Mongoose Bio

# Epigenetically Programmed Memory TCR-T Cell Therapy for Solid Tumors

December 2024

# Revolutionizing the Treatment of Cancer

- **Pioneering discoveries by Dr. Cassian Yee at MD Anderson Cancer Center (MDACC)**
- **Advancing two very important technologies:**
  - Epigenetic Reprogramming of T-cells: to generate active, long-lived Central Memory T cells (Tcm)
  - Immunopeptidome Discovery Platform: highly immunogenic, novel targets and their associated T-cell receptors (TCRs)
- **Pipeline of 4 unique and qualified programs for patients with common and rare solid tumors**
  - Ph1b to target gastric, esophageal and lung
  - Ph 1b initiation expected 2H ‘25
- **Strong Financial Support**
  - Raising $20M to complete Phase 1 study: $15M+ already secured
    - Awarded $10.6 M in non-dilutive funding from the prestigious CPRIT Product Development
    - Executed term sheet with Cancer Focus Fund for $5.1M
    - Closing $5M in seed financing

# Mongoose Bio Principals

## Neil Warma, MBA, President & CEO

- Global Healthcare Leader
- President & CEO, Mongoose Bio
- Former CEO, Representative Director, Genexine (Seoul, S. Korea)
- Former CEO, I-Mab Biopharma U.S. (Shanghai, San Diego)
- Former President and CEO, Opexa Therapeutics (Houston)
- Former CEO, Viron, and President and Co-Founder of MedExact
- Senior executive, Novartis Pharma, Basel, CH
- Member of Board of Directors of Biotechnology Innovation Organization (BIO)
- Member of Board: ProMIS Neurosciences, Inc.
- Member of Board: GenrAb, Inc.
- Member of Board: Ridgeline Therapeutics

## Cassian Yee, MD, Scientific Founder

- Endowed Professor and medical oncologist in the Division of Cancer Medicine, University of Texas MD Anderson
- Director, Solid Tumor Cell Therapy and TCR-based Therapeutics
- Professor, Dept of Melanoma Medical Oncology
- 25+ years experience in ACT
- Pioneered Endogenous T Cell (ETC) therapy, precursor to TCR-T therapy
- 80+ publications, 16,000 citations in field of ACT and immunotherapy

# The Promise of TCR-T cell Therapy

**Mongoose Bio, Scientific Founder, Dr. Cassian Yee, MD,**
Endowed Professor and Medical Oncologist in the Division of Cancer Medicine,
MD Anderson Cancer Center

*"TCR-T therapy is a **revolutionary approach** to cancer treatment, designed to unleash the power of the immune system by **targeting tumor-specific antigens inside cancer cells**—something no other therapy can do. Its vast potential lies in its ability to transform how we treat **solid tumors**, offering a new frontier of precision medicine with the promise of **durable responses** and breakthroughs where traditional therapies have failed."*

# Mission Statement

## TCR-T - Differentiated from CAR-T, TIL Therapies

Our mission is to revolutionize adoptive T cell therapies by the epigenetic reprogramming of Tcm cells harboring TCR's against highly immunogenic autochthonous tumor specific targets to create long lived efficacious TCR-T cell therapies that will eradicate common and rare solid tissue malignancies

| | Mongoose Bio | CAR-T, TIL Therapies |
|---|---|---|
| **Number of Targets** | **Many** | Few |
| **Target Location** | **Extracellular or Intracellular** | Extracellular (CAR-T) |
| **Persistence and Activity** | **High** | Low |
| **Antigen Loss** | **Low** | High |
| **Serious Toxicities** | **Low** | High |
| **High-dose Lymphodepletion** | **Not Required** | Required |
| **Combination Strategies** | **Easily Implemented** | Problematic |

# Critical Challenges to Cellular Therapy

## The Challenge

### ? Identifying and accessing novel and meaningful cancer targets

- How to identify and target intracellular targets
- <3% of cancer patients are eligible for CAR-T therapy
- How to access intracellular immunogenic antigens?

