# INTECHNOLOGY

TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER NYSE AMERICAN: MAIA

September 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, 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 gualification 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 vear 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**



#### 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**



THIO Telomere targeting agent	PHASE 1	PHASE 2	PHASE 3	E 3 COLLABORATION & RIGHTS		
<b>THIO-101</b> NSCLC-2+ (THIO $\rightarrow$ Libtayo <sup>®</sup> )		Enrollment mplete		Worldwide rights owned by MAIA	Clinical supply agreement with <b>REGENERON</b>	
<b>THIO-102</b> CRC, HCC, SCLC, ST (THIO $\rightarrow$ CPI)	Ph 2 Planning			Worldwide rights owned by MAIA		
<b>THIO-103</b> NSCLC-1, SCLC-1 (THIO $\rightarrow$ CPI)	Ph 2/3 Planning			Worldwide rights owned by MAIA		
2 <sup>nd</sup> Generation Telomere targeting agents						
MAIA-2021-020 Multiple Ind. IND Enabling				Developed i	n-house	
MAIA-2022-012 Multiple Ind. IND Enabling				fully-owned by MAI		
MAIA-2021-029 Multiple Indications						



# MISSION AND APPROACH



Cancer is the most dominant age-related disease

**Population aged >80** expected to triple by 2050 142 million 426 2020 million 2050

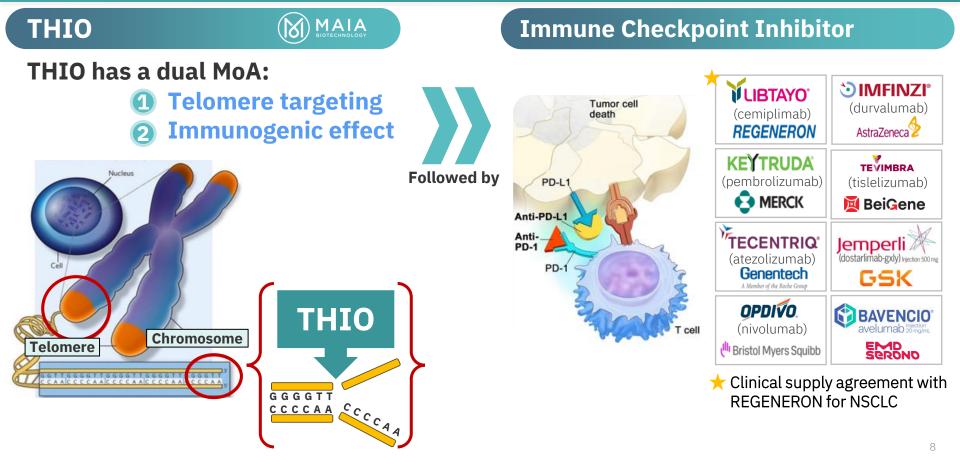
At age 90: 40% will be diagnosed 20% will die of it



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

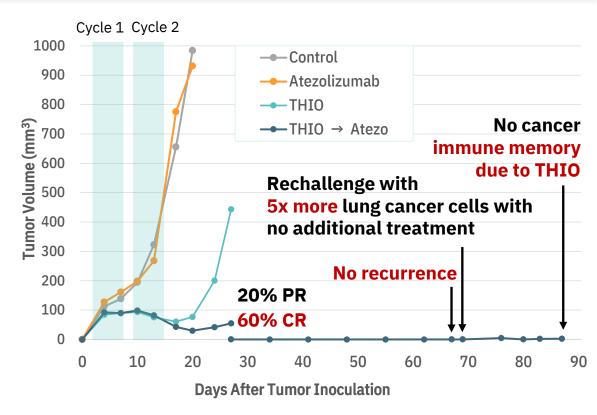
## THIO – NOVEL MECHANISMS OF ACTION





## **THIO-101 NSCLC TRIALS - 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 followup
- 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

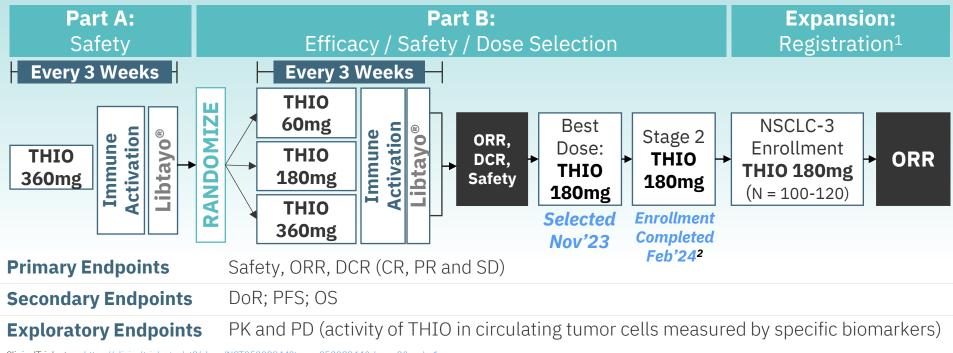


MAIA Biotechnology, Inc. Announces Clinical Supply Agreement with Regeneron for Phase 1/2 Clinical Trial Evaluating THIO in Sequential Administration with Libtayo<sup>®</sup> (cemiplimab) in Advanced Non-Small Cell Lung Cancer

