



**DELIVERING BREAKTHROUGH THERAPIES  
FOR THE TREATMENT OF BLOOD  
DISEASES**





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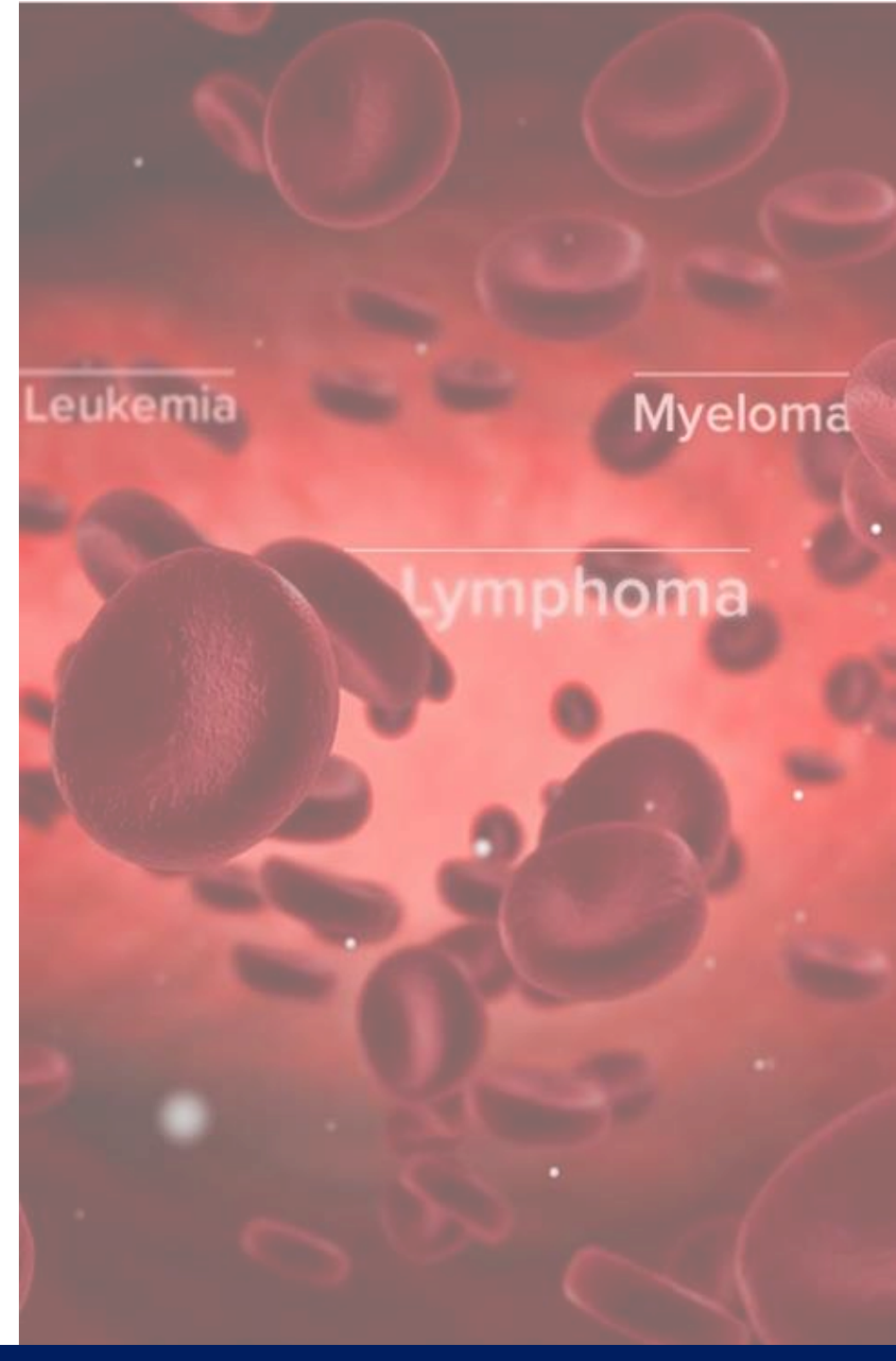
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# Company Overview

