  
**Genentech**  
A Member of the Roche Group
- OPDIVO**  
(nivolumab)  
Bristol Myers Squibb
- IMFINZI**<sup>®</sup>  
(durvalumab)  
AstraZeneca

★ Partnership with REGENERON for NSCLC



# **THIO-101 TRIAL**

## **NON-SMALL CELL LUNG CANCER**



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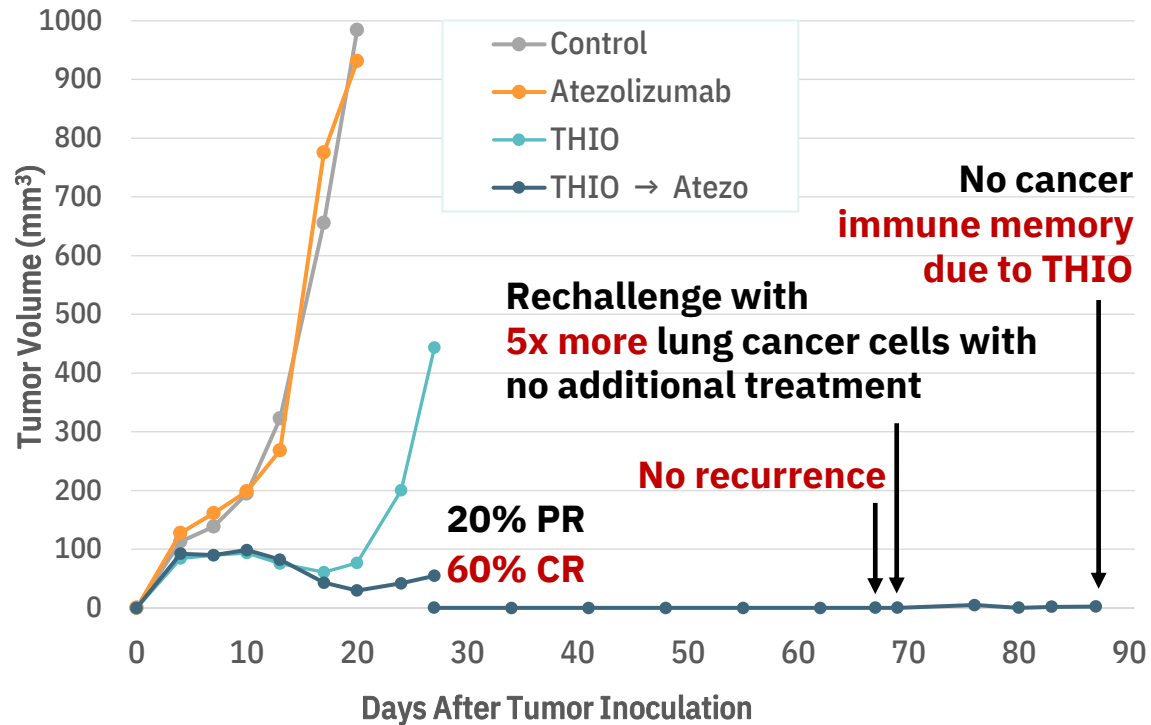
&