### ? Overcoming T-Cell Exhaustion

- Exhausted T cells are less effective at fighting cancer, impaired proliferation and poor in vivo survival
- Exhausted T cells are a key reason why cancer immunotherapies, especially cell therapies, fail to produce lasting responses in patients.

## Mongoose Solution

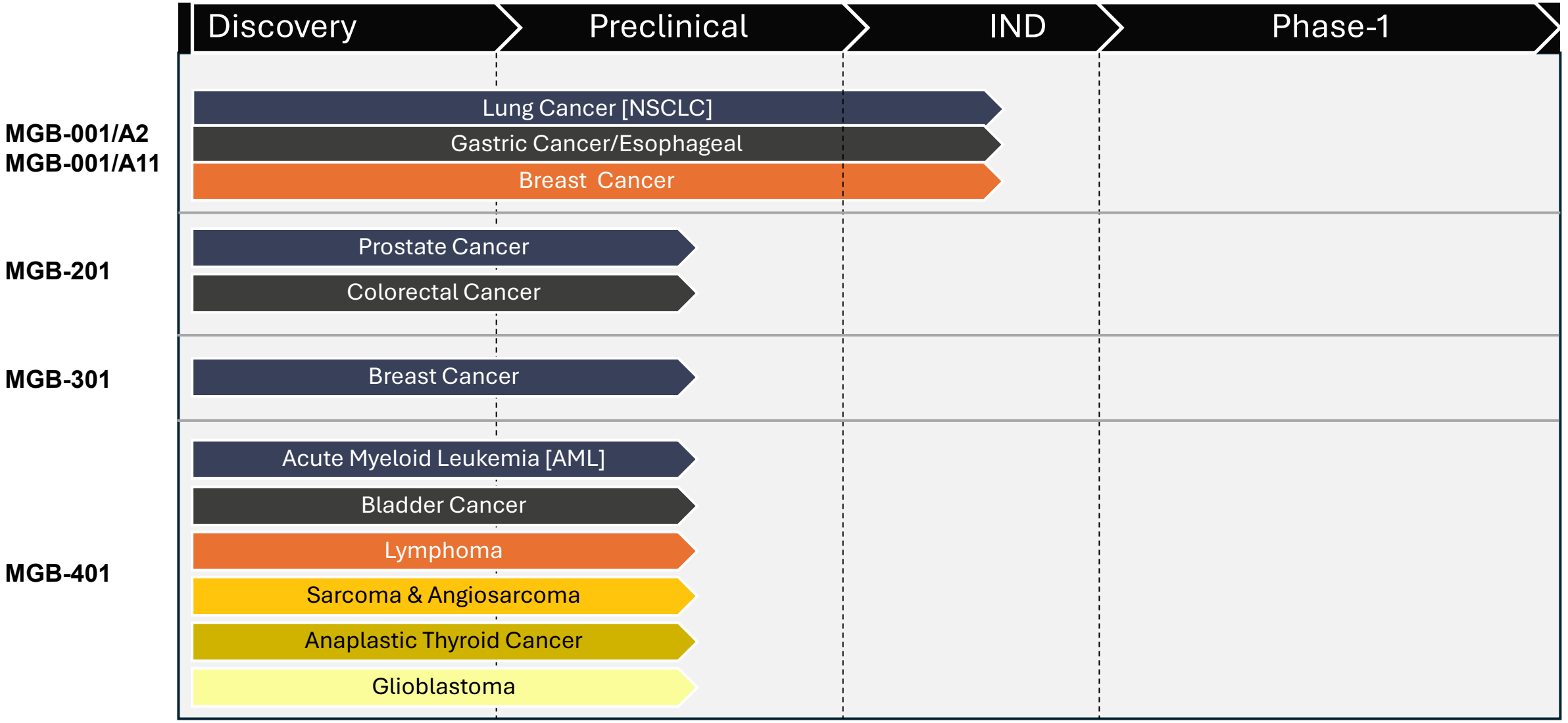
### ✓ Tumor Immunopeptidome Discovery Platform

