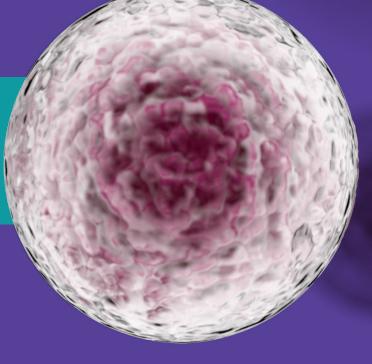
# CO celularity



# THE NEXT EVOLUTION IN CELLULAR MEDICINE

July 2021

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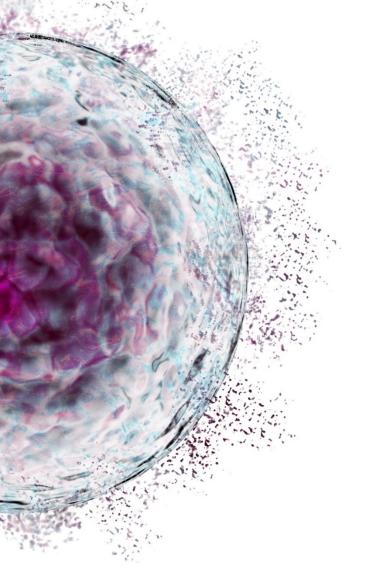
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## **OUR VISION**

Next Evolution in Off-the-shelf Allogeneic Cellular Therapies, at Greater Scale & Quality with Attractive Economics





# To harness the placenta's unique biology and ready availability to develop therapeutic solutions

## Lead the evolution in placental-derived therapeutics:

advance the discovery of the placenta as a limitless, renewable source of neonatal cells, which are biologically preferred to cells from adult bone marrow or peripheral blood

## Target large markets with high unmet need:

broad therapeutic application including cancer, degenerative, and infectious diseases

## **Develop safe and effective therapies:**

leverage inherent advantages of placental-derived cells to produce uniform, scalable and optimized cellular therapies

## **Deliver off-the-shelf, cost effective therapies:**

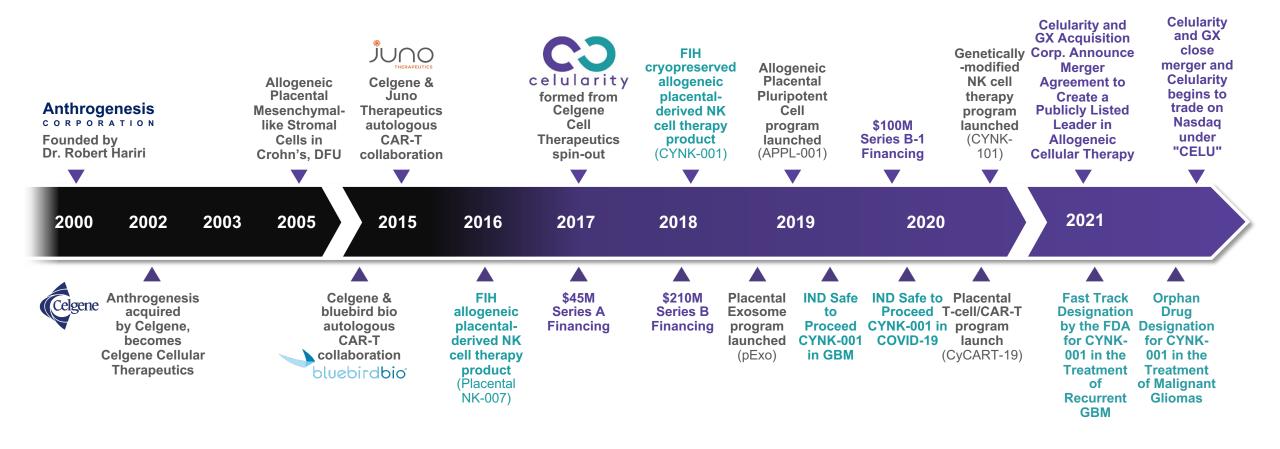
cryopreserved allogeneic cellular therapies that clinicians can access on demand and off-the-shelf, enabling repeat dosing/multiple cycles as required in an outpatient setting



- Robust preclinical differentiation, encouraging clinical data and rapid path to approval
- 2 Broad pipeline of novel, investigational product candidates across therapeutic areas and indications of high unmet need
- **3** Proprietary placenta-based platform developed over a 20-year history
- 4 Purpose-built 150,000 sqft cell manufacturing facility with a highly scalable and optimized production process
- 5 Strong intellectual property portfolio with over 1,500 issued and pending patents worldwide
- 6 Experienced management team with deep expertise in cell therapy to advance the Company

# **CELULARITY: COMPANY HISTORY**

Celgene Spin-out (2017) Leveraging 20+ Years of Cellular Therapeutics Innovation

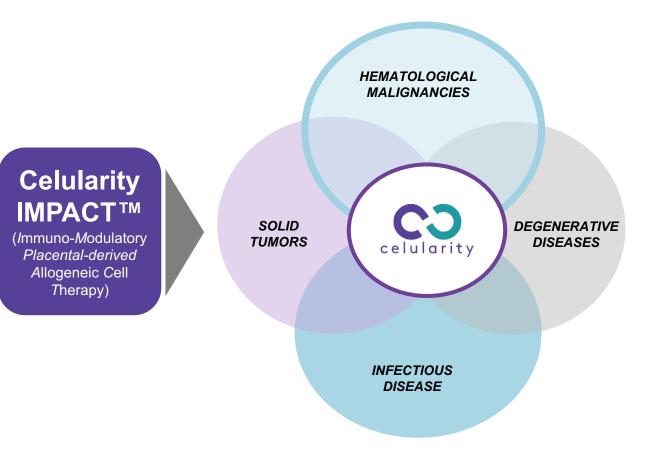


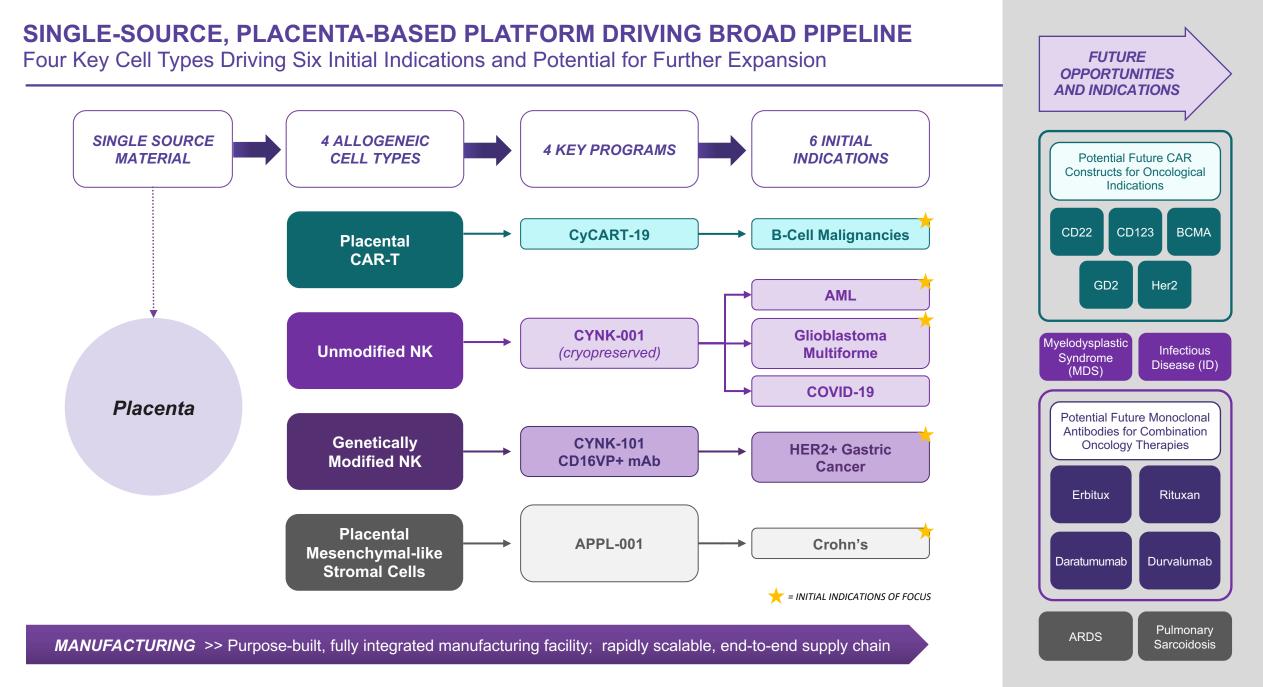
## **CELULARITY IMPACT™ PLATFORM**

## Capitalizing on the Benefits of Placental-Derived Cells to Target Multiple Diseases

#### INHERENT ADVANTAGES OF PLACENTAL-DERIVED CELLS

- ✓ Abundant and evergreen starting cell source for allogeneic off-the-shelf therapies
- High expandability, persistence and stemness
- Can be administered off-the-shelf, as this abundantly available source material possesses a low potential to provoke an immune response
- No requirement for matching between a patient and donor
- Innate stemness represent a flexible foundation that can be repeatedly genetically modified without losing potency
- ✓ 100-100K doses of therapeutic per placenta