***REGENERON***

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

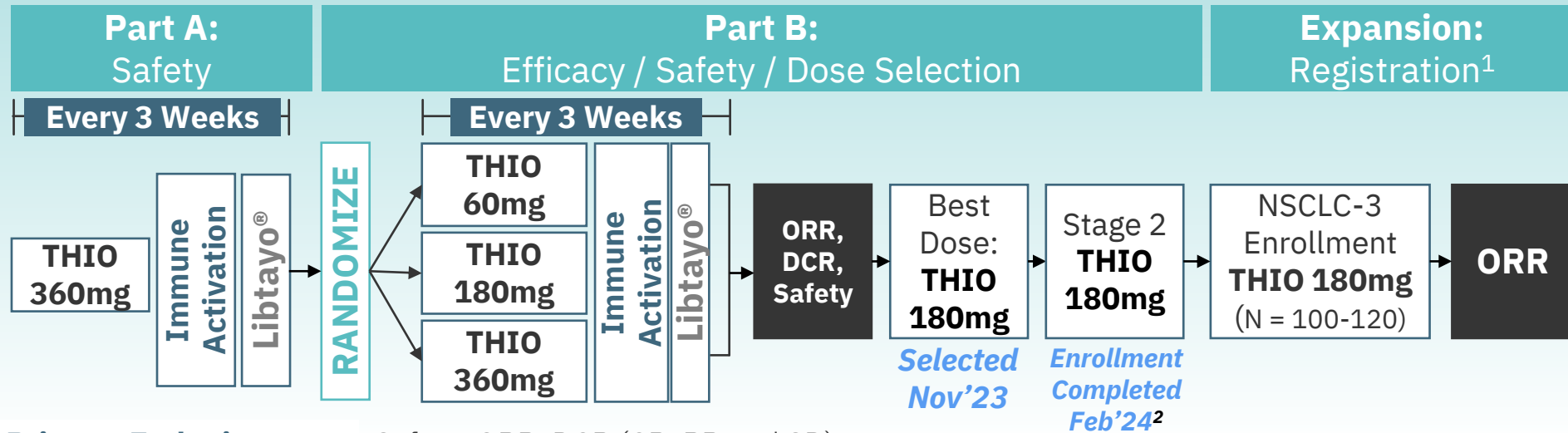
# THIO-101 - RATIONALE

- 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



# THIO-101 - TRIAL DESIGN

**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**



**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)

# DISEASE CONTROL RATE (DCR) BY LINE OF THERAPY

- DCR = SD+PR
  - PR = Partial Response = tumor decrease by at least 30%
  - SD = Stable Disease = -30% to +20%
- DCR is a very important metric of efficacy
  - Can be measured in the first scan
  - DCR is superior OS predictor vs PR<sup>1</sup>
- Observed DCRs far better than SoC DCR

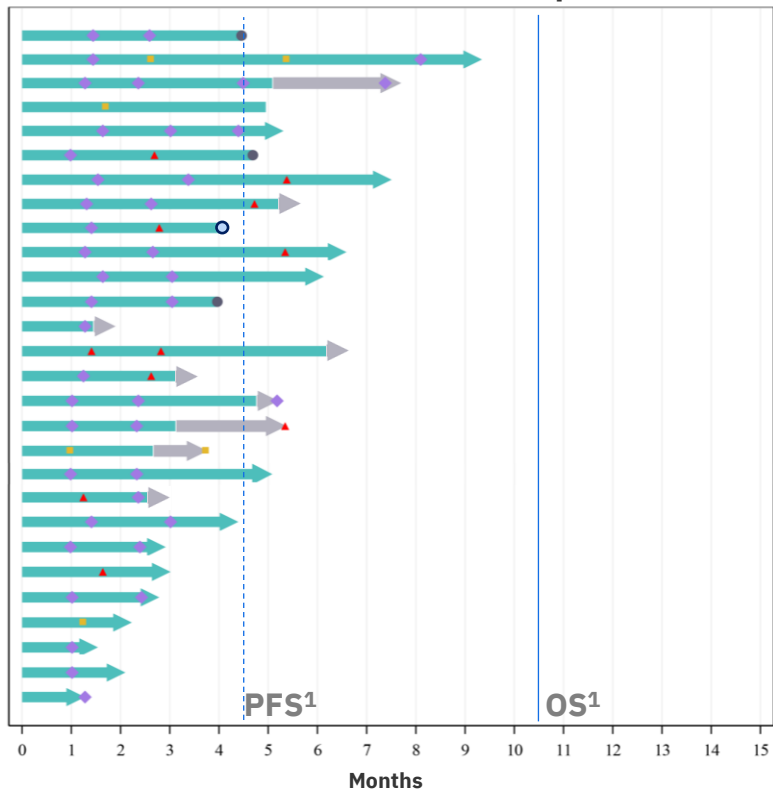
Treatment Line	Standard of Care DCR [checkpoint inhibitor-naïve]	THIO + Libtayo® (cemiplimab)* [checkpoint inhibitor-resistant]
<b>NSCLC-1</b>	<b>71%</b> KEYTRUDA (pembrolizumab; KEYNOTE 024)	<b>TBD</b>
<b>NSCLC-2</b>	<b>64%</b> CYRAMZA (ramucirumab) + docetaxel (REVEL) <b>53%</b> docetaxel monotherapy (REVEL)	<b>90%</b>
<b>NSCLC-3</b>	<b>25-35%</b> chemotherapy (RWD)	<b>83%</b>