- Identified bona fide tumor MHC-derived epitopes
- 250 high value TCR target epitopes empirically validated
- 4 top scoring targets that cover > 80% of Class I MHC (HLA) have been selected for the pipeline

### ✓ Epigenetic T-cell Reprogramming to create Memory T-cells persisting over months/years

- We generated *true* human central memory T cells
- Established in vivo persistence of Tcm for months-years
- We have demonstrated clinically proven durable anti-tumor responses
- Requires little to **no immunodepletion**

# Pipeline and Timeline



# Pipeline of Four Novel Cancer Targets

| Antigen | HLA Epitopes Defined | Common Cancers | Rare Cancers | T Cell Lines | TCR-T Viral Vector |
|---|---|---|---|---|---|
| MGB-001 | HLA-A2<br>HLA-A11 | Lung<br>SCCHN, Cervical, Bladder | Esophageal<br>Gastric | YES | YES (pre-clinical) |
| MGB-201 | HLA-A2<br>HLA-A24 | Prostate, TNBC, Lung, Colorectal | Chordoma | YES | YES (pre-clinical) |
| MGB-301 | HLA-A2<br>HLA-A3/A11 | Breast Cancer | | YES | YES (pre-clinical) |
| MGB-401 | HLA-A2 | AML, Bladder Cancer<br>Breast, Cervical, Esophageal,<br>Lymphoma, Sarcoma | Angiosarcoma.<br>Anaplastic Thyroid Cancer<br>Glioblastoma | YES | YES (pre-clinical) |

- Lead program (targeting MGB-001) is available for both HLA-A2+ and HLA-A3/A11+ patients
- Targets MGB-201, MGB-301 and MGB-401 were selected for prevalence across tumor types, immunogenicity and functional upregulation in resistant tumors
- Targets MGB-201 and MGB-401 have been shown to display high intra-tumoral expression and high prevalence among rare cancer types

# Mongoose advantages and Process flow

- **TCR-T therapy, or T-cell receptor-engineered T cell therapy**, is a form of adoptive cell therapy

  A cutting-edge approach where the patient's own T cells, (white blood cells) crucial for the immune response, are genetically modified to better recognize and attack cancer cells.

  Unlike **CAR-T (chimeric antigen receptor T-cell)** therapy, which targets cell surface antigens, TCR-T therapy recognizes a broader set of **intracellular antigen fragments** presented by **MHC (major histocompatibility complex)** molecules.

- **Advantages**:

  **Broad Antigen Recognition**: TCR-T cells can recognize a wider range of tumor antigens, including those within the cell.

  **High Antigen Sensitivity**: TCRs exhibit high sensitivity to antigens, enhancing tumor cell detection.

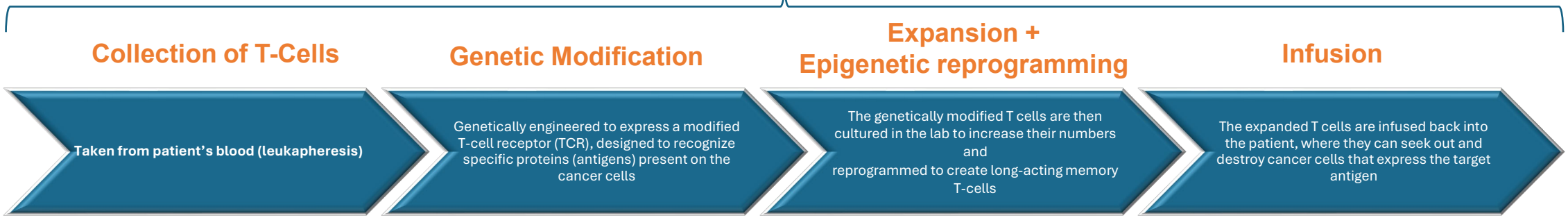
  **Near-Physiological Signaling**: TCR-T cells mimic natural T-cell responses.

- **Clinical Applications**:

  TCR-T therapies are being explored for various tumor antigen families.