## PIPELINE

Overview

CELL TYPE	PROGRAM	INDICATION	2021	2022
CAR-T	CyCART-19	B-Cell Malignancies	IND Submission	Phase I Phase II
Unmodified Natural Killer Cell	<b>CYNK-001</b> (cryopreserved)	Acute Myeloid Leukemia (AML)	Phase I	Phase II
Genetically Modified Natural Killer Cell	CYNK-101 + mAb	HER2+ Gastric Cancer	IND Submission	Phase I/IIa Phase II
Unmodified Natural Killer Cell	<b>CYNK-001</b> (cryopreserved)	Glioblastoma Multiforme (GBM)	Phase I/IIa	Phase II
Placental Mesenchymal-like Stromal Cell	APPL-001	Crohn's Disease		IND Submission Phase I/IIa

2 Upcoming IND Submissions (2021E) & 5 Clinical Trials by end of 2021

## **Program Milestones**

#### **CYNK-001**

- 2H21: Dose Selection & Initiation of Expansion Cohorts (AML)
- 2H21: Establish Phase II Dose (GBM)

#### **CYNK-101**

- 2H21: IND Submission
- 2H21: Phase I/IIa Study Start

#### CyCART-19

- 2H21: IND Submission Expected
- 2H21: Phase I Study Start

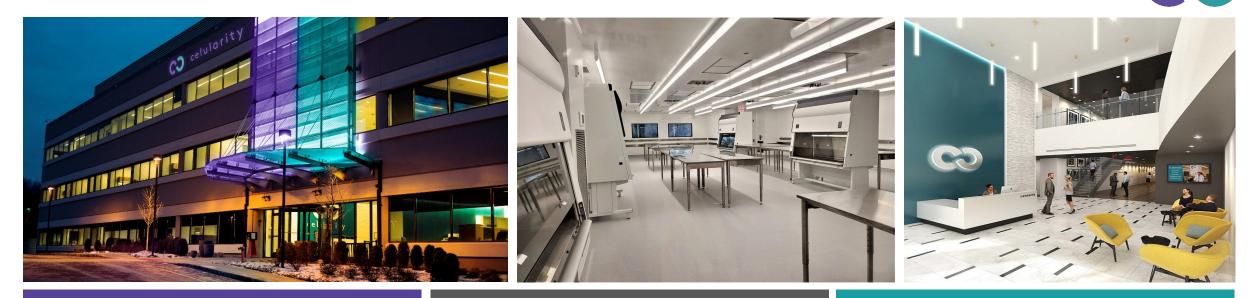
#### APPL-001

• 1H22: Phase I/IIa Study Start

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## **MANUFACTURING OVERVIEW**

Fully Integrated, Purpose Built Commercial Scale Manufacturing Site Including Translational Research & Biorepository



#### PURPOSE BUILT FACILITY FOR COMMERCIAL-SCALE CELLULAR THERAPEUTIC MANUFACTURING

- \$80M investment in cGMP/cGTP manufacturing
- Enables greater control, efficiency and optimization than is achievable by outsourcing to contract manufacturing organizations (CMOs) alone

#### STAFFED BY OVER 100 HIGHLY SPECIALIZED SCIENTISTS, ENGINEERS & TECHNICIANS.

- Optimized, product-specific CMC, QA/QC and manufacturing processes accelerate product development, production and commercialization
- Over 2 decades of experience with source material procurement

#### COMMERCIAL SCALE, GMP-READY

- 9 Grade C/ISO 7 suites
- 6 Grade D/ISO 8 labs
- Dedicated translational research labs

Celularity benefits from Celgene's 20 year+ investment in developing the technologies and capabilities required to manufacture cellular products at scale with consistent and reliable quality

# PLACENTA DERIVED CELLS

Biological Characteristics Suggest Greater Therapeutic Potential At the core of Celularity's approach is the innate stemness of its starting material



### **Greatest Proliferative Potential** and Sustained Activity:

Placental-derived pluripotent stem cells have the highest natural ability to replicate while maintaining their activity, which could overcome the challenge of cell exhaustion.

### **Extended Persistence:**

As nature's universal donor tissues, placental-derived pluripotent stem cells can be administered off-the-shelf with little or no modification and potentially persist longer in patients through their ability to avoid immune detection.

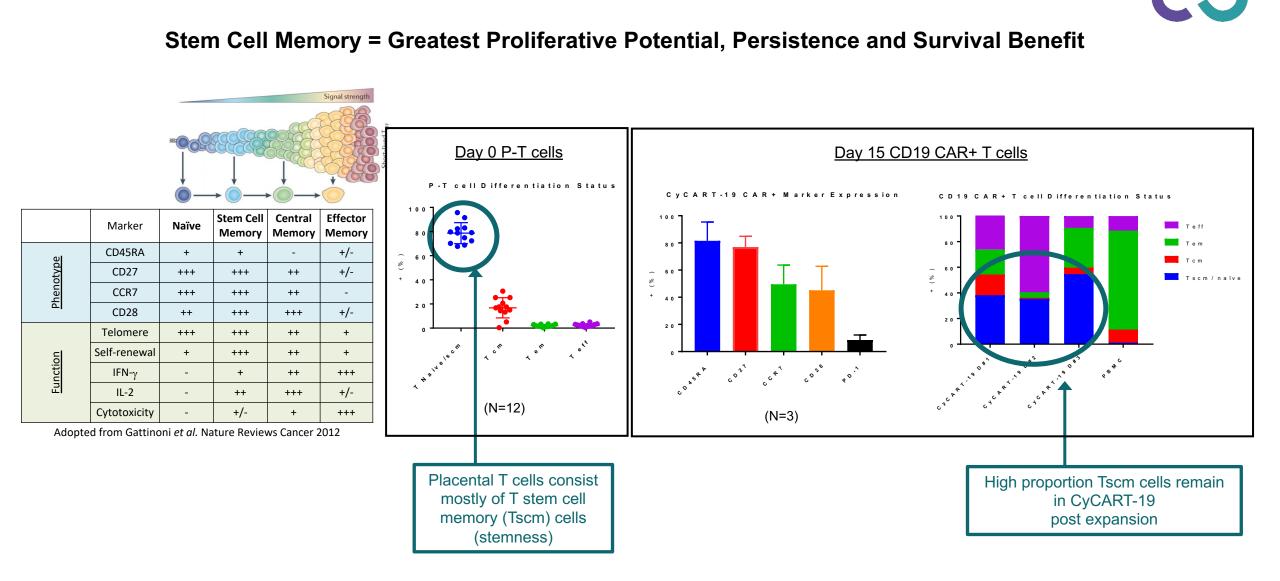
### **Flexible Engineering:**

By starting with cells with high levels of innate stemness, Celularity has the opportunity for extensive genetic modifications focused on improving and directing the activity of its cellular therapies.

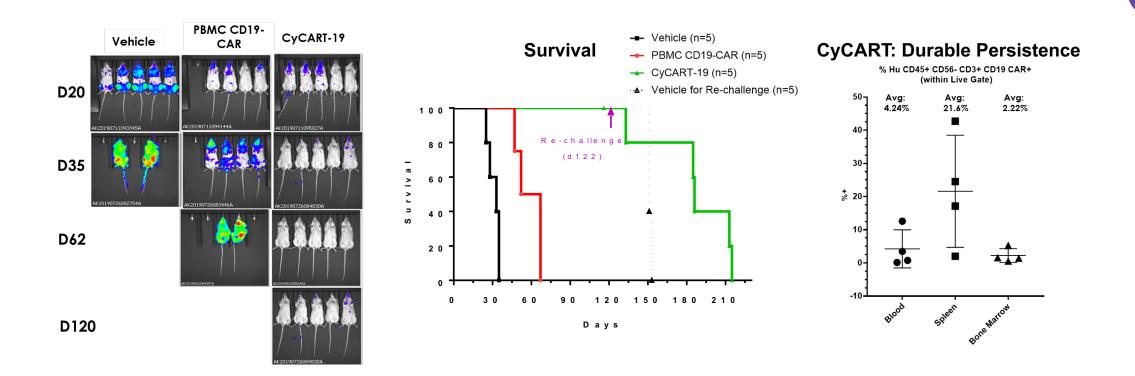
#### **Superior Scalability and Economics:**

Ethically sourced and screened, a single placenta can produce up to 100,000 doses of therapies through a manufacturing process that is highly efficient, modular and reproducible.