1. Matsumoto H et al. Transl Lung Cancer Res. 2021 May; 10(5): 2278–2289 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8182707/>)

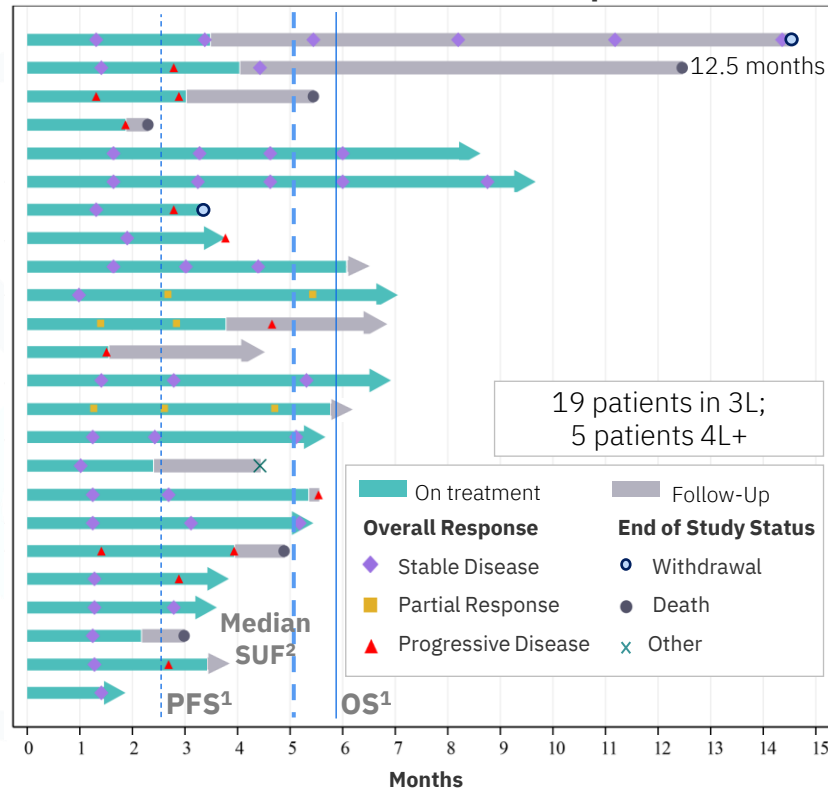
**Note:** Clinical data presented from 13Nov2023 data cut of ongoing study, THIO-101.

# PATIENTS' SURVIVAL BY LINE OF THERAPY

## Second Line (All Doses) – 28 pts



## Third Line+ (All Doses) – 24 pts



14.6 months

**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 08Jan2024 data cut.

<sup>1</sup>PFS and OS lines are estimates based on currently available treatments; <sup>2</sup>Median Survival Follow-Up line based on 3L+ patients N=19 IQR=(14,25)

# TREATMENT IN THIRD-LINE

## Extended Survival

- 19 subjects in 3L completed at least 1 post baseline assessment at time of cut-off
- 10/19 (53%) patients crossed 5.8 months OS threshold
- 16/19 (84%) crossed 2.5 months PFS threshold