  They hold promise for solid tumors, where CAR-T therapies have shown limited efficacy in solid tumors

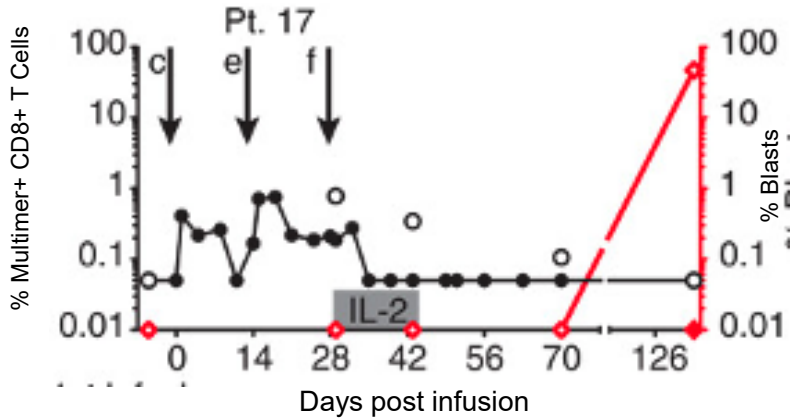
## Mongoose Process



# MB-001 A2/A11
# TCR-T for Common & Rare Solid Tumor Malignancies

# Clinical Evidence of Tcm Epigenetic Reprorgramming

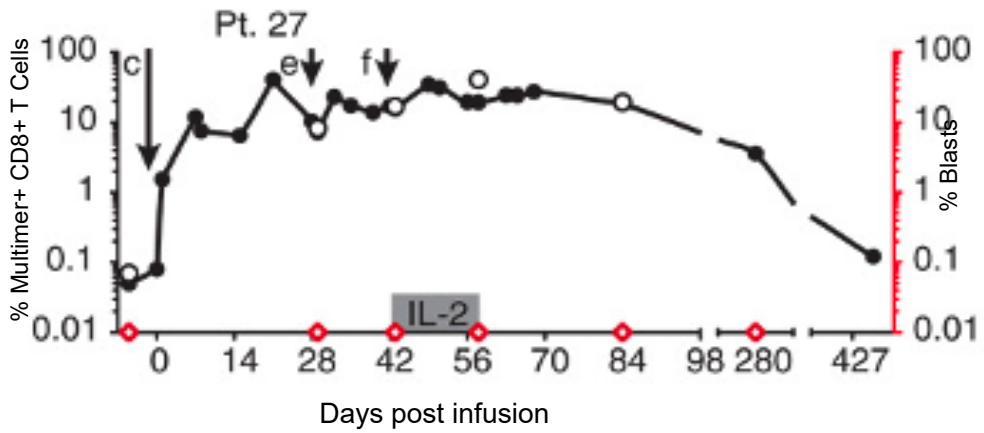
## *Untreated WT1-specific $T_{eff}$ CTL*




CTL infusion
CTL frequency
Leukemic fraction

Patients receiving $T_{eff}$ CTL for high-risk AML relapse when WT1-CTL do not persist