## **Greater T Stem Cell Memory Characteristics**

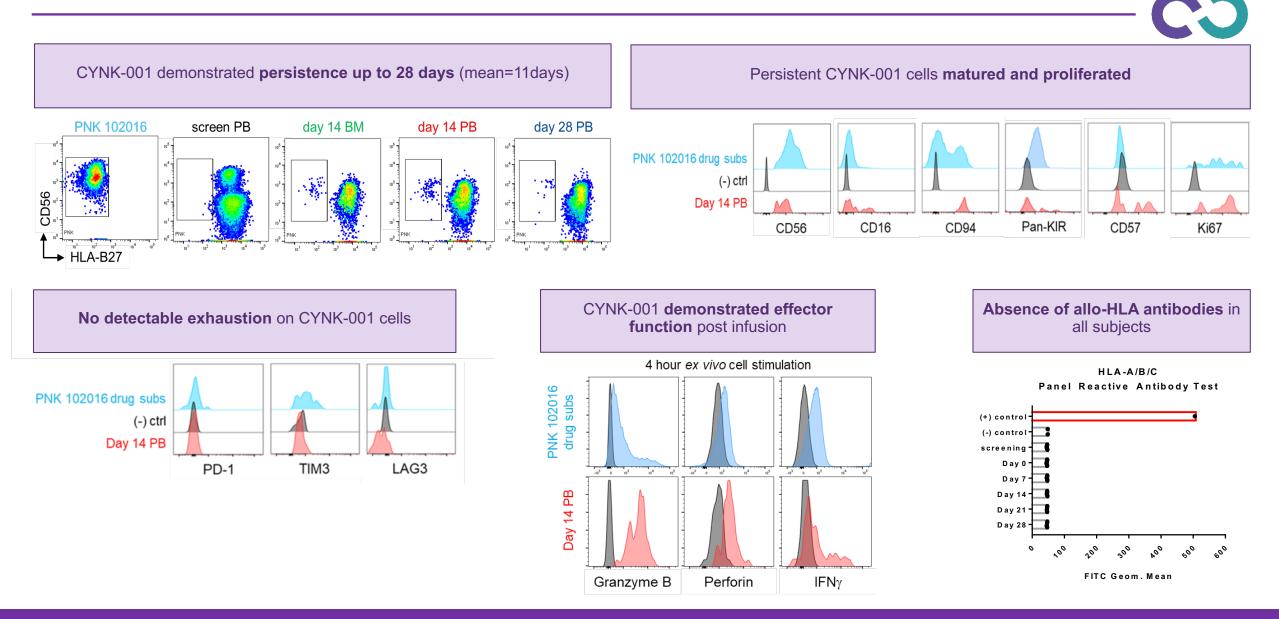


## Enhanced Efficacy & Persistence, Prolonged Immune Attack upon Tumor Recharging



- CyCART-19 demonstrates significantly reduced tumor burden and survival benefit compared to adult blood-derived CD19 CAR-T cells
- CyCART-19 eliminated tumor and resulted in 100% survival out to 120 days
- CyCART-19 "memory" characteristics demonstrated via:
  - Extended survival out to 215 days upon tumor re-challenge on Day 122
  - Differentiated persistence at end of study to elicit prolonged antitumor activities

## Persistence, Maturation and Proliferation with Absence of Allo-HLA Antibodies



# CYNK-001 AML & GBM

# CYNK-001(unmodified NK cellular therapy)

## Overview

## RATIONALE

- NK cells are natural immune cells that eradicate both cancer and virusinfected cells
  - Key mediators of antibody-dependent cellular cytotoxicity (ADCC)
- Placental-derived NK cells exhibit:
  - distinct, maturation and activation states
  - an immature phenotype
  - longer telomere length in comparison to PB NK cells, which suggests high in-vivo proliferation and persistence

## **KEY HIGHLIGHTS**

CYNK-001 (unmodified NK cellular therapy)

- Preclinical data support anticancer activity against a range of hematological malignancies and solid tumors.
- Phase 1 study in R/R AML showed early signs of clinical benefit and a positive safety profile

## **CLINICAL PLAN**

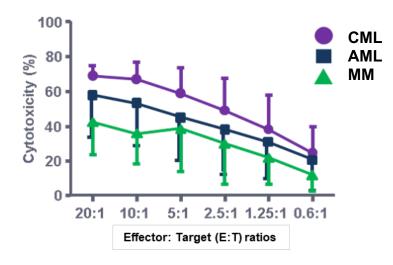
- Dose Selection & Initiation of Expansion Cohorts (AML) in 2H 2021
- Phase 1 study in adults with Recurrent Glioblastoma Multiforme
- Establish Phase II Dose (GBM) in 2H 2021

		NK CELL THERAPIES		
	Cell Therapy Technology Scorecard	ADULT DONOR DERIVED	CELULARITY CYNK-001 & CYNK-101	
	Source Procurement Non-invasive Collection / Reliable Procurement	$\checkmark$	$\checkmark$	
MANUFACTURING COMPLEXITY	Lower COGs Standardized, Scalable Manufacturing	$\checkmark$	$\checkmark$	
	Starting Material Consistent Quality and Phenotype	$\checkmark$	√+	
	Ability to Readily Expand While Maintaining a Less Differentiated Phenotype	×	$\checkmark$	
MANU	"Off-the-Shelf" Treatment	$\checkmark$	√+	
	Ability to Re-dose Patients (if Necessary)	×	√+	

Evidence of Significant Leukemia Killing

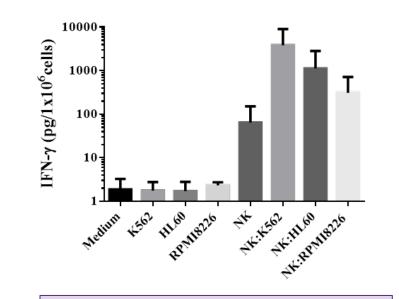


#### CML, AML, MM IN VITRO KILLING



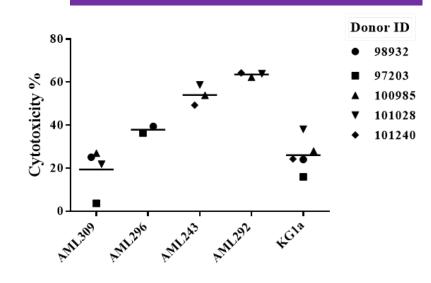
CYNK-001 demonstrates robust killing (cytolytic) against CML, AML, MM cell lines and primary AML samples

#### IFN-G PRODUCTION



CYNK-001 activation releases high concentration of IFN-g, favoring Th1 responses

#### PRIMARY AML KILLING



CYNK-001 exerted up to 60% specific lysis against primary AML samples at an Effector: Target (E:T) ratio of 3:1

# **CYNK-001-AML-001 FIRST-IN-HUMAN STUDY**

Phase I Study in Relapsed / Refractory Acute Myeloid Leukemia Showed Early Signs of Clinical Benefit

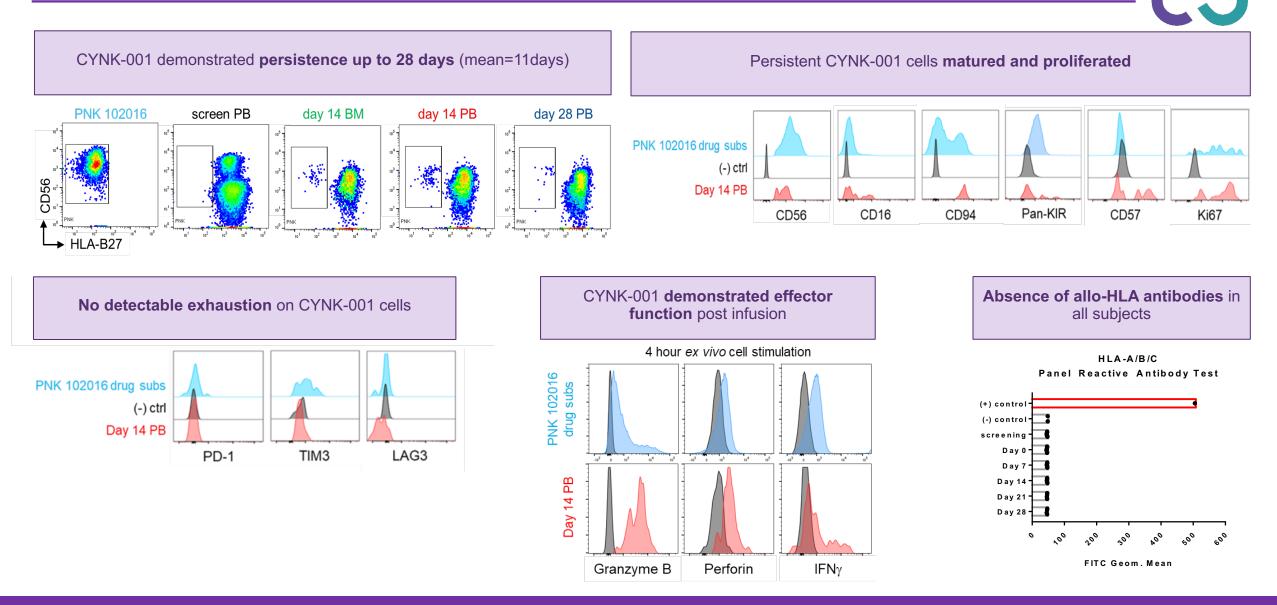
## **PHASE I RESULTS**

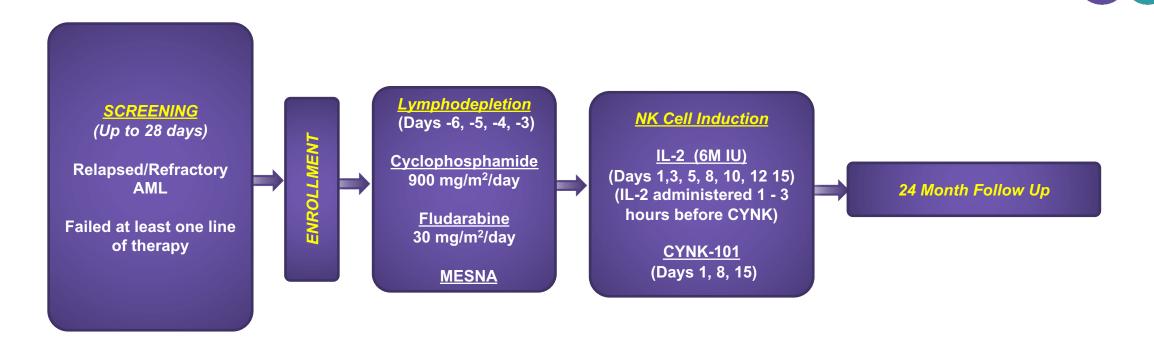
- CYNK-001 well tolerated in a heavily pre-treated AML patient population
  - 11 r/r AML patients enrolled, 10 treated with single dose of CYNK-001, no DLTs<sup>1</sup>, no GvHD, no detectable HLA allo-antibody
  - 8 of 10 patients were efficacy evaluable; the other 2 patients were not due to inadequate bone marrow (BM) for evaluation
    - 2 patients, both treated at the highest dose, had evidence of clinical benefit
      - $\circ~$  CRp<sup>2</sup> at Day 21
      - $\circ$  MLFS<sup>3</sup> at Day 14