## Unprecedented Efficacy

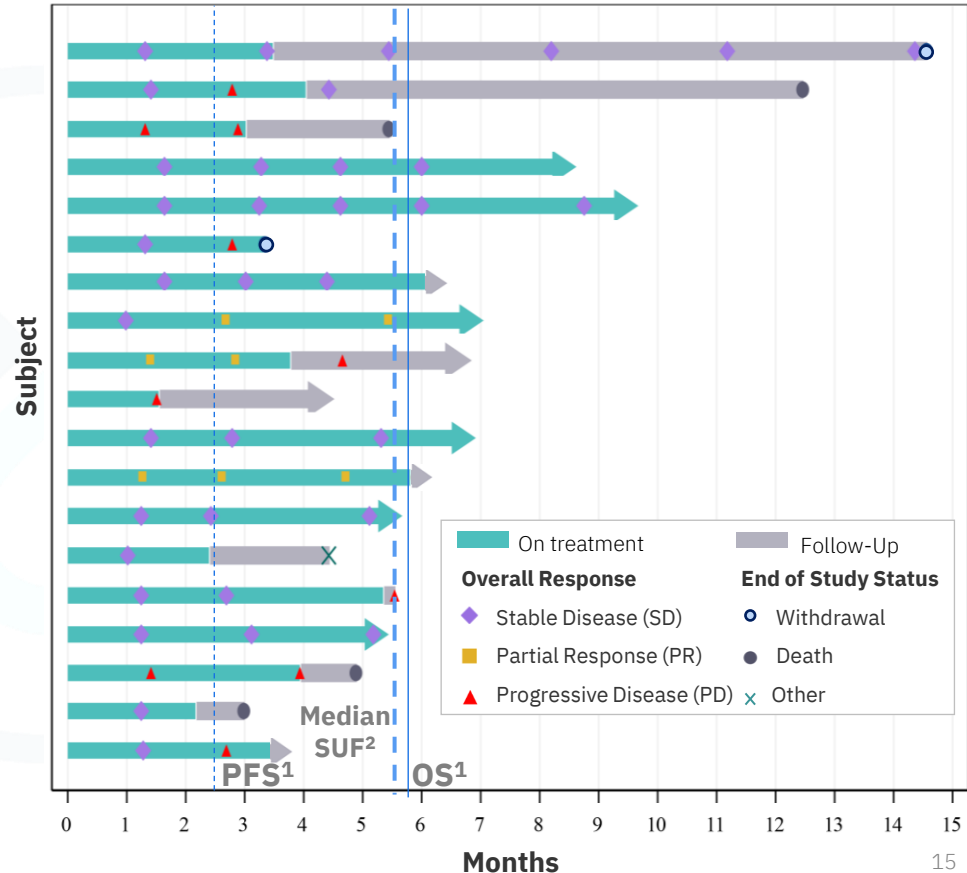
- DCR 83% vs 25-35% chemotherapy
- ORR (180mg dose) 38% vs 6-10% chemotherapy<sup>3</sup>

**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 08Jan2024 data cut.

<sup>1</sup> PFS and OS lines are estimates based on currently available treatments

<sup>2</sup> Median Survival Follow-Up line based on 3L patients N=19 IQR=(17,29)

<sup>3</sup> <https://ir.maiaibiotech.com/news-events/press-releases/detail/94/maia-biotechnology-announces-strong-efficacy-of-thio-as>



# EXPECTED EFFICACY IN THIRD-LINE

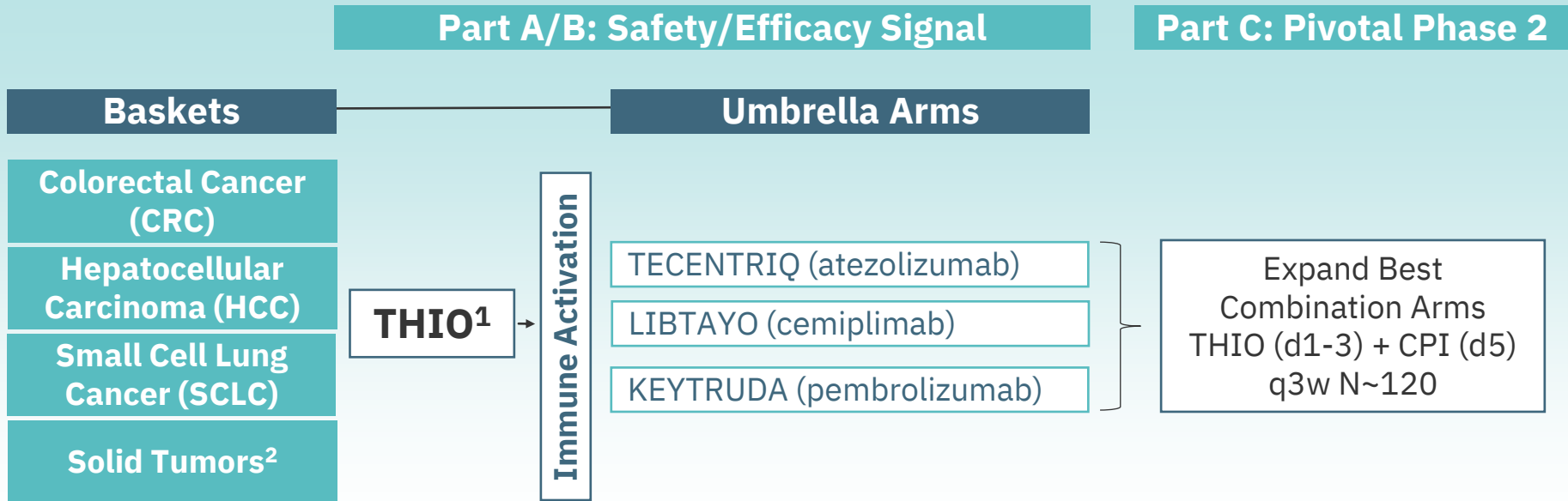
Indication	NSCLC Third-Line		
Treatment	<b>Baseline (Estimated)</b> Real-world data	<b>Threshold for Approval</b> Statistical plan	<b>THIO (Estimated)</b> Based on DCR from THIO-101
Overall Survival	5.8 months	7.8 months (HR 0.74)	> 11 months
Disease Control Rate	25% - 35%		83%
Overall Response Rate	6% - 10%		38%