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- **Hemogenyx Pharmaceuticals: A Clinical Stage Drug Development Company Targeting Unmet Needs in AML, ALL, and Oncology with Three Groups Of Product Candidates:**
  - **HG-CT-1:** A proprietary, next-generation CAR-T therapy developed to provide a more effective and safer treatment for adult and pediatric patients with relapsed/refractory AML, and certain ALL subsets, by targeting FLT3 receptor CAR T-cell mediated cytotoxicity. HG-CT-1 has entered clinical trials.
  - **CDX:** A novel, humanized bi-specific antibody developed in collaboration with Eli Lilly. CDX is developed for selective targeting and elimination of FLT3<sup>+</sup> cells in relapsed/refractory AML, and subsets of ALL. IND-enabling studies are anticipated in 2026.
  - **Chimeric Bait Receptors (CBR):** A groundbreaking approach using synthetic proteins to reprogram myeloid immune cells, such as macrophages, for combating cancer and viral infections.
- **A Pipeline of Distinct Yet Complimentary Products:** Our diverse product portfolio is strategically powered by novel technologies that have the potential for groundbreaking product development.
- **Vertical Alignment Through Strategic Manufacturing Collaboration:** Program execution is strengthened by partnering with a CDMO specializing in cell therapy manufacturing, enabling seamless development and production of our product candidates.
- Founded in 2013 and listed on LSE since 2017 (LSE: HEMO), with its operations located in New York City at its state-of-the-art research and manufacturing facility

# Pipeline Overview



Modality	Program	Target	Indication	Discovery	Lead Optimisation	IND Enabling studies	Phase 1	Phase 2
Cell Therapy	HG-CT-1	FLT3	R/R AML adults	[Red bar spanning Discovery, Lead Optimisation, and IND Enabling studies]				
	HG-CT-1	FLT3	R/R AML, pediatric	[Red bar spanning Discovery, Lead Optimisation, and IND Enabling studies]				
	HG-CT-1	FLT3	ALL	[Red bar spanning Discovery, Lead Optimisation, and IND Enabling studies]				
	CBR	Undisclosed	GBM	[Red bar spanning Discovery and Lead Optimisation]				
	CBR	Undisclosed	R/R NHL	[Red bar spanning Discovery]				
	CBR	Undisclosed	R/R Multiple Myeloma	[Red bar spanning Discovery and Lead Optimisation]				
Biologics	CDX	CD3-FLT3	R/R AML	[Red bar spanning Discovery, Lead Optimisation, and IND Enabling studies]				
	CBR	Undisclosed	R/R Multiple Myeloma	[Red bar spanning Discovery and Lead Optimisation]				
	CBR	Undisclosed	Epithelial Ovarian Carcinoma	[Red bar spanning Discovery]				
	CBR	Undisclosed	Other Solid Tumors	[Red bar spanning Discovery]				

IND-enabling studies in H1 2026-H2 2026  
 Ph1 initiation in H2 2027  
 WW exclusive license from Lilly

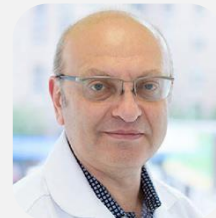
# Leadership Team



**Sir Marc Feldmann**  
*Chairman*



- Medicine and PhD in Immunology from the Walter and Eliza Hall Institute of Medical Research
- Discovered the pivotal role of TNF in rheumatoid arthritis and led development of anti-TNF antibodies, the world's best selling drug class
- Received multiple prizes for his discovery including Crafoord prize in Sweden, **Albert Lasker Clinical Medical Research Award (2003)**, and Canada-Gairdner award



**Vladislav Sandler, PhD**  
*Chief Executive Officer,  
Co-Founder*



- Widely published stem cell scientist with decades of experience in scientific research at world leading institutes such as Children's Hospital at Harvard Medical School, the Salk Institute for Biological Sciences, Harvard University, Albert Einstein College of Medicine, and Weill Cornell Medical College as well as Advanced Cell Technologies, Inc
- Awarded the inaugural Daedalus Fund Award for Innovation at Cornell



**Peter Redmond**  
*UK-based Director*



- Over 30 years' experience in corporate finance and venture capital
- Has reconstructed AIM companies which have subsequently been acquired and established operating businesses
- Director of Gem Resources plc



**Alexis M. Sandler, JD**  
*Non-Executive Director,  
COO & Co-Founder*



- Co-founder and COO in US
- Attorney specialising in IP
- Over 20 years of experience representing a range of companies and institutions

# Scientific, Clinical, Business Advisors and Team Principals



**H. Michael Shepard, PhD**



Genentech

- PhD in Cellular Molecular Developmental Biology
- Discovered importance of HER2 in tumor resistance and developed trastuzumab/Herceptin to treat breast cancer
- **In 2019 received Albert Lasker-De Bakey Clinical Research Award** for discovery of trastuzumab/Herceptin
- Warren Alpert Prize for treatment of breast cancer

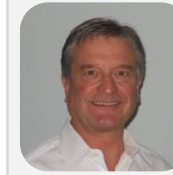


**Koen van Besien, MD**

University Hospitals  
The Science of Health. The Art of Compassion.