## PHASE I DESIGN

- Dose escalation study
- Conditioning with cyclophosphamide and fludarabine
  - Fludarabine 25 mg/m2 x 5 days start day -6
  - Cyclophosphamide 60 mg/kg x 2 days on day -5 and -4 (omit Day -4 if within 4 months of prior transplant)
- CYNK-001 administered IV followed by up to 6 rhIL-2 injections
  - rhIL-2 at 6 million units subcutaneously beginning Day 0, every other day for 6 total doses





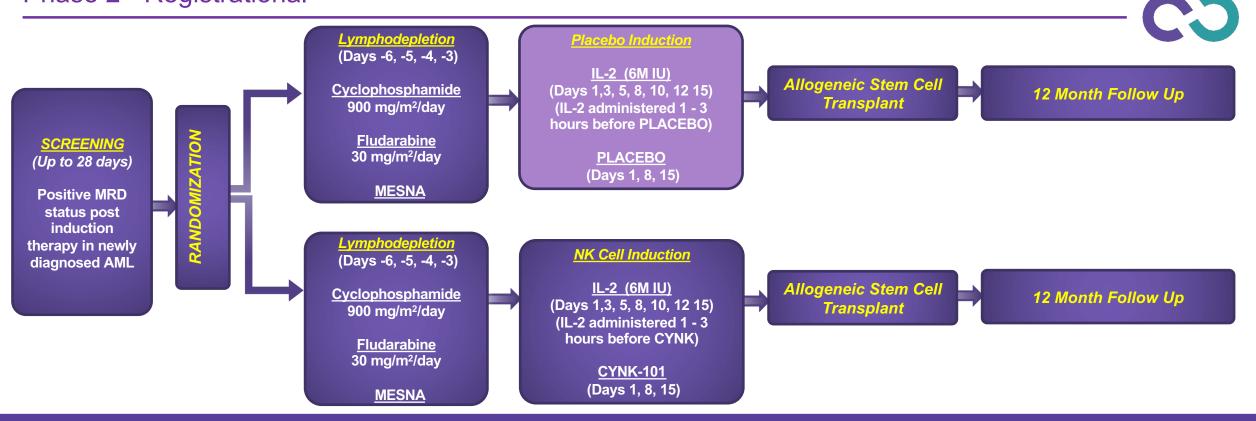


#### Phase 2 Registrational Trial Open Label Single Arm

- N = 45 patients
- North American sites (~15 sites)
- Primary Endpoints: Overall Response Rate (CR+CRi)
  - 10% Null hypothesis vs 30% target response
  - Power 90%. Significant level 2-sided at 0.05.

- Secondary Endpoints:
  - Leukemia Free Survival
  - Duration of Response
  - Overall Survival
  - MRD conversion
  - Safety
- Exploratory Endpoints: Persistence/expansion of CYNK-001

## CYNK001-AML-003 (AML MINIMAL RESIDUAL DISEASE POSITIVE) Phase 2 - Registrational



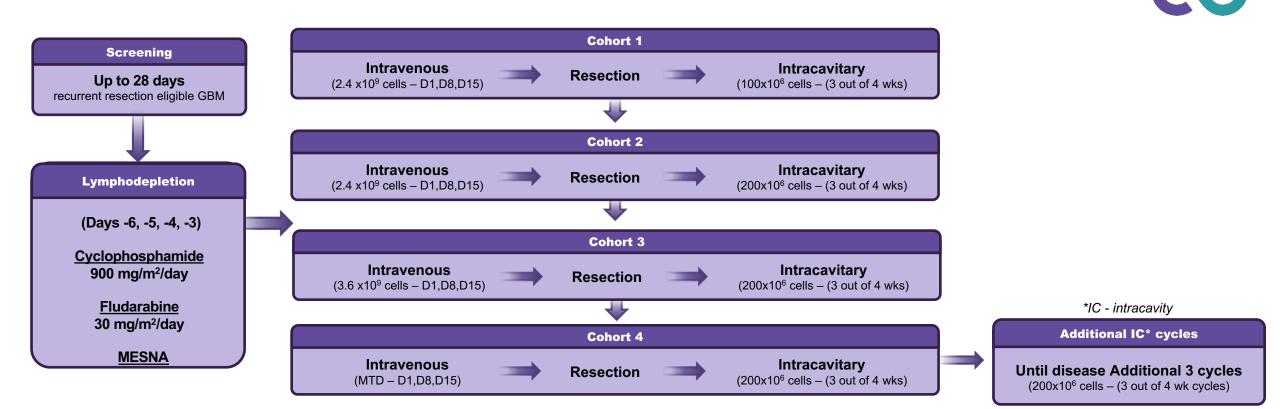
### Phase 2 Registrational Trial Randomized Placebo Control

- N = 122 (61 patients in each arm)
- North American sites (~30-40 sites)
- Primary Endpoints: Leukemia Free Survival at 12 months
  - 50% patients in Placebo group and 25% patients in CYNK-001 group will be relapsed.
  - Power 90%. Significant level 2-sided at 0.05.

- Secondary Endpoints:
  - Duration of Response
  - Overall Survival
  - MRD conversion
  - Safety
- Exploratory Endpoints: Persistence/expansion of CYNK-001

# CYNK001-GBM-002 (GLIOBLASTOMA PROGRAM)

## Phase 1 Dose Escalation / Phase 2 Registrational



### Phase 1 Dose Escalation

- N = ~ 15 patients
- North American sites (~5 sites)
- Primary Endpoints: Safety, Feasibility and Tolerability (42 Day DLT period)
- Secondary Endpoints: Progression Free Survival

#### **Phase 2 Registrational Trial**

- N = 47 patients (80% Power Target 35% 6-month PFS)
- North American sites (5 10 sites)
- Primary Endpoints: 6-month Progression Free Survival
- · Secondary Endpoints: Overall Survival, ORR post resection
- Exploratory Endpoints: NK cell persistence and trafficking

# **CYNK-101** HER2+ Advanced Esophageal / Gastric Adenocarcinoma

# **CYNK-101 IN HER2+ GASTRIC CANCER**

#### Overview

#### RATIONALE

 Engineering CYNK cells with high affinity and cleavage resistant (CD16VP) expected to improve affinity for IgG1 therapeutic antibodies, resist activation induced cleavage and improve overall ADCC potential

#### **KEY HIGHLIGHTS**

- CYNK-101 adds "punching power" to the CYNK-001 platform via genetic modification
- When combined with Herceptin demonstrates ADCC activity against HER2+ Gastric Cancer cells
  - Joint impact of modified NK cells + mAb shows improved immunologic response with added NK cell killing

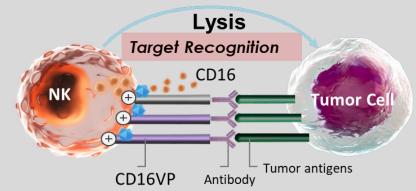
### **OPPORTUNITIES**

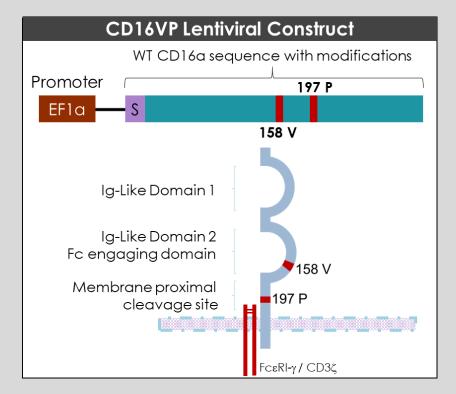
- Enable combination therapy with ADCC mediating therapeutic mAb therapies
- Augment CYNK clinical program with added "punching power" of Genetic Modification

#### CLINICAL PLAN

- 2H21: IND Submission
- 2H21: Phase I/IIa Trial Start
- 1H22: Phase II Study Start