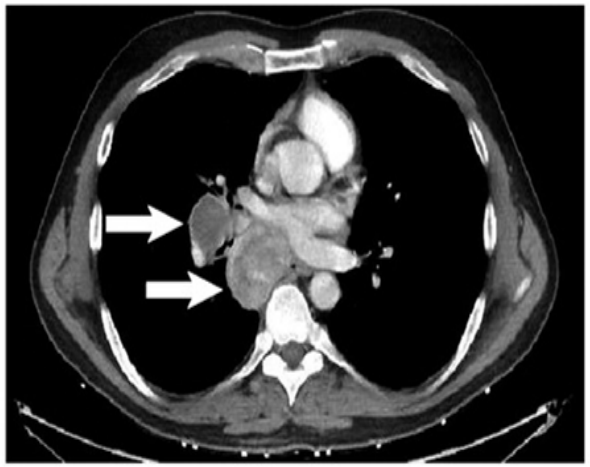
## *WT1-specific $T_{cm}$ CTL*

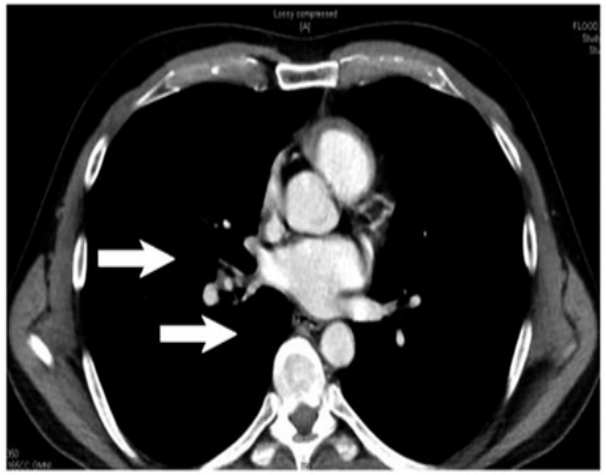


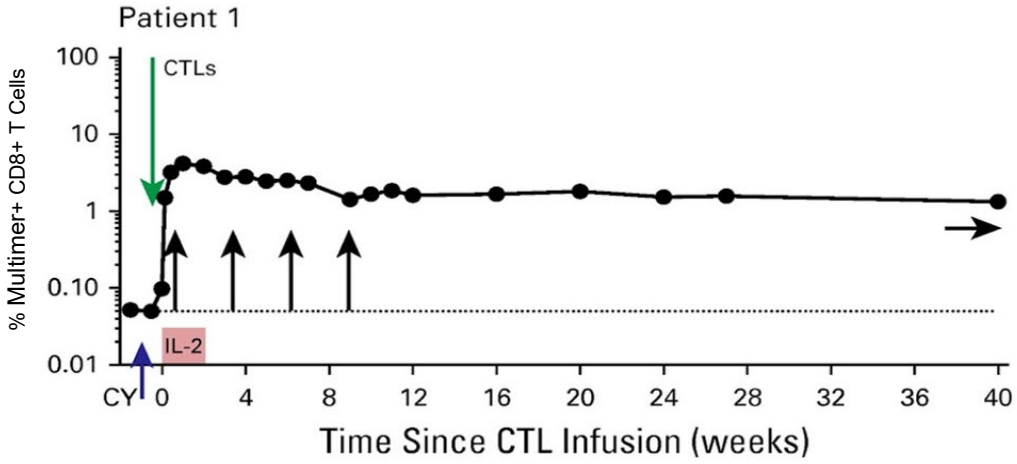

Patients receiving WT-1 specific Tcm CTL remain in CR; WT1-specific CTL persist

# Epigenetic Reprogramming Leads to Persistance

## Memory T cells in combination strategies eradicate metastatic cancer








Patient failing anti CTLA4 monotherapy, Rx with MART-1 specific Tcm + ICI ➡ complete response of intrathoracic metastases

MART-1 specific Tcm persist long term (> 40 weeks)

Chapuis A…Yee C *J. Clin Onc 2017*

# MGB-001 Novel Target Expression

## MGB-001: Validated as a target, unexploited in solid organ treatment

- Lead candidate: MGB-001 is a classic cancer-testis antigen
  - Over 60% in breast cancer
  - Approximately 45% in prostate, lung, bladder, gastric, ovarian, head/neck cancers
  - Presented by both HLA-A2 and A3/A11 subtypes representing >60% of all Western & Asian cancer patients
- No previously known epitopes; not previously targeted. Well characterized tumorigenic function
- Highly tumor selective and tumorigenic
  - Associated with epithelial mesenchymal transformation (EMT) and DNA repair following radiation and chemotherapy
  - Expressed at high levels across multiple common and rare cancers
  - Highly tumor-selective: restricted expression to germinal tissues and tumors