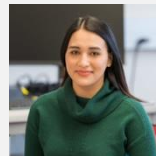
- Professor of Medicine and Director of the Stem Cell Transplant Program at the NYP-Weill Cornell College of Medicine
- Developed novel methods of transplantation for patients who lack matching donors
- >200 publications in peer reviewed journals
- Editor in Chief of the journal Leukemia and Lymphoma



**Alan Walts, PhD**



- Venture Partner at Advent Life Sciences, Director at Eloxix, Executive Chairman of Artax
- 25 years Genzyme in BD, business strategy, R&D, management of Genzyme's corporate venture fund, Genzyme Ventures (now Sanofi Ventures)
- Founder and director of The Termeer Foundation

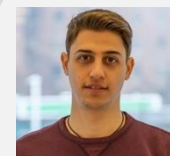


**Elina Shrestha, PhD**  
*Director of Preclinical Development*



NYU Grossman  
School of Medicine

- PhD in Cellular Molecular Biology
- Developed HEMO-CAR-T prototype
- Supervised IND-enabling studies and filing IND for HEMO-CAR-T



**Ronen Ben Jehuda, PhD**  
*Principal Scientist*

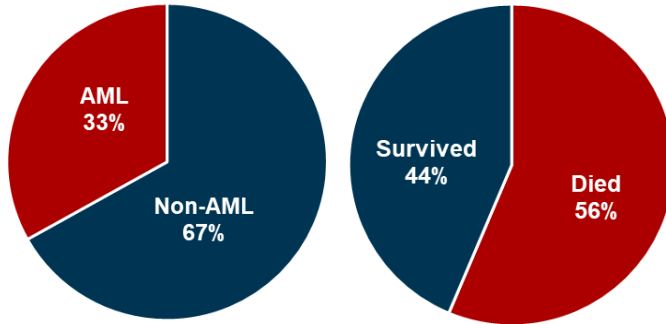


- PhD in Physiology
- Responsible for the development of CBR
- Responsible for the development manufacturing of HEMO-CAR-T

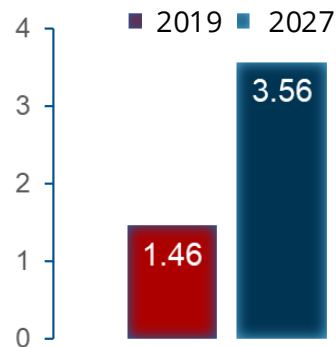


# AML Market, Treatment Paradigm, Unmet Need

Estimated 61,090 cases of leukemia diagnosed in the US in 2021\* 20,240 new cases of AML diagnosed in the US in 2021\*

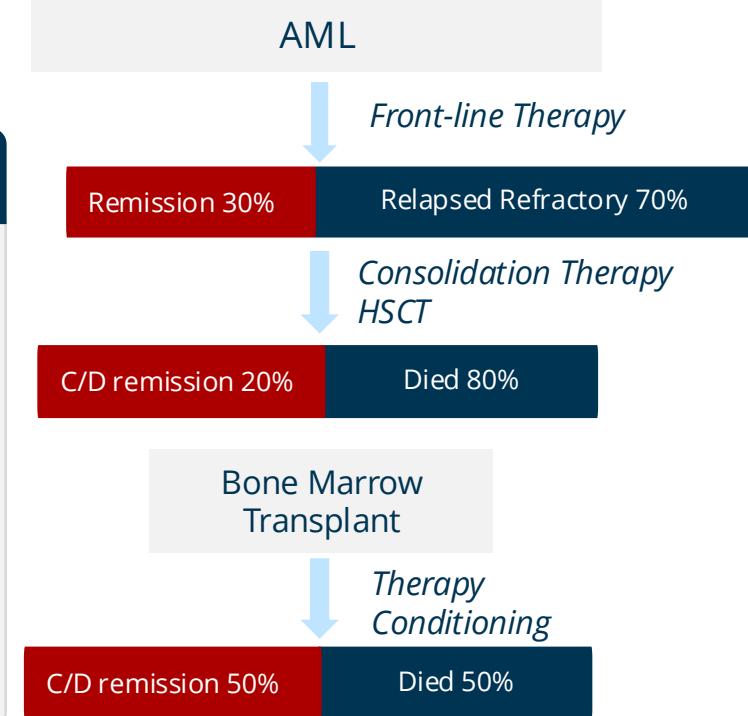


Global market Size in US\$ Billion\*\*  
CAGR = 13.1%



## r/r AML is Almost Universally Fatal

- Most patients lack sensitivity to currently available therapies
- The only curative treatment is allogeneic HSCT but:
  - Poor outcomes following allogeneic HSCT
  - Less than 50% success rate in patients with chemo-refractory disease



***A Bone Marrow or Hematopoietic Stem Cell Transplant (HSCT) is a potentially life-saving option in treating blood diseases such as Relapsed or Refractory Acute Myeloid Leukemia***