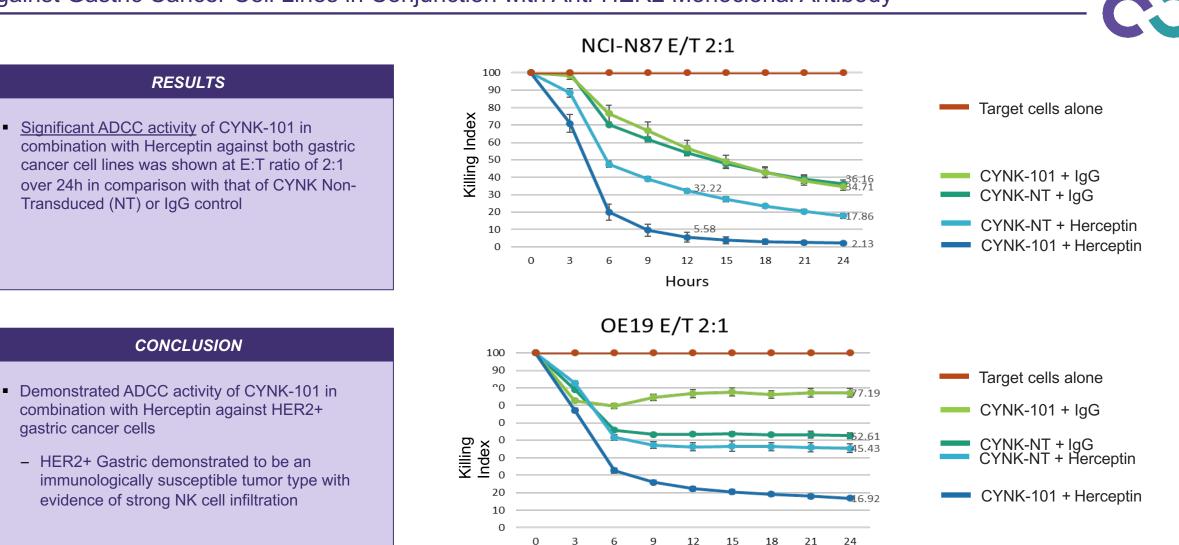
## Antibody-Dependent Cellular Cytotoxicity





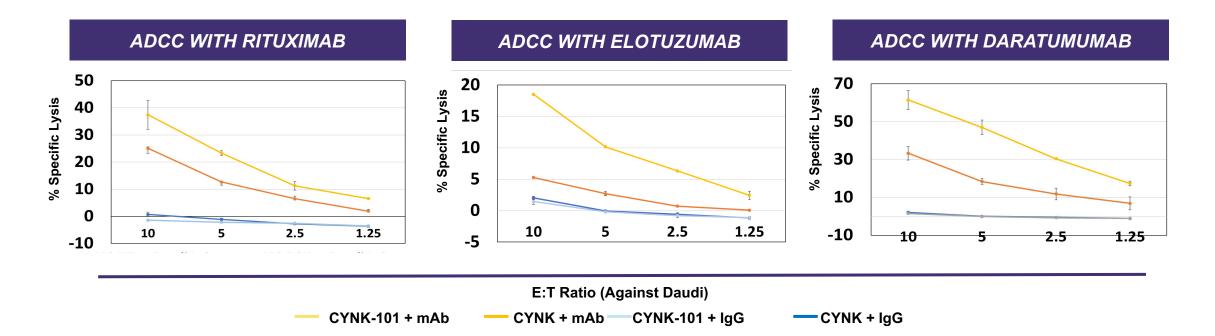
# **CYNK-101 DEMONSTRATES EFFECTIVE ANTITUMOR ACTIVITY**

Against Gastric Cancer Cell Lines in Conjunction with Anti-HER2 Monoclonal Antibody



Hours

Enhanced ADCC with Multiple Antibodies Forms the Basis of Combination Therapy



- Improved ADCC response observed from CYNK-101 compared to unmodified CYNK cells against lymphoma cell lines in combination with: Rituximab, Daratumumab and Elotuzumab antibodies
- IND-enabling studies on-going to evaluate CYNK-101 + mAbs in subcutaneous and orthotopic tumor models

# CYNK101-HER2-001 (HER2+ GASTRIC/GEJ CANCER)

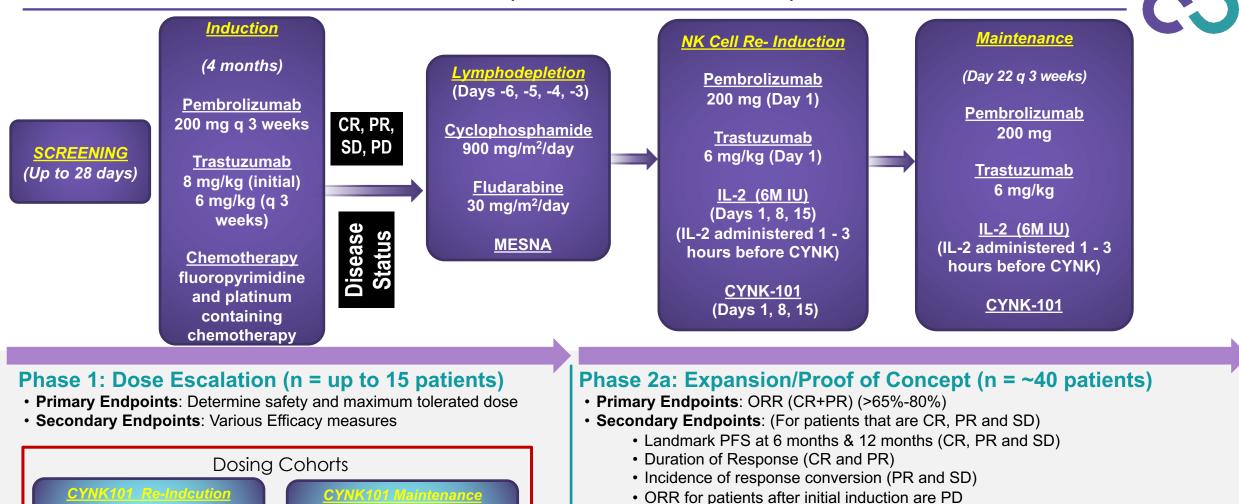
Phase 1 - Dose Escalation / Phase 2a Expansion/Proof of Concept

Cohort -1: 1.2 x 10<sup>9</sup> cells

Cohort 1: 1.8 x 10<sup>9</sup> cells

Cohort 2: 3.6 x 10<sup>9</sup> cells

Cohort 3: 3.6 x 10<sup>9</sup> cells



- Safety
- Maintenance Dosing
  - Patients in CR after CYNK-101 to dose an additional 2 cycles of NK cells combination
  - Patients in PR/SD after CYNK-101 to dose until CR or Progression
  - Patients in PD after CYNK-101 to discontinue to from study

Cohort -1: 1.2 x 10<sup>9</sup> cells

Cohort 1: 1.8 x 10<sup>9</sup> cells

Cohort 2: 3.6 x 10<sup>9</sup> cells

Cohort 3: 7.2 x 10<sup>9</sup> cells

# **CyCART-19** B-Cell Malignancies

## **CyCART-19 OVERVIEW**

## Celularity Approach and Advantages

#### RATIONALE

- Rationale for greater stemness, expandability, persistence
- Abundant renewable starting cell source for allogeneic therapies
- Potential for improved safety profile due to immunological naivety

#### **KEY HIGHLIGHTS**

- Celularity has established a robust process to obtain placental T naive/scm population as source materials to produce off-the-shelf, highly scalable CyCART-19 cells
- CyCART-19 demonstrates stem cell memory characteristics as evidenced by greater in vivo persistence and durable antitumor activity in preclinical models
- Strong pre-clinical evidence of anti-tumor activity
  - CyCART-19 cells outperform adult blood-derived CART cells by significantly greater persistence and longer survival in preclinical studies
- Early data suggesting no signs of GvHD
- Note: If Phase 1 successful, Celularity plans to pursue a Phase 2 basket trial across major B-cell malignancies (subject to FDA discussions)

#### **CLINICAL PLAN**

- 2H21: IND Submission Expected
- 2H21: Phase I Study Start
- 1H22: Phase II Study Start

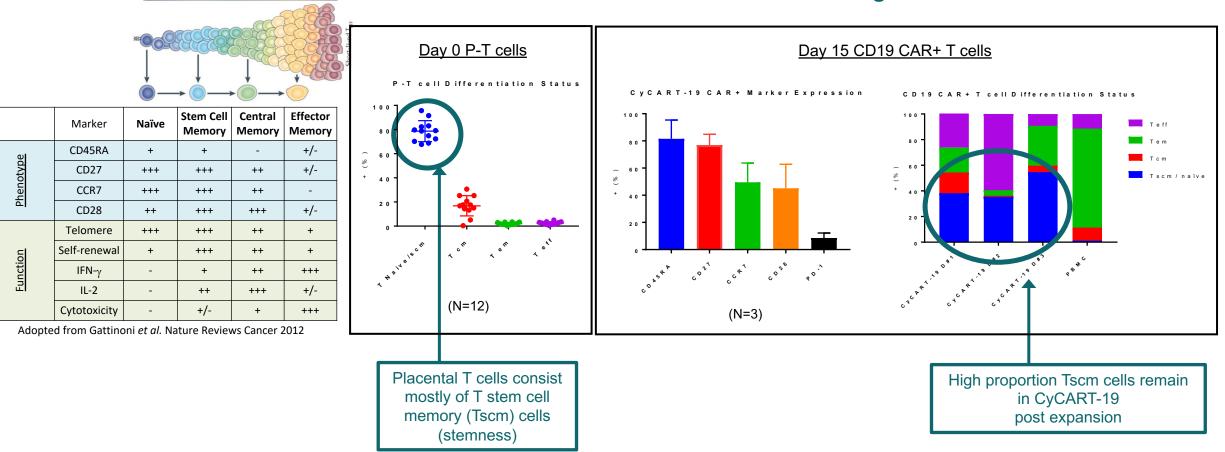
		CAR-T THERAPIES		
	Cell Therapy Technology Scorecard	AUTOLOGOUS	OTHER ALLOGENEIC	CELULARITY CyCART-19
MANUFACTURING COMPLEXITY	Source Procurement Non-invasive Collection / Reliable Procurement	×	×	$\checkmark$
	Lower COGs Standardized, Scalable Manufacturing	×	$\checkmark$	$\checkmark$
	Starting Material Consistent Quality and Phenotype	×	×	√+
	Ability to Readily Expand While Maintaining a Less Differentiated Phenotype	×	×	~
	"Off-the-Shelf" Treatment	×	$\checkmark$	√+
	Ability to Re-dose Patients (if Necessary)	x	$\checkmark$	√+