# PLANNED UPCOMING TRIALS

# THIO-102 TRIAL (PLANNED)

## 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

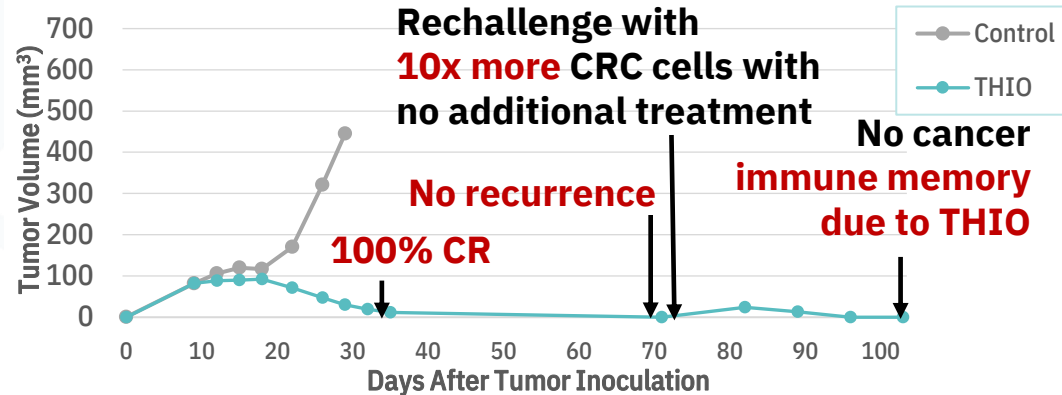
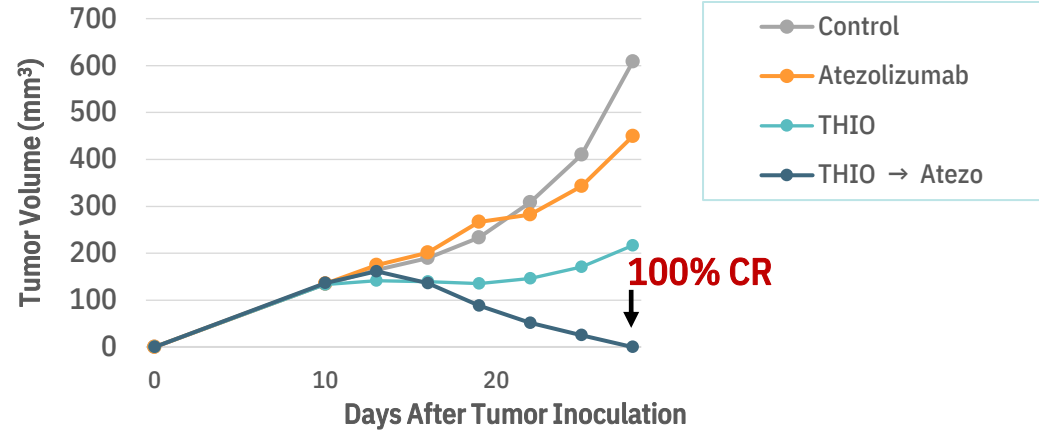