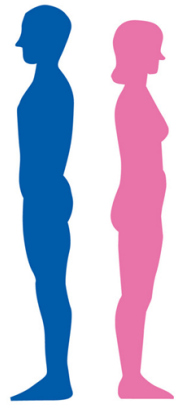
# Addressing Signifcant Unmet Need

## Unmet Medical Need

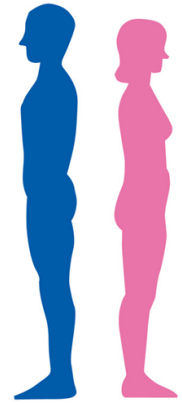
- Mongoose Bio is developing novel and differentiated adoptive T cell therapies to address common and rare cancer indications
- **Bold**: Phase 1b cancer targets

| Common | Rare |
|---|---|
| • Prostate | • Angiosarcoma |
| • Breast Cancer | • Anaplastic Thyroid |
| • **Lung** | **Esophageal** |
| • Colorectal | • Chordoma |
| • Bladder Cancer | • **Gastric / Stomach** |
| • AML | • Glioblastoma |
| • Cervical | |
| • Lymphoma | |
| • Sarcoma | |

**Estimated New Cases**

| | | | Males | Females | | | |
|---|---|---|---|---|---|---|---|
| Prostate | 248,530 | 26% |  |  | Breast | 281,550 | 30% |
| Lung & bronchus | 119,100 | 12% | | | Lung & bronchus | 116,660 | 13% |
| Colon & rectum | 79,520 | 8% | | | Colon & rectum | 69,980 | 8% |
| Urinary bladder | 64,280 | 7% | | | Uterine corpus | 66,570 | 7% |
| Melanoma of the skin | 62,260 | 6% | | | Melanoma of the skin | 43,850 | 5% |
| Kidney & renal pelvis | 48,780 | 5% | | | Non-Hodgkin lymphoma | 35,930 | 4% |
| Non-Hodgkin lymphoma | 45,630 | 5% | | | Thyroid | 32,130 | 3% |
| Oral cavity & pharynx | 38,800 | 4% | | | Pancreas | 28,480 | 3% |
| Leukemia | 35,530 | 4% | | | Kidney & renal pelvis | 27,300 | 3% |
| Pancreas | 31,950 | 3% | | | Leukemia | 25,560 | 3% |
| **All Sites** | **970,250** | **100%** | | | **All Sites** | **927,910** | **100%** |

**Estimated Deaths**

| | | | Males | Females | | | |
|---|---|---|---|---|---|---|---|
| Lung & bronchus | 69,410 | 22% |  |  | Lung & bronchus | 62,470 | 22% |
| Prostate | 34,130 | 11% | | | Breast | 43,600 | 15% |
| Colon & rectum | 28,520 | 9% | | | Colon & rectum | 24,460 | 8% |
| Pancreas | 25,270 | 8% | | | Pancreas | 22,950 | 8% |
| Liver & intrahepatic bile duct | 20,300 | 6% | | | Ovary | 22,950 | 5% |
| Leukemia | 13,900 | 4% | | | Uterine corpus | 12,940 | 4% |
| Esophagus | 12,410 | 4% | | | Liver & intrahepatic bile duct | 9,930 | 3% |
| Urinary bladder | 12,260 | 4% | | | Leukemia | 9,760 | 3% |
| Non-Hodgkin lymphoma | 12,170 | 4% | | | Non-Hodgkin lymphoma | 8,550 | 3% |
| Brain & other nervous system | 10,500 | 3% | | | Brain & other nervous system | 8,100 | 3% |
| **All Sites** | **319,420** | **100%** | | | **All Sites** | **289,150** | **100%** |

Siegel, RL, Miller, KD, Fuchs, H, Jemal, A. Cancer Statistics, 2021. CA Cancer J Clin. 2021: 71: 7-33. https://doi.org/10.3322/caac.21654

# Phase 1b Clinical Trial Design

- Phase IB basket trial targeting MGB-001-associated tumors
- An expansion cohort is planned that will include gastric, esophageal and non small cell lung cancers
- Combining gastric, esophageal, and lung cancers into one trial was done for several strategic reasons:
    1. Unmet need and global and sector prevalence
    2. Opportunity for a Breakthrough Designation
    3. High accrual rates and catchment area