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Signal strength

- CJ

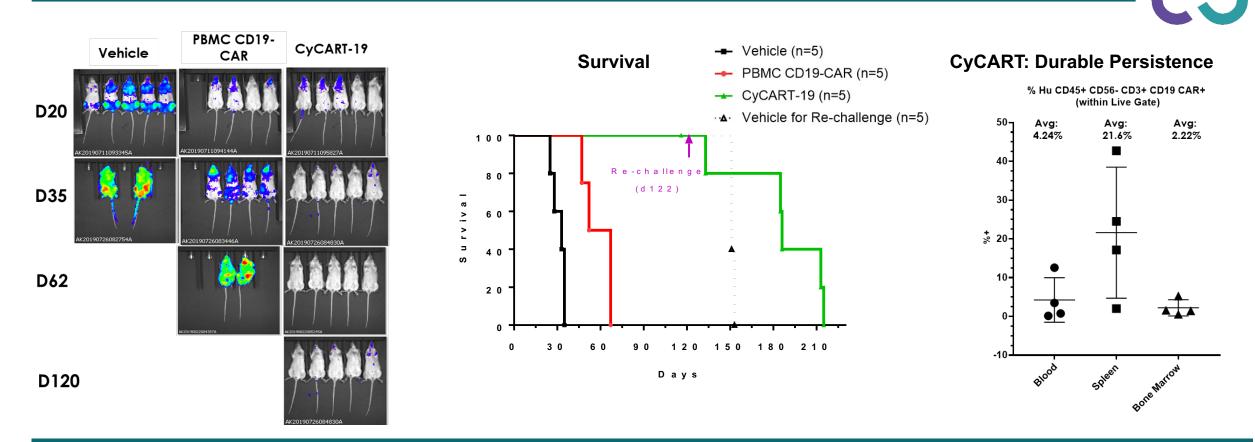
## Stem Cell Memory = Greatest Proliferative Potential, Persistence and Survival Benefit



## **Established Robust Manufacturing Process**

## **CyCART-19 DEMONSTRATES GREATER ANTI-LYMPHOMA ACTIVITIES & SURVIVAL**

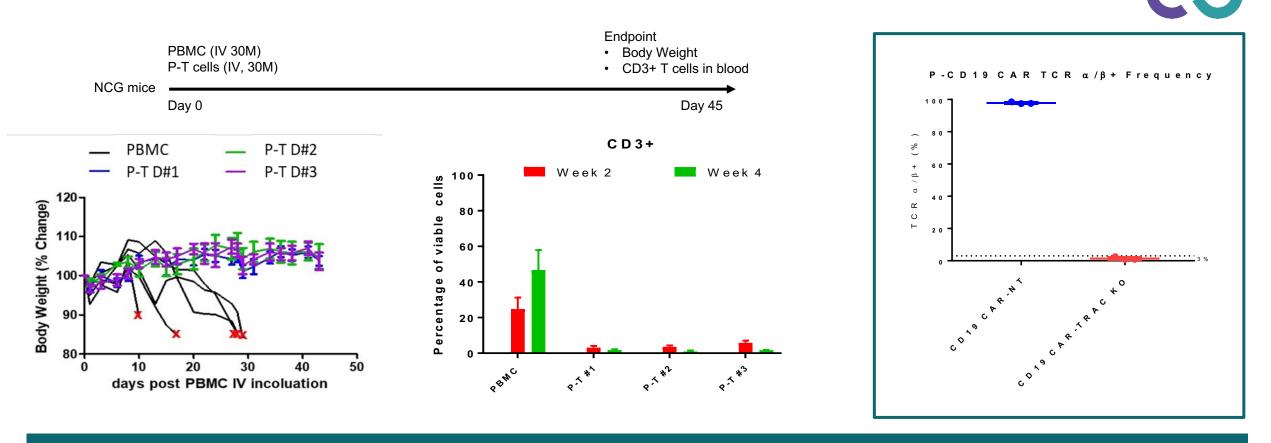
Enhanced Efficacy & Persistence, Prolonged Immune Attack upon Tumor Recharging



- CyCART-19 demonstrates significantly reduced tumor burden and survival benefit compared to adult blood-derived CD19 CAR-T cells
- CyCART-19 eliminated tumor and resulted in 100% survival out to 120 days
- CyCART-19 "memory" characteristics demonstrated via:
  - Extended survival out to 215 days upon tumor re-challenge on Day 122
  - Differentiated persistence at end of study to elicit prolonged antitumor activities

# **CyCART-19 CELLS DO NOT INDUCE XENOGENEIC GvHD IN VIVO**

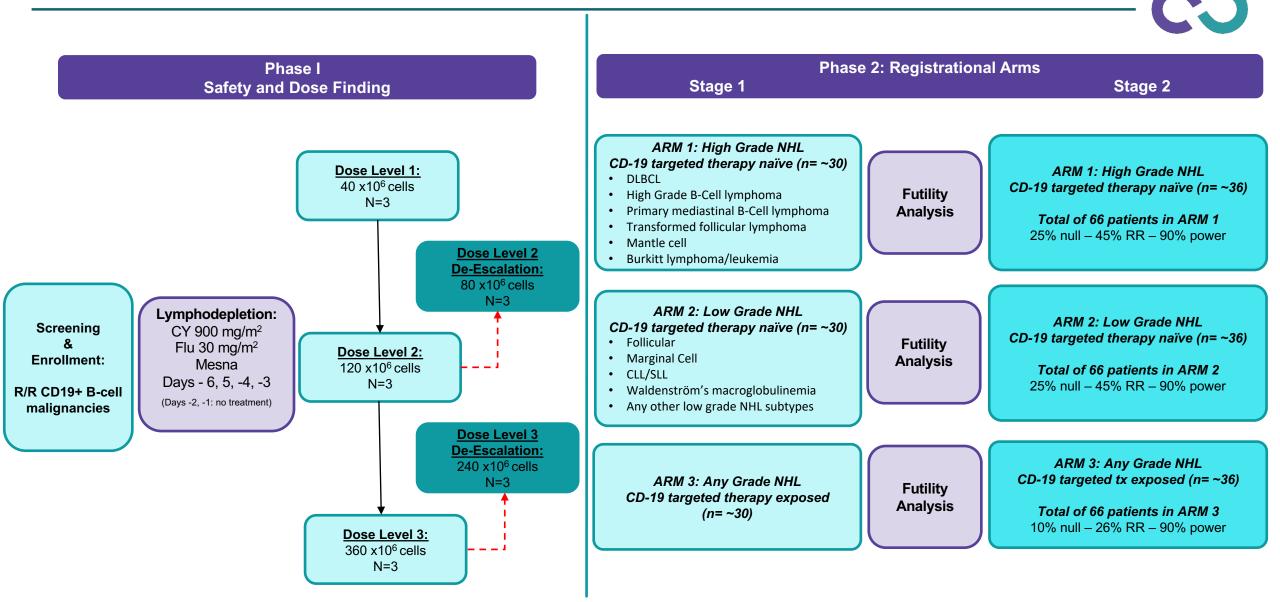
## Efficient TCR Knockout as Risk Mitigation



- Placental T (P-T) cells do not induce xenogeneic GvHD in vivo
  - Evidenced by 100% survival, no weight loss, no increase in detection of any human CD3+ T cells in P-T treated mice
  - PBMC-treated mice exhibited significant weight loss, death of all mice, and increase of detection of human CD3+ T cells at Day 28
- Celularity includes CRISPR-mediated TRAC KO in its process as a risk mitigation strategy to prevent GvHD
  - 97-99% TRAC KO efficiency achieved in CyCART-19 cells

## CYCART19-BCM-001 (RELAPSED/REFRACTORY B-CELL MALIGNANCIES)

## Phase 1 Dose Escalation / Phase 2 Registrational



# **Degenerative Diseases**

# **APPL-001 OVERVIEW**

## Celularity Approach and Advantages

#### RATIONALE

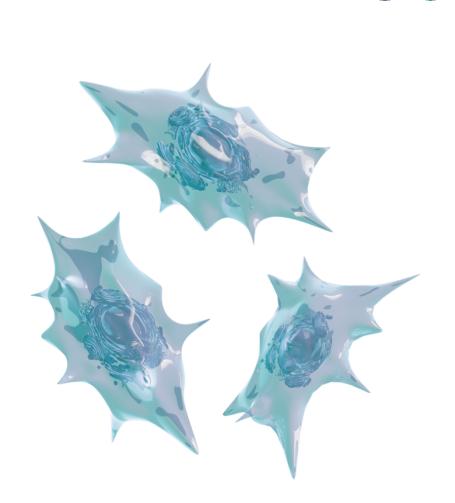
- Immune-modulatory properties of mesenchymal-like adherent stromal cells (ASCs) have the potential to alleviate autoimmunity and possess anti-inflammatory activity
- Off-the-shelf potential
  - ASCs are immune-privileged due to relatively low-level MHC class I and II protein expression

#### **KEY HIGHLIGHTS**

- Clinical evidence supporting ASCs potential applications
  - 1st generation ASCs demonstrate signs of clinical activity in Crohn's Disease, Diabetic Foot Ulcers and Diabetic Peripheral Neuropathy
  - Well-tolerated and no SAE's at therapeutic dose
- Placental-derived ASCs (APPL) are potentially more immune privileged due to their fetal origin
- Celularity is developing the next generation of ASCs with APPL-001, a genetically modified placental-derived ASC, for the treatment of Crohn's Disease
  - Engineered Tissue factor (TF) Knockout (KO) is designed to reduce potential toxicities and lower the risk of adverse effects.
- One placenta can yield more than 100,000 Doses.