## **THIO-101 – 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 <u>RESISTANT TO CHECKPOINT INHIBITORS</u>



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**



16.3

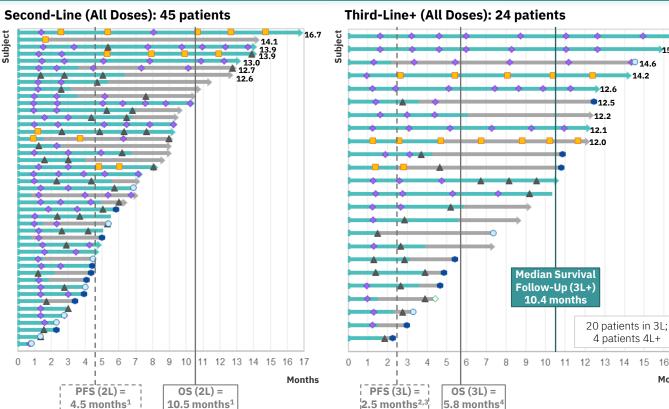
15.6

14.6

14.2

- As of 01-Aug-2024, 16 patients had survival follow-up above 12 months:
  - $\checkmark$  7 in 2L, 7 ongoing  $\checkmark$  9 in 3L, 7 ongoing ✓ 1 patient with 23 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 01Aug2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

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.

16 17

Months

## **TREATMENT IN THIRD-LINE**



#### **Extended Survival**

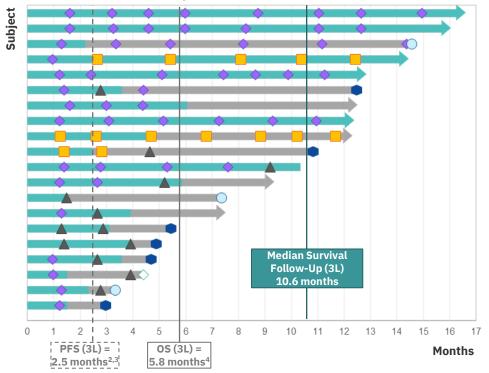
- 20 subjects in 3L completed at least 1 post baseline assessment at time of cut-off
- 14/20 (70%) patients crossed 5.8 months OS threshold
- 17/20 (85%) crossed 2.5 months PFS threshold

#### **Unprecedented Efficacy**

- DCR 85% vs 25-35% chemotherapy
- ORR (180mg dose) 38% vs 6-10% chemotherapy<sup>5</sup>



Third Line (All Doses): 20 patients



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 01Aug2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

**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.

5. https://ir.maiabiotech.com/news-events/press-releases/detail/94/maia-biotechnology-announces-strong-efficacy-of-thio-as

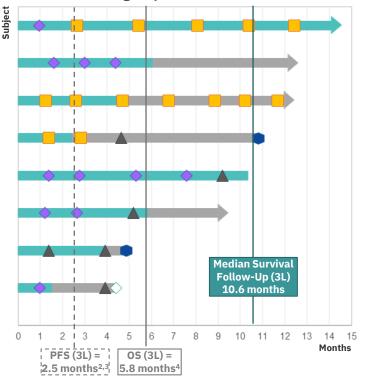
## **BEST 3L RESULTS IN THE 180MG DOSE**



#### NSCLC-3 – 180mg:

- 6/8 (75%) patients crossed 5.8 months OS threshold
- 7/8 (88%) crossed 2.5 months PFS threshold

#### Third-Line (180mg): 8 patients



#### Legend

	Treatment
	Follow-Up
<b></b>	Stable Disease (SD)
	Partial Response (PR)
	Progressive Disease (PD)
۲	Death
0	Withdrawal

Others

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 01Aug2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

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.