**Global New Cases and Deaths (2020)**

| Site | New Cases (% of All Sites) | New Deaths (% of All Sites) |
|---|---|---|
| Lung | 2,206,771 (11.4) | 1,796,144 (18.0) |
| Gastric | 1,089,103 (5.6) | 768,793 (7.7) |
| Esophageal | 604,100 (3.1) | 544,076 (5.5) |

- Gastric, esophageal and non-small cell lung cancers represent clinical unmet needs following 1st or 2nd line therapy as there are no standard treatment options
- Gastric and esophageal cancers are considered rare cancers in the US (< 40,000/yr) and effective therapies for rare cancer may receive ‘Breakthrough Therapy’ designation with the FDA
- Gastric and esophageal cancers are among the most lethal and prevalent cancers in SE Asia and globally
- Non small cell lung cancer is among the most lethal and prevalent cancers in US and globally
- The MD Anderson Investigational Cancer Therapeutics (ICT) Dept (PI David Hong) is designed for precisely this type of trial that includes more than one cancer type and receives feeder referrals from one of the largest cancer centers that sees patients with GI and thoracic malignancies

# Patient Selection

## Trial Eligibility

- Patients screened by IHC of tumor for MGB-001and HLA typing
- MGB001 + (>50) and HLA*0201+ (40%)
- Failing 1L or 2L or refractory with measurable disease will be eligible
- Patients undergo leukapheresis
- HMD1-TCRT cells manufactured at Cellipont Bioservices
- Dose Escalation ($10^8$ to $10^9$ cells/$m^2$)
- Dose Expansion for MTD + immune checkpoint inhibitor
- Dose Escalation patient accrual: up to 18
- Dose Expansion patient accrual: 12

# World-Class CMC & Clinical Support

- **Phase 1b trial site: MD Anderson**
  - Largest cancer treatment center ion the world
  - Specializes in rare and common tumors, high enrolling site, and specialized inpatient units.
  - Treated over 1000 patients with CAR-T and other cellular therapy regimens; more than any other academic institution in the world

- **Principle Investigator: David Hong, M.D.**
  - Deputy Chair, Department of Investigational Cancer Therapeutics
  - Has managed and overseen multiple cellular therapy trials

- **cGMP Manufacturing (CDMO):**
  - Partnered with Matica Bio (Texas) for Vector Manufacturing
  - Partnered with Cellipont (Texas) for cGMP T-cell Manufacturing
  - Strong expertise in tech transferring, industrializing the process, interacting with the FDA to assure phase appropriate adherence to all specifications

**Investors & Partners**

CPRIT

CANCER FOCUS FUND

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

Matica BIOTECHNOLOGY
Manufacturing Breakthroughs

Cellipont BIOSERVICES

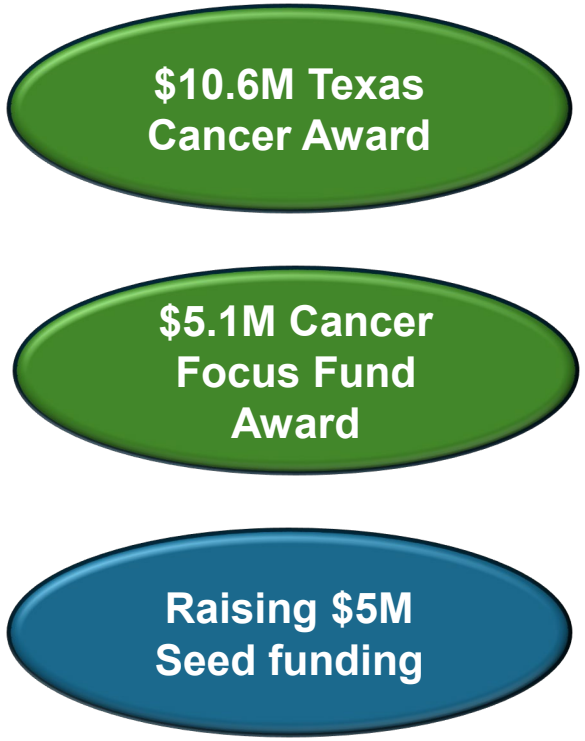
# Capital Formation

1. **Targeting $20M to advance first TCR-T through Phase 1 (generate first-in-human data)**
   - Awarded $10.6M from CPRIT
   - Term sheet for $5.1 from Cancer Focus Fund
   - Raising $5M seed round