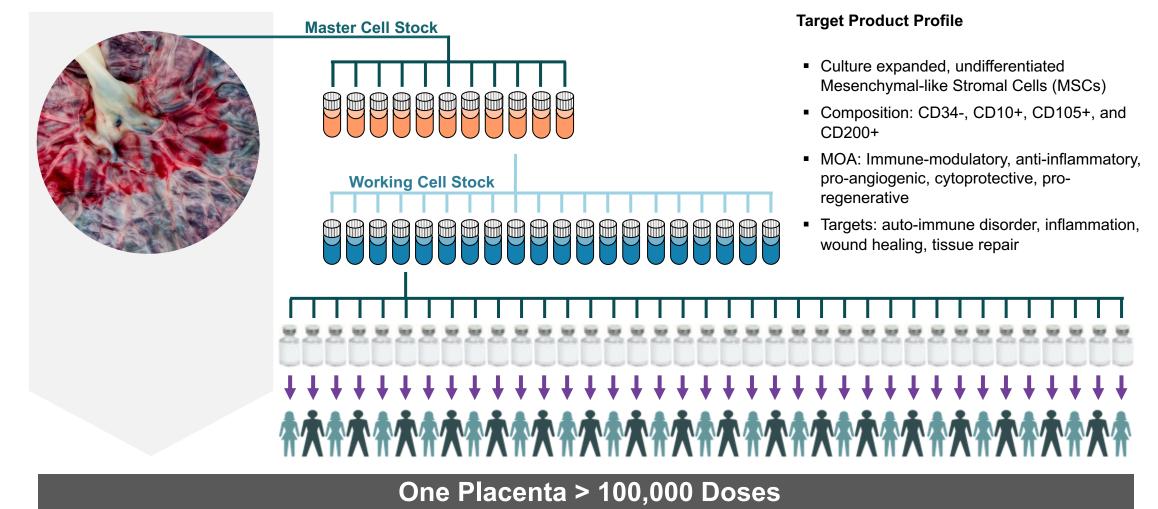
#### CLINICAL PLAN

- Crohn's Disease
  - 1H22: IND Submission Expected
  - 1H22: Phase I/IIa Study Start



## ALLOGENEIC PLACENTAL PLURIPOTENT CELLS: SCALABLE & OFF-THE-SHELF Clinical Stage





## **NEWLY DEVELOPED APPL PROGRAM**

Leveraging Legacy Placental Mesenchymal-like Stromal Cell Studies to Expand to Degenerative Diseases



#### IV Formulation

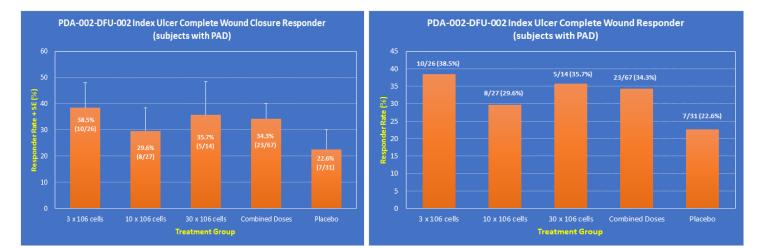
50+ patients dosed in **multiple Crohn's Disease studies** 

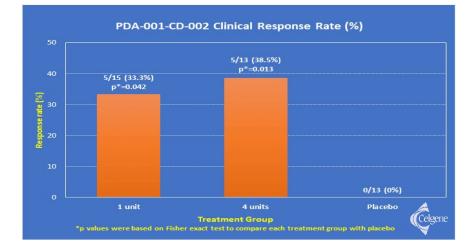
- Clinical response rates were significantly higher in IV Formulation treatment groups compared with the placebo group
- Response rates were 43% points in the treatment group vs 0% in the placebo group on Day 365
- Well-tolerated, no SAEs at therapeutic dose

#### IM Formulation

#### 140+ patients dosed in **Diabetic Foot Ulcer (DFU) and Diabetic Peripheral Neuropathy Ph II studies**

- IM Formulation has systemic microvascular/neovascularization effects
- Enhanced healing of diabetic foot ulcers compared to placebo
- Improvement of retinopathy
- Well-tolerated, no SAEs at therapeutic dose





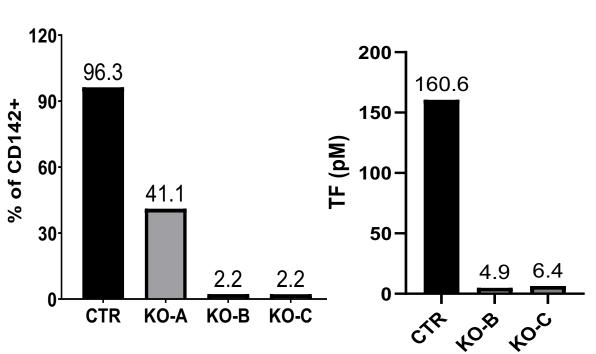
Leveraging PDA Cells and Develop New APPL Candidate

#### Genetically Modified APPL with Greater Safety Profile

- Tissue factor (TF) Knockout (KO) in APPL using CRISPR/Cas9 to reduce potential safety risk associated with TF
- Identified two of four CRISPR guide RNAs showing >95% high KO efficiency
- Demonstrated sustained TF KO throughout culture expansion
- APPL-TFKO cells significantly reduced TF activity
- TF KO showed no effect on cell proliferation and viability

## Novel Media and Culture Method Established to Develop APPL with Greater Potency

- Demonstrate immune modulation and regenerative functionality
- New IP opportunities in process and product composition





#### KEY TAKEAWAYS

- Culture-expanded, undifferentiated mesenchymal-like stromal cells
  - Genetically modified with tissue factor (TF) knockout (KO)
- Mechanism of Action:
  - Immune-modulatory, anti-inflammatory, pro-angiogenic, cytoprotective and pro-regenerative

#### CLINICAL PLAN

- 1H22: IND Submission
- 1H22: Phase I/IIa Study Start

# Corporate Summary

## **EXPERIENCED MANAGEMENT TEAM**

With Deep Expertise in Cell Therapy



### To Achieve the Next Advance in Placenta-based Cell Therapy

#### Achievements to Date

- April 2020:Received FDA Safe to proceed on IND<br/>for CYNK-001 in COVID-19
- September 2020: Completion of Facility at Florham Park
- January 2021: Announce merger with GXGX Acquisition Corp.

Completed concurrent \$80m PIPE financing

- March 2021:Received Fast Track Designation by the<br/>FDA for CYNK-001 in recurrent GBM
- April 2021: Received Orphan Drug Designation by the FDA for CYNK-001 in malignant gliomas

July 2021: Complete public listing on NASDAQ (CELU)

#### **Key Near-Term Development Milestones**

#### **CYNK-001**

- 2H21: Establish Phase 2 Dose (GBM)
- 2H21: Dose Selection & Initiation of Expansion Cohorts (AML)