#### **EXPECTED EFFICACY AND CURRENT TREATMENTS**



Third-Line NSCLC	THIO (180mg) + Libtayo® (cemiplimab)	Chemotherapy Tarceva® (erlotinib)		Taxotere® (docetaxel)	
Population	CPI Resistant (3L)	CPI Naïve (3L)	CPI Naïve (2L+)	CPI Naïve (2L)	
DCR	88%	36%	45%	54%	
ORR	38%	6%	9%	5.7%	
PFS	5.5 months		2.2 months	1.9 months (8.3 weeks Time to Progression)	
OS	> 10 months (projected <sup>1</sup> )	5.8 months	6.7 months	5.7 months	
Trial / Study	THIO-101	Third-Line Chemotherapy in Advanced NSCLC (Girard et al, JTO)	BR.21	TAX320	
Source	https://clinicaltrials.gov/study/NCT 05208944	https://www.jto.org/article/S1 556-0864(15)31281-8/pdf	https://www.nejm.org/doi/full/ 10.1056/NEJMoa050753	https://pubmed.ncbi.nlm.nih. gov/10856094/	

**1.** Projected efficacy measures of treatment with THIO are indicative and estimated by MAIA Biotechnology exclusively and based on interim observed trends of ongoing Phase 2 clinical trial. Final efficacy measures 16 may differ as follow-up continues.

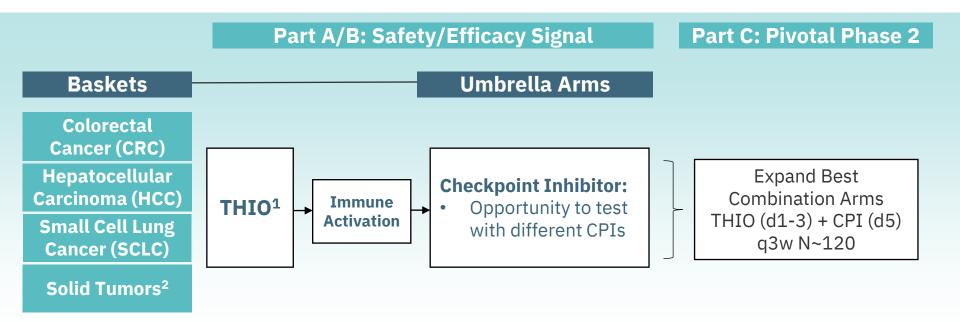


# PLANNED UPCOMING TRIALS

## THIO-102 TRIAL (PLANNED)

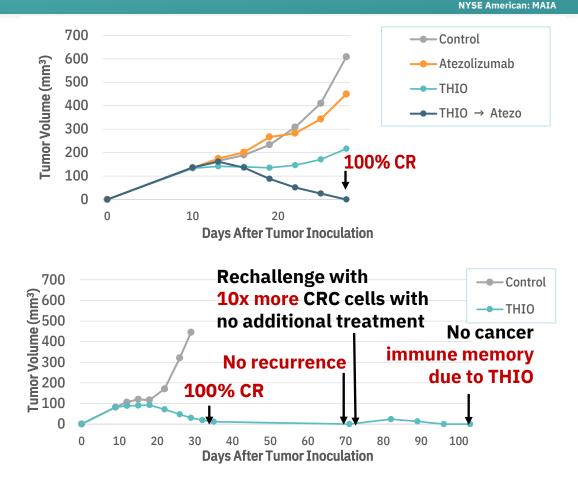


A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with Anti-PD-1 or Anti-PD-L1

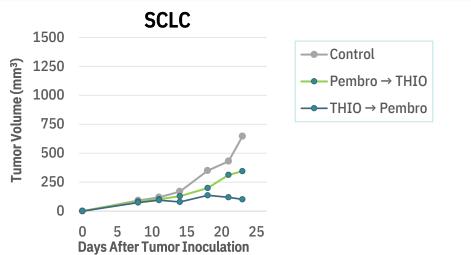


## **THIO-102 – COLORECTAL RATIONALE**

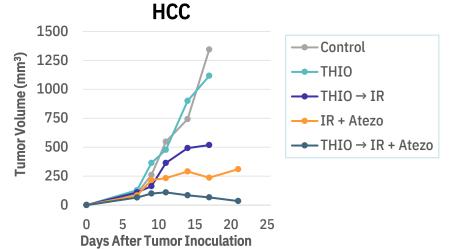
- THIO followed by CPI results in 100% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 10x more CRC cells with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



## SCLC & HCC – ORPHAN DRUG DESIGNATION



- 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



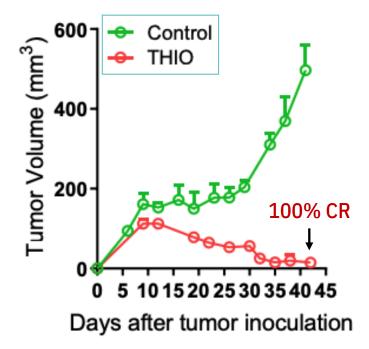
- THIO is highly synergistic and effective in combination with anti-PD-L1 agent Atezolizumab and Ionizing Radiation (IR 10Gy) in HCC53N Hepatocellular Carcinoma
- Treatment with THIO in combination with IR and Atezolizumab results in a complete regression of aggressive HCC tumors. The combination of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