**Hemogenyx Pharmaceuticals is currently developing therapies to address unmet need in the treatment of AML**

C/D: Complete/durable remission

\* <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>

\*\* <https://www.globenewswire.com/news-release/2020/07/22/2066107/0/en/Acute-Myeloid-Leukemia-Therapeutics-Market-To-Reach-USD-3-56-Billion-By-2027-Reports-And-Data.html>



## **CAR-T program**

*for treatment of relapsed/refractory  
Acute Myeloid Leukemia*



# HG-CT-1: a novel CAR-T therapy for AML



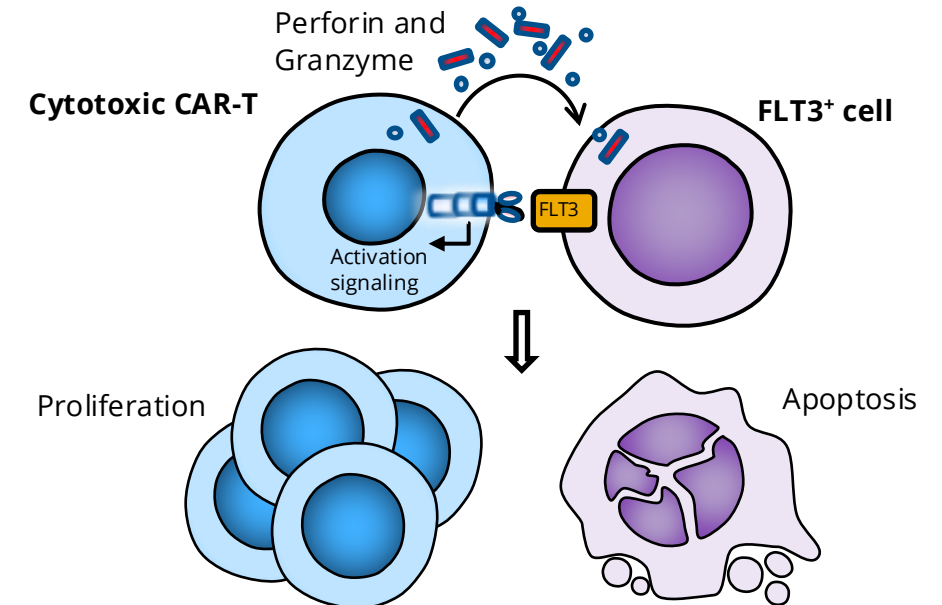
## Autologous 3<sup>rd</sup> generation CAR-T therapies:

- **Mechanism of Action:** cytotoxic T lymphocyte (CTL)-mediated cytotoxicity
- Clinically proven safety<sup>1</sup>
- Established Freedom to Operate

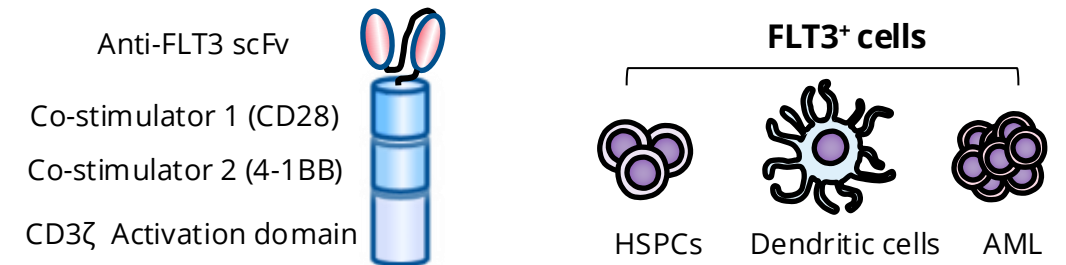
## HG-CT-1:

- Targeting FMS-like tyrosine kinase 3 receptor (**FLT3**) which is highly expressed by AML blasts in a majority of patients
- Improved vector design for **safety**
- **Proprietary** anti-FLT3 humanized **antibody** (scFv)
- **No off-target** binding other than FLT3
- **No FLT3 Ligand (FLT3L) competition**, avoiding possible reduction of HG-CT-1 efficacy
- Proven ***in vitro*** and ***in vivo*** antitumor activity
- **Phase 1:** three patients dosed, DSMB cleared dose escalation; Pediatric arm is ready to start patient recruitment