2. **Use of Proceeds**
   - Complete IND preparation and submission
   - CMC
   - Hire key personnel
   - Conduct a Ph I clinical trial with MGB-001 in multiple cancers

3. **Future financing**
   - Global Partnership envisioned
   - Series A financing in 2026 to conduct expansion study and advance additional proprietary TCR-T therapeutic into clinic

## Validation



# Team: Management, Advisors, & Board

## Team

**Neil Warma, MBA**
Chief **Executive** Officer

- Former CEO | Genexine, I-Mab BioPharma, Opexa, Viron
- Senior Management | Novartis
- Director of the Board | BIO, and ProMIS Neurosciences

**Cassian Yee, MD**
Co-Founder
Chief **Scientific** Officer

- Endowed Professor | Medical Oncology & Melanoma
- Director| Solid Tumor Cell Therapy & TCR-based therapy
- Pioneer | Holds >15 patents on Adoptive Cell Therapy

**Oumar Diouf, MBA**
CMC

- 20 years experience with expertise in GMP manufacturing of Cell Therapy.
- Manager of CGT at BCM, Director of manufacturing at Cell Medica, and VP at Marker Therapeutics.

**Lori McDermott, MS.**
Regulatory & Clinical Operations

- 25 years experience in clinical research
- Founder, COO, and VP | Overseen numerous submissions & clearance of oncology INDs.

## Board

**Neil Warma**
Chief **Executive** Officer

**Katie Chudnovsky, JD**
Independent Director

## Advisors

**Donna Rill**
CMC Advisor

- Accomplished expert in CGT manufacturing leading the design and qualification of CGT laboratories, & cGMP vector production facilities. VP of manufacturing at Cell Medica & Director of Malcom Brenner CGT lab

**Shailbala Singh, Ph.D.**
Pre-Clinical and Laboratory Advisor

- 20+ years experience in pre-clinical & clinical research
- Extensive expertise in T Cell biology, and immunology.
- Group Scientist and Director | Biomarker discovery, novel technology platforms for precision medicine

**David Hong, MD**
MD Anderson Cancer Center

- Deputy Chair | Investigational Cancer Therapeutics
- PI Phase 1 clinical trial

**Andrew Strong, JD**
Licensing, Legal
Hogan-Lovells

- Experienced advisor and counsel to global life sciences, pharma, and emerging technology | Corporate formation, public/private finance, M&A, cross-border licensing, joint ventures, and IP

# Investment Highlights

| | |
|---|---|
| **Next Generation Cell Therapy Cancer Treatment** | Overcomes two key challenges<br>➢ Identified 4 novel, highly immunogenic, validated targets<br>➢ Reprogram T-cells to prevent T-cell exhaustion |
| **Lead Asset to Initiate Phase-1b in 9-Months** | MGB-001 Phase 1b trial is set for open-enrollment in the second half of 2025 at MD Anderson Cancer Center supported by the Cancer Focus Fund |
| **Strong Financial Support & Capital Management** | Phase 1 development of MGB-001 is supported by $10.6M CPRIT Product Development (non-dilutive) award and $5.1 from Cancer Focus Fund |
| **Experienced Team** | ➢ World-Class scientific founder, world leader in cancer therapy<br>➢ Global CEO with 20+ years of private and public company expertise |
| **Robust and enhanced cGMP Manufacturing** | ➢ Matica Bio partnership for streamlined vector production<br>➢ Cellipont partnership for cGMP manufacturing of T-cells |

Mongoose Bio

Revolutionizing
the treatment
of cancer.

# Thank You

info@mongoosebio.com

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