<sup>1</sup> Dose to be selected from THIO-101 study results

<sup>2</sup> E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc

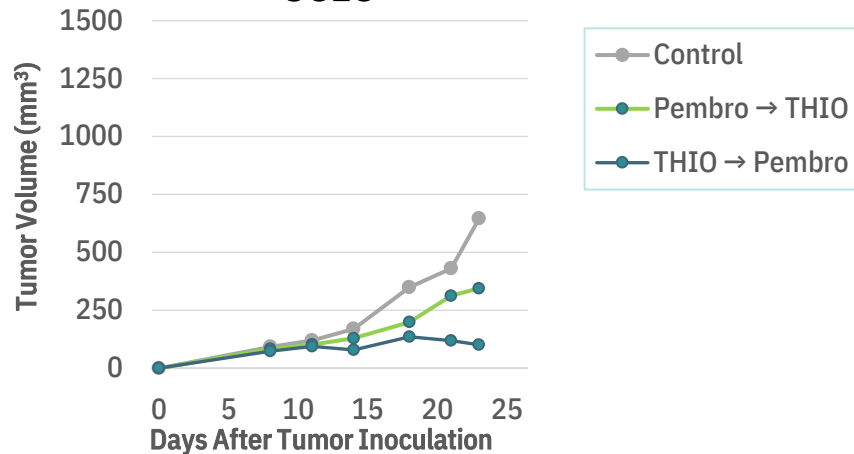
# THIO-102 – COLORECTAL RATIONALE

- 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



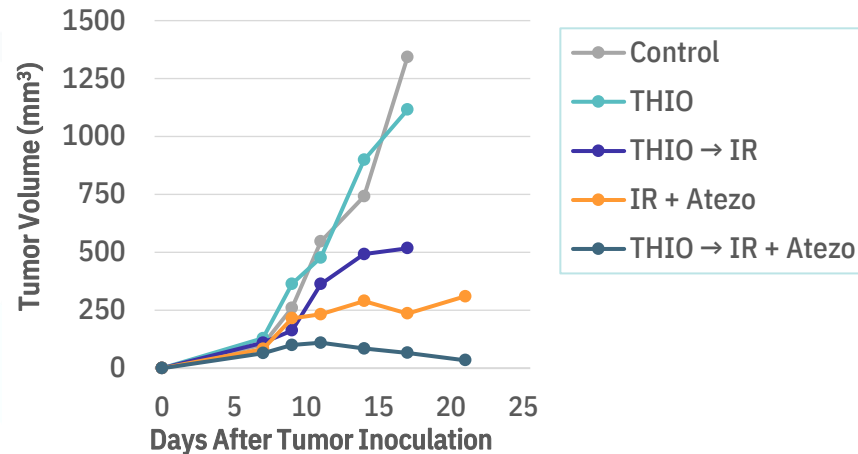
# SCLC & HCC – ORPHAN DRUG DESIGNATION

## SCLC



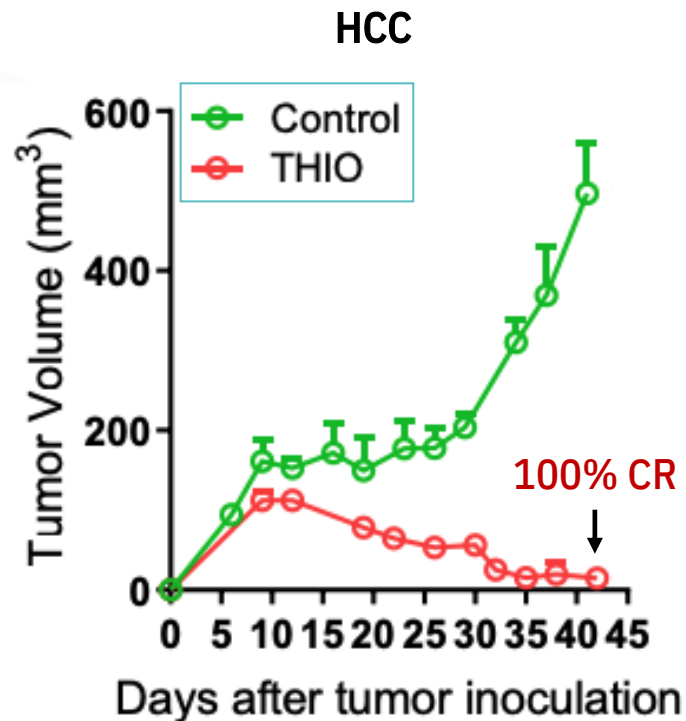
- THIO is synergistic with anti-PD-1 agent Pembrolizumab in Small Cell Lung Carcinoma (H2081) *in vivo* in humanized murine cancer model
- Treatment with THIO followed by Pembrolizumab results in highly potent anticancer effect, as compared to Pembrolizumab alone
- THIO converts immunologically “cold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