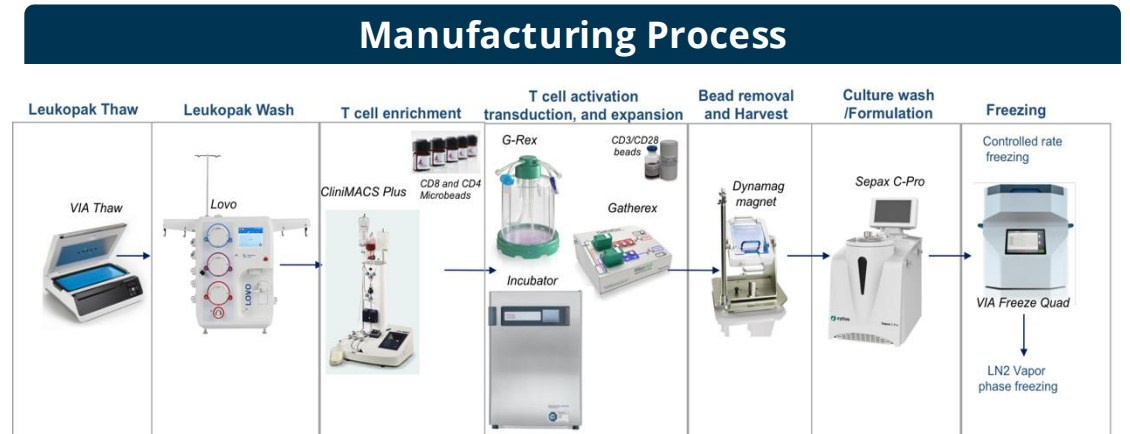
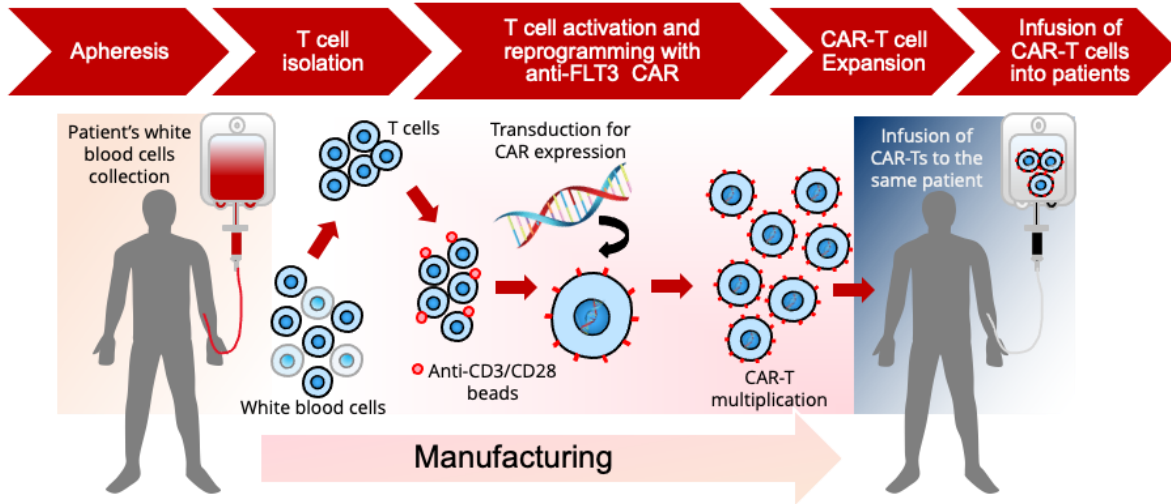
## CAR-T mediated cytotoxicity



## CAR structure



# HG-CT-1: an Autologous CAR-T Therapy; Manufacturing



Modality	Area	Program	Target	Indication	Discovery	Lead Optimisation	IND Enabling studies	Phase 1	Phase 2
Cell Therapy	Oncology	HG-CT-1	FLT3	R/R AML (adults)	Completed			IND opened in Q1 2024 Phase I initiated in H1 2025	
Cell Therapy	Oncology	HG-CT-1	FLT3	R/R AML (children)	Completed			IND amendment Q2 2025 Phase I initiation in H2 2025	

# HG-CT-1: Clinical Development Strategy



## Development Goal – Cure patients suffering from R/R AML

- For adult patients with R/R AML
- For pediatric patients with R/R AML

## Clinical positioning

- Single administration of HG-CT-1 to FLT3+ R/RAML patients

## Trial design

- Phase 1 dose escalation study to determine the safety of HG-CT-1 cells in subjects with relapsed/refractory AML
- Up to 18 evaluable adult and pediatric subjects defined as those who have received an infusion of HG-CT-1

## Primary clinical objective

- Determine the **safety of HG-CT-1** based on the proportion of subjects infused with HG-CT-1 who experience dose limiting toxicity (DLT)

## Secondary clinical objectives

- **Efficacy** of HG-CT-1 according to standard clinical response criteria for AML
- **Overall survival** of evaluable subjects
- **Progression-free** survival of evaluable subjects
- **Duration of response** in evaluable subjects who achieve a response.