#### **EXCELLENT EFFICACY IN HCC MODELS**





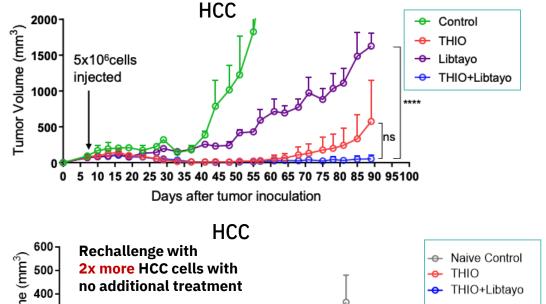
• THIO achieved complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology in primary liver cancer (90%), in *in vivo* models

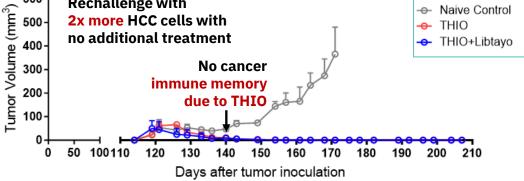


## HCC ANTI-CANCER IMMUNE MEMORY

NYSE American: MAIA

- When combined with immunotherapy checkpoint inhibitor Libtayo<sup>®</sup>, 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<sup>®</sup> generated anti-cancer immune memory

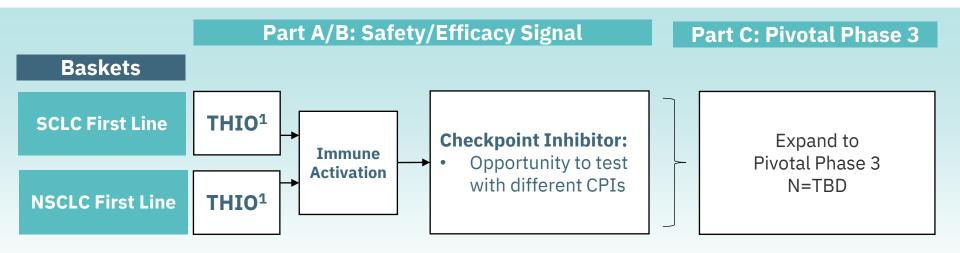




## THIO-103 TRIAL (PLANNED)



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





# INVESTMENT OPPORTUNITY

## EXCLUSIVITY AND INTELLECTUAL PROPERTY M MAIA



#### **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)

Cephalon

**U** NOVARTIS



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

lansser

Incyte



## SIGNIFICANT MARKET OPPORTUNITY





#### Developing agents for the top tumor types markets globally

> 30% of NSCLC drug sales

Keytruda<sup>®</sup>: \$9B in NSCLC of \$25B total

> 40% of total CPI sales

•

•

**Checkpoint Inhibitors Market** 



•

2023 Sales (\$B)

Keytruda<sup>®</sup> 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 <u>\$4.1B</u> in equity value
- On October 9, 2023, BMS acquired Mirati for **<u>\$4.8B</u>** in cash, plus up to **\$1B** in contingent value right
- Commercial stage companies: Mirati (on acquisition), Iovance
- Phase 2 companies: Arcus, Bicycle Therapeutics and Turning Point (on acquisition)

<sup>1.</sup> Market caps as of September 06, 2024 (source: Citadel Securities)

<sup>2.</sup> Last known market cap before acquisition (source: companiesmarketcap.com)

### MULTIPLE VALUE-DRIVING MILESTONES



#### $\star$ Major inflection points

-									
		2024		2025			2026		
<b>THIO-101</b> <b>Ph2</b> NSCLC-2+	Early Efficacy Update (Biotech	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	Accelerated	
	Showcase)	*	*	*				*	
THIO-102 Ph2 CRC, SCLC,				<b>Enrollment</b> First Patient In		Early Safety Report		Early Efficacy Report	
HCC, ST				*		*			
THIO-103 Ph2/3				<b>Enrollmen</b> First Patient				Early Safety Poport	
SCLC-1, NSCLC-1				*				Report	

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





# **THANK YOU**

#### **Investor Relations Contact**

+1 (872) 270-3518 ir@maiabiotech.com

#### MAIA Biotechnology, Inc.

444 West Lake Street, Suite 1700 Chicago, IL 60606



## **APPENDIX**

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



- The FDA's Orphan Drug Act of 1983 is designed to <u>incentivize the</u> <u>development of therapies that demonstrate promise for the treatment</u> <u>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
  - $\checkmark$  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)



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