## HCC



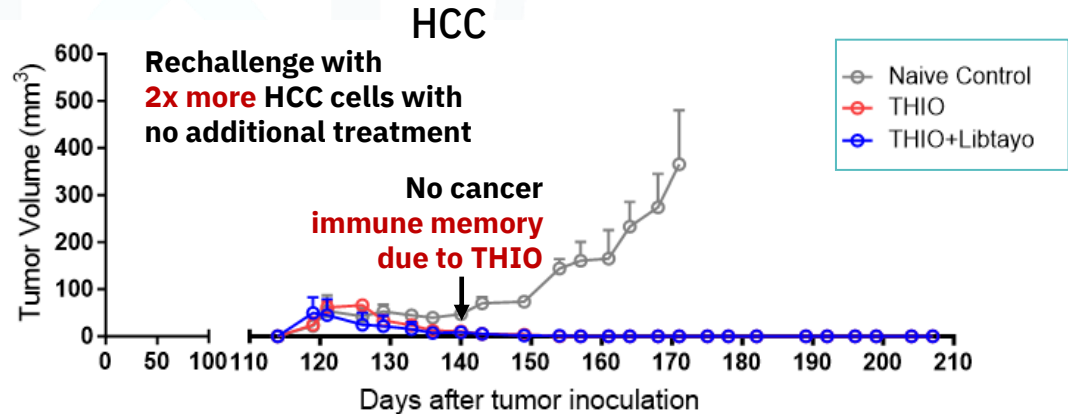
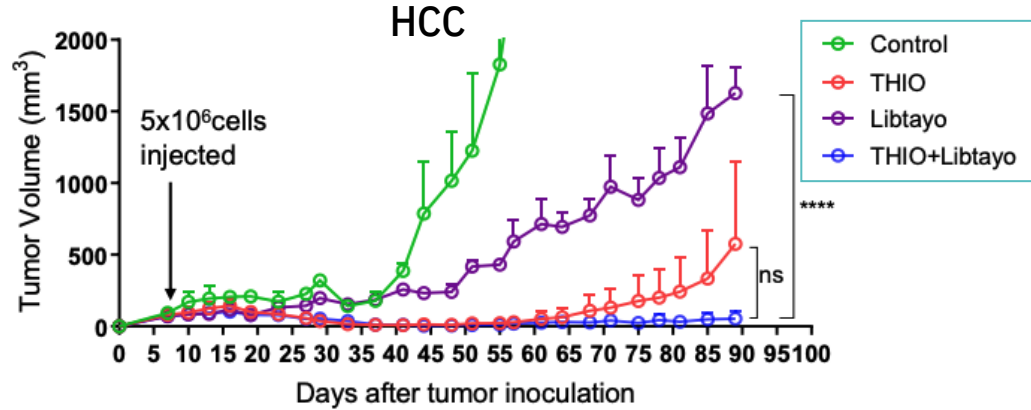
- THIO is highly synergistic and effective in combination with anti-PD-L1 agent Atezolizumab and Ionizing Radiation (IR 10Gy) in HCC53N Hepatocellular Carcinoma
- Treatment with THIO in combination with IR and Atezolizumab results in a complete regression of aggressive HCC tumors. The combination of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