## Secondary scientific objectives

**Persistence and trafficking** of HG-CT-1  
**HG-CT-1 bioactivity**

## Phase I trial 12-18 months

- Clinical development initiated at MD Anderson Cancer Center (MDA)
- PI of the study is Dr. Nicholas Short
- Pediatric expansion of the trial is cleared and to be conducted at MDA

## Phase II trial expected to start in 12-24 months

- Expected to be designed and sized to support accelerated approval with Phase III as pivotal trial

## Primary clinical objective of Phase II

- **Efficacy** of HG-CT-1 according to standard clinical response criteria for AML
- **Duration of response** in evaluable subjects who achieve a response
- **Overall survival** of evaluable subjects
- **Progression-free** survival of evaluable subjects

# Phase 1 Study of HG-CT-1 in Adults and Children with Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML)



Designed to establish safety and early signal in a high-mortality AML population with limited treatment options

## Study Overview

- Phase 1 3+3 modified dose escalation study in **R/R AML**
- Evaluating **safety** and preliminary efficacy
- Includes **adult** and **pediatric** (12-18 years old) patients

## Endpoints

### Primary

- **Safety and tolerability**
- **Dose-limiting toxicities (DLTs)**

### Secondary

- Clinical response
- Duration of response (DoR)
- Overall survival (OS) and progression-free survival (PFS)

### Exploratory

- CAR T persistence and expansion
- CAR T trafficking and biological activity

## Treatment Approach

- **Autologous FLT3-directed CAR T (HG-CT-1)**
- Study workflow:

Leukapheresis > manufacturing > lymphodepletion > infusion

- **Three dose levels** evaluated (up to  $3.5 \times 10^8$  CAR<sup>+</sup> cells)
- Stepwise dose escalation based on observed safety

Initial data validate safety, feasibility, and early activity supporting continued clinical development and dose escalation

## Safety Profile (Lowest Dose Cohort)

- 3 patients treated
- 36 adverse events observed
  - 2 treatment-related
  - 1 considered serious
- No dose-limiting toxicities

**Favorable initial safety profile supports continued dose escalation**

## Early Clinical and Biological Activity

- Evidence of bone marrow blast reduction in evaluable patients
- CAR T expansion and persistence observed
- Early signals of **biologic activity at lowest dose level**

**Supports potential for efficacy at higher dose levels**

## Operational Feasibility

- 3/3 successful manufacturing runs for R/R AML patients
- 3/3 patients infused

**Demonstrates reliable manufacturing and clinical execution**

# HG-CT-1 – Clinical Plan



Activity	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Phase I (adults):</b> <ul style="list-style-type: none"> <li>Safety</li> <li>Potential efficacy</li> </ul>					
<b>Phase I (pediatric)</b> <ul style="list-style-type: none"> <li>Safety</li> <li>Potential efficacy</li> </ul>					
<b>Phase II (adults)</b> <ul style="list-style-type: none"> <li>Efficacy</li> <li>Duration of response in evaluable subjects who achieve a response</li> <li>Overall survival of evaluable subjects</li> <li>Progression-free survival of evaluable subjects</li> </ul>			 Registration/Phase III	 Registration/Phase II	
<b>Phase II (pediatric)</b> <ul style="list-style-type: none"> <li>Efficacy</li> <li>Duration of response in evaluable subjects who achieve a response</li> <li>Overall survival of evaluable subjects</li> <li>Progression-free survival of evaluable subjects</li> </ul>			 Registration/Phase III	 Registration/Phase III	

★ Potential to accelerate into Phase II if no DLT in three cohorts and efficacy signal

★ Pivotal Phase III clinical trial



## **CDX program**

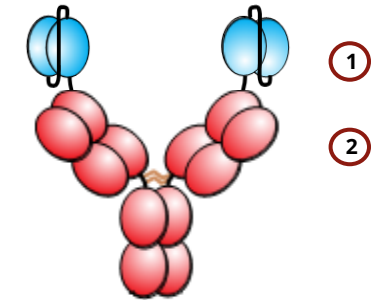
*for treatment of relapsed/refractory  
Acute Myeloid Leukemia*



# CDX: a Novel Humanized FLT3-CD3 Bispecific Antibody



- An “**off the shelf**” (non patient-specific) product
- **Eliminates AML-derived cells** transplanted into humanized mice and **conditions** humanized mouse bone marrow *in vivo*
- **High affinity** binding to FLT3
- **No FLT3 Ligand (FLT3L) competition**
- **Unique bi-specific structure:** bi-valent FLT3 and bi-valent CD3 binding
- **Highly Potent** and allows to **target low-FLT3 expressing cells** of different sizes
- **Designed to minimize** potentially dangerous non-specific T-cell activation
- **Cross-reacts with Rhesus monkeys** that will be used for further *in vivo* testing
- **Functional synergy** with epigenetic modifying drugs, BET inhibitors and checkpoint inhibitors or conditioning regimens for HSCT
- **Market Expansion:** effective and non-toxic conditioning would extend the use of HSCT to older and more frail patients and potentially target several additional indications including autoimmune and rare genetic disorders
- Exclusively licensed global rights and developed in **collaboration with Eli Lilly**