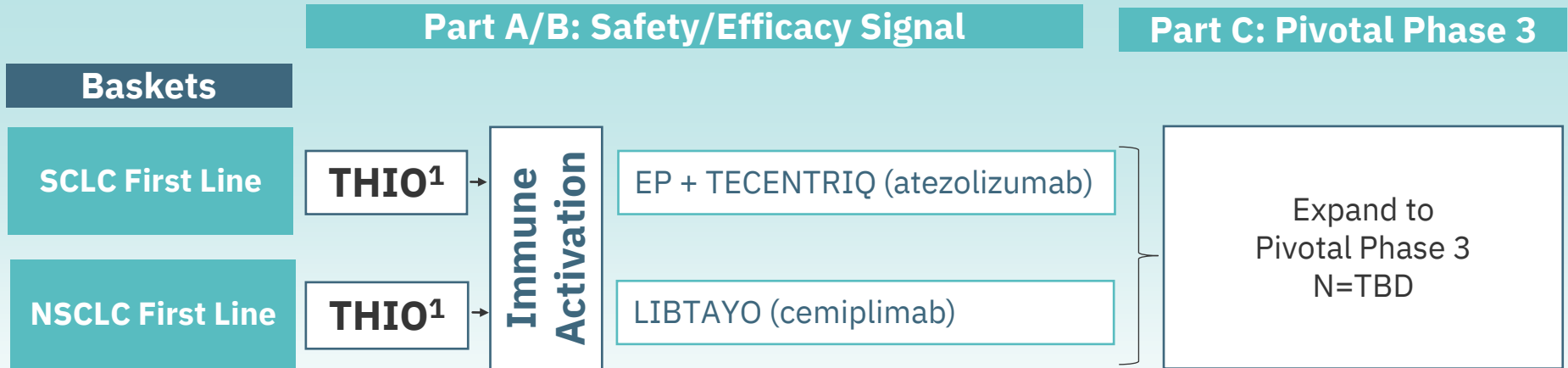
# HCC ANTI-CANCER IMMUNE MEMORY

- 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



# THIO-103 TRIAL (PLANNED)

## 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



<sup>1</sup> Dose to be selected from THIO-101 study results

# 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





## Developing agents for the top tumor types markets globally

### NSCLC (#1 WW)

Mortality: 1.7M  
Sales: \$ 34B

### CRC (#2 WW)

Mortality: 1.0M  
Sales: \$ 20B



## \$42B CPIs Group

- 5 CPIs approved for NSCLC sold \$12B
- >30% of NSCLC drug sales
- >40% of total CPI sales
- Keytruda®: \$7.5B in NSCLC of \$21B total



## Partnership with Regeneron (Libtayo®)

- Profile similar to Keytruda®
- Libtayo® is entrant #5 in CPIs
- Needs superior efficacy to Keytruda®
- Sequential combination with THIO is key

## Checkpoint Inhibitors Market

\$42B combined



# COMPARABLE COMPANIES



**\$47M**

Market Cap

**\$2.35/share**

**MIRATI**  
THERAPEUTICS

**\$4.1B**

Market Cap

**\$58/share**

 **zentalis**

**\$1.0B**

Market Cap

**\$15/share**

**IOVANCE**  
BIOTHERAPEUTICS

**\$3.8B**

Market Cap

**\$14/share**

 **K U R A**  
ONCOLOGY

**\$1.5B**

Market Cap

**\$21/share**

 **Turning Point**  
Therapeutics

**\$4.1B**

Market Cap

**\$76/share**

- 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: Zentalis, Iovance, Kura and Turning Point (on acquisition)

# MULTIPLE VALUE-DRIVING MILESTONES

## ★ Major inflection points

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



# THANK YOU

## **Investor Relations Contact**

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ir@maiabiotech.com

## **MAIA Biotechnology, Inc.**

444 West Lake Street, Suite 1700  
Chicago, IL 60606

# APPENDIX

- 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 3 ODDs:**
  - ✓ Hepatocellular Carcinoma (HCC, 90% of primary liver cancers)
  - ✓ Small Cell Lung Cancer (SCLC, deadliest lung cancer)
  - ✓ Glioblastoma (brain cancer)



3x



## 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.maiaibotech.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.maiaibotech.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.maiaibotech.com/news-events/press-releases/detail/83/fda-grants-orphan-drug-designation-to-maia-biotechnology>