- ① Binds to FLT3 (HSC, AML, DC)
- ② Binds to CD3 (T cells)

# CDX: Potential Path to IND and Clinical Plan



Activity	Year 1	Year2
<b>Preclinical ADME/toxicology studies Rhesus monkeys (cross-reactive species) to demonstrate:</b> <ul style="list-style-type: none"> <li>• Safety</li> <li>• Potential for functional activity (elimination of HSC/HP)</li> </ul>		
<b>Establishment of master cell line, process development and formulation</b>		
<b>Preparation cGMP material, release testing and stability</b>		
<b>IND Enabling Studies</b>		
<b>Pre-IND Meetings</b>		

## Clinical Plan

- Initial clinical study to be conducted in relapsed or refractory FLT3<sup>+</sup> AML and ALL patients pre-qualified for HSC/HP transplantation to obtain preliminary data on safety (dose escalation), tolerability (expected initiation in 2027)
- The study will be expanded into pediatric R/R AML and KMT2A rearranged acute lymphoblastic leukemia (ALL)
- Potential upside for early signal of activity demonstrated as:
  - Elimination of malignant cells (FLT3<sup>+</sup> AML)
  - Elimination of HSC/HP (myeloablative conditioning)



# Chimeric Bait Receptor Platform



# CBR Program

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A **novel paradigm** for targeting **Cancer, Neurodegenerative disease** treatments and creating **Antivirals**

Mechanism of action: Programming or redirection of myeloid immune cells such as macrophage using novel synthetic proteins

Expected significant advantages:

**As CBR-programmed macrophages:**

- a. Penetrate solid tumors
- b. Modulate solid tumor microenvironment for better efficacy
- c. Better safety profile than standard-of-care treatments
- d. Immunize host against targeted malignant cells

**As Antivirals:**

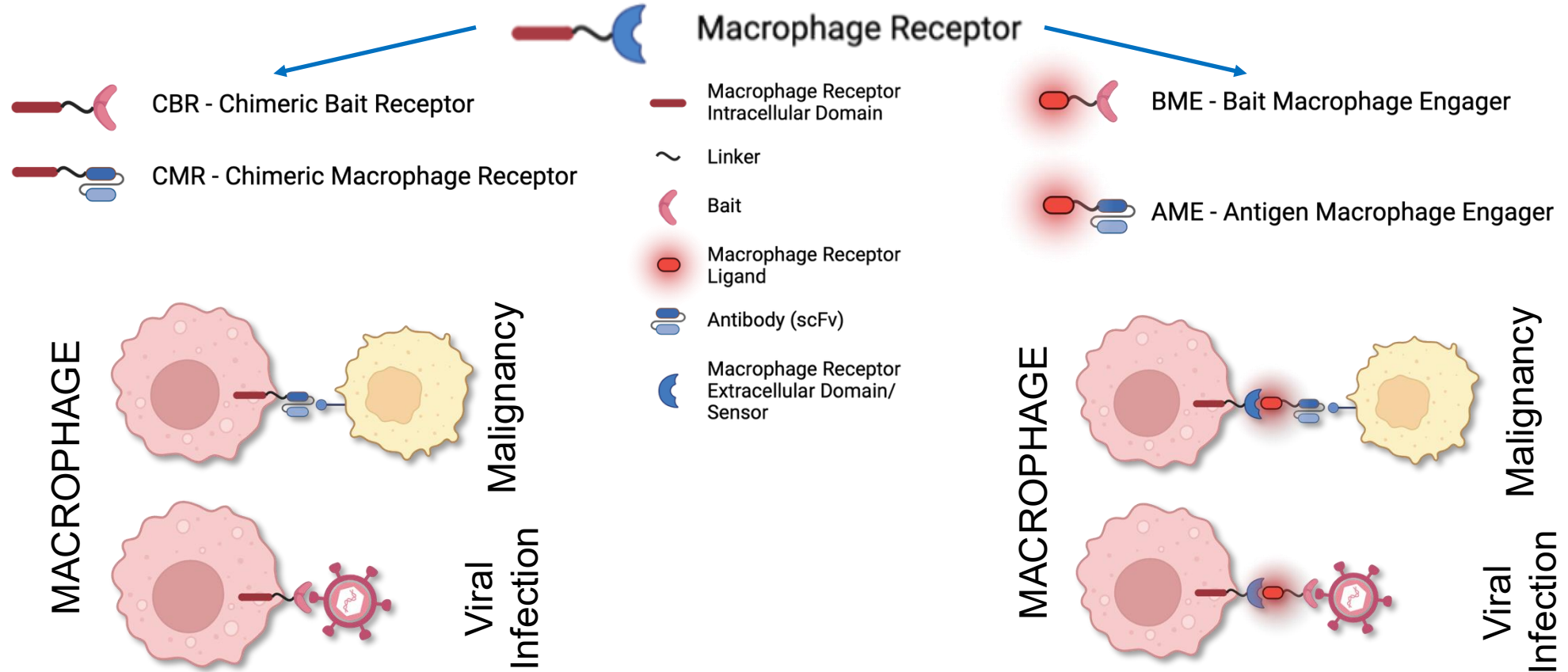
- a. Single therapeutic targeting multiple viral infections
- b. Long shelf life at ambient temperature
- c. Easy deployment/administration at ambient temperature

# Synthetic Macrophage Receptors - Design Concepts



## Cell Therapy

## Biologics





# Intellectual Property



# Intellectual Property Position

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- Hemogenyx has a strong Intellectual Property position and know-how
- Patents cover compositions of matter and methods of use for the CAR-T and CDX programs, in major jurisdictions
- In addition, other granted US patents are:
  - *"Method of eliminating hematopoietic stem cells/hematopoietic progenitors (HSC/HP) in a patient using bi-specific antibodies"*
  - *"Post-natal hematopoietic endothelial cells and their isolation and use"*
- Seminal patent application (current PCT) covering CBR platform
- More are in prosecution or planned to be filed in 2025-2026
- Patent protection is expected to around 2037-2042, excluding any potential extensions or further applications
- Freedom to operate has been conducted for all current product candidates

# Company Foundation



## Our Mission: A Focus on Solutions Not Just Technology

From day one, Hemogenyx Pharmaceuticals was founded with a clear purpose:

- To create new products that solve real, unmet medical needs
- To develop therapies that directly address life-threatening diseases
- To drive innovation not for its own sake, but to cure patients

Unlike many biotech companies that prioritize technology development, our approach has always been **product-first**—leveraging cutting-edge science only as a means to an end: **creating life-saving treatments**.

## Our Scientific Foundation: Integrating Expertise to Solve the Toughest Challenges

As a co-founder, I brought together my expertise in:

- Stem cell biology
- Studies of hematopoietic system
- Cell reprogramming
- Mathematical modeling of neural networks

Unlike many biotech companies that prioritize **technology development**, our approach has always been **product-first**—leveraging cutting-edge science only as a means to an end: **creating life-saving treatments**.

## The Power of Self-Selected Team

While my expertise laid the foundation for the company, our ability to **generate transformative ideas and translate them into life-saving therapies** would have been **impossible without the extraordinary team we were able to assemble**

- A team of superlative, self-selected scientists and professionals who have greatly expanded my own knowledge and expertise.
- Their insights, dedication, and ingenuity have been instrumental in not just developing new ideas, but in **turning those ideas into tangible, potentially life-saving therapies**.
- Hemogenyx Pharmaceuticals is a collective effort, built on a shared commitment to revolutionizing medicine

*We innovate not for the sake of innovation, but to cure disease and save lives. Without the incredible people at Hemogenyx Pharmaceuticals, this would be impossible.*

## Our Competitive Edge

- First-in-class therapies – Unique HG-CT-1, CDX and CBR programs
- Strong IP & proprietary technologies
- A world-class team

## Looking Ahead

- Accelerating clinical trials for HG-CT-1
- Continuing to develop transformative products that address critical health challenges
- Expanding manufacturing capabilities

# Summary



## Advancing product candidates towards the clinic

- HG-CT-1 therapy for the treatment of relapsed/refractory AML and subset of ALL in adults and pediatric patients; IND cleared by US FDA and Phase I trial is initiated, first patient treated, second patient consented.
- CDX bi-specific antibody for the treatment of relapsed/refractory AML, subset of ALL in adults and pediatric patients and conditioning of bone marrow transplantation; developed in collaboration with Eli Lilly & Co. with exclusive world-wide license
- CMR (Chimeric Macrophage Receptor) and BME (Bait Macrophage Engager) for rare cancers

## Conclusion

- Experienced team
- Established in-house capability for program execution
- Deep translational program pipeline
- HG-CT-1 is advanced to the clinic
- Large and fast-growing market (>\$1.5B p.a. for two leading product candidates)
- Strong IP portfolio
- Proprietary Chimeric Bait Receptor platform for treatment of rare cancers and emerging viral infections



**Thank You!**

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