#### **CYNK-101**

- 2H21: IND Submission
- 2H21: Phase I/IIa Study Start

#### CyCART-19

- 2H21: IND Submission
- 2H21: Phase I Study Start

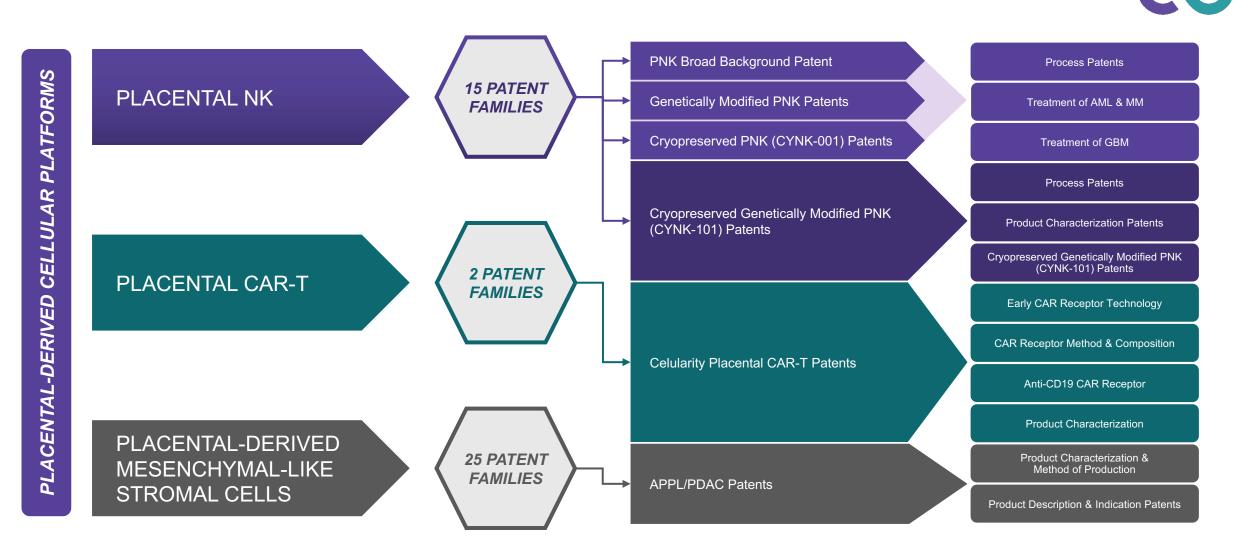
#### APPL-001

IH22: Phase I/IIa Study Start

## Appendix Clinical Programs Additional Detail

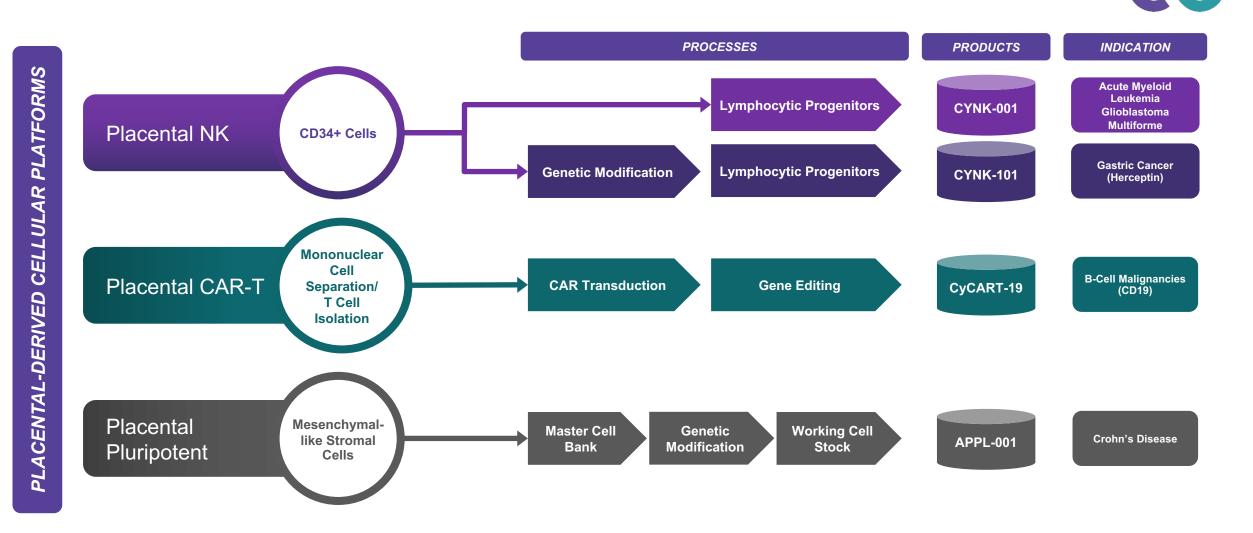
## **CELULARITY IMPACT™ PLATFORM**

Broad IP Protection Across All Lead Programs



## **CELULARITY IMPACT™ PLATFORM**

The Placenta as a Renewable Allogeneic Source, with Purpose-Built Commercial Scale Manufacturing



Solving the Downside of Autologous CAR-T Therapies

AUTOLOGOUS CAR-T THERAPY		ALLOGENEIC PLACENTAL CAR-T
Status Quo	Downside	Celularity's Scalable Solution
All CAR T-cell therapies on the market and most (~75%) of clinical assets are autologous	<ul> <li>Complex, high COGS manufacturing and one-batch, one-patient supply chain</li> </ul>	<ul> <li>No apheresis capacity constraints</li> <li>High volume manufacturing</li> <li>On-demand, off-the-shelf cryopreserved packaged product</li> </ul>
<ul> <li>Peripheral blood-derived T- cell is the immune cell 'vehicle' used to express a CAR</li> </ul>	<ul> <li>Multiple rounds of lymphocyte- depleting therapies cause inconsistent apheresis cell recovery in relapsed or refractory patients</li> </ul>	<ul> <li>Placentas provide a profuse, renewable source of healthy, ready to use lymphocytes</li> <li>Placental T-Cells containing abundance of stem cell memory conferring greater expansion and persistence potential</li> </ul>
"Patient as their own donor" automatically makes the patient part of the supply chain	<ul> <li>Therapeutic outcomes affected by collection-manufacturing- release-administration timeframe "Long vein-to-vein time"</li> </ul>	<ul> <li>UNIQUE ADVANTAGES OF PLACENTAL-DERIVED CELLS</li> <li> <ul> <li>Dynamic &amp; flexible supply chain</li> <li>Patient-responsive, not patient-dependent</li> <li>Simplified logistics, ability to pre-position cryopreserved product at treatment sites</li> </ul> </li> </ul>

### Providing Upside to Adult-donor Allogeneic CAR-T Therapies

ALLOGENEIC CAR-T THERAPY		ALLOGENEIC PLACENTAL CAR-T
Status Quo	Downside	Celularity's Scalable Solution
Requires selection, screening & testing T cells from healthy adult donors e.g. donor bone marrow	<ul> <li>Complex logistics, multistep manufacturing process to source, limited scalability, improved speed vs. autologous but still measured in days</li> </ul>	<ul> <li>✓ No apheresis capacity constraints</li> <li>✓ High volume manufacturing</li> <li>✓ On-demand, off-the-shelf cryopreserved packaged product</li> </ul>
High cost of treatment inherent of engineered T cell therapy	<ul> <li>Requires separate engineering for each new therapeutic candidate</li> </ul>	<ul> <li>✓ Placentas provide an abundant, renewable source of healthy, ready to use lymphocytes</li> <li>✓ Placental T-Cells containing abundance of stem cell memory conferring greater expansion and persistence potential</li> </ul>
		UNIQUE ADVANTAGES OF PLACENTAL-DERIVED CELLS
➤ Adult donor ≠ universal donor	<ul> <li>Potential safety complications observed from graft versus host disease (GvHD), as well as CRS and cerebral edema</li> </ul>	<ul> <li>✓ Dynamic &amp; flexible supply chain</li> <li>✓ Patient-responsive, not patient-dependent</li> <li>✓ Simplified logistics, ability to pre-position cryopreserved product at treatment sites</li> </ul>

Providing Upside to both Adult-donor NK Cells

ADULT DONOR NK CELL THERAPY		ALLOGENEIC PLACENTAL NK
Peripheral Blood NK	iPSC NK	Celularity's Scalable Solution
<ul> <li>Apheresis of peripheral blood from healthy donor / patient</li> <li>Requires voluntary donor</li> </ul>	<ul> <li>De-differentiated adult fibroblasts</li> <li>Additional processing required</li> </ul>	<ul> <li>✓ No apheresis capacity constraints</li> <li>✓ High volume manufacturing</li> <li>✓ On-demand, off-the-shelf cryopreserved packaged product</li> </ul>
Cytokine activation without expansion or direct expansion on feeder cell platform	<ul> <li>Two-stage differentiation:         <ul> <li>First from iPSC's to iCD34 cells, and then to NK cells</li> </ul> </li> <li>Expression of multiple de-differentiation genes higher risk of insertional mutagenesis</li> </ul>	<ul> <li>✓ Feeder cell-free, cytokine cocktail-based NK cell expansion and differentiation</li> <li>✓ No prior exposure to physiological or environmental factors; no exhaustion</li> </ul>
<ul> <li>Heterogeneous NK cells with high expression of both NK cell activating receptors and inhibitory receptors (KIRs)</li> <li>Potential for fratricide exists with CD38 mAb</li> </ul>	<ul> <li>NK cells with high expression of both NK cell activation and inhibitory receptors (KIRs)</li> <li>Potential for fratricide necessitated knock out of CD38 when combined with CD38 mAb</li> </ul>	<ul> <li>✓ Heterogeneous NK cells with high expression of natural cytotoxicity receptors (NCRs) with low expression of inhibitory receptors (KIRs)</li> <li>✓ No fratricide observed in combination with CD38 targeted approaches</li> </ul>

#### PIPELINE

## **NK CELL THERAPY FOR CANCER IMMUNOTHERAPY**

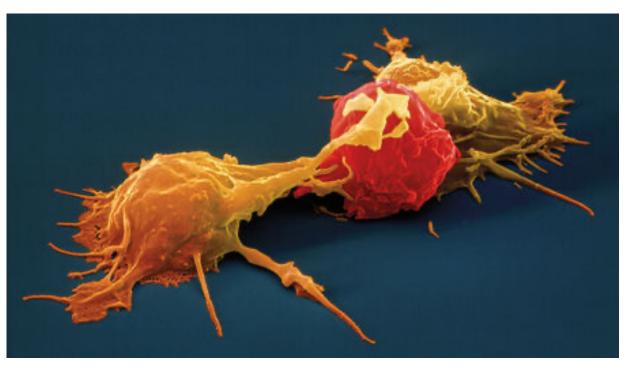
Preclinical & Clinical Data Supporting Role of NK cells in the Treatment of Cancer

#### NK CELLS ARE A MAJOR COMPONENT OF THE INNATE IMMUNE SYSTEM

- Natural immune cells that eradicate both cancer and virus-infected cells
  - Directly via cytolytic granule mediated lysis
  - Indirectly via secretion of immunoregulatory cytokines (e.g. IFN-g)

#### NK CELL ACTIVITY IS THERAPEUTICALLY RELEVANT

- Kills cancer cells (e.g., leukemic blasts) without prior sensitization, in a non-MHC restricted or tumor antigen-restricted manner
- Key mediators of ADCC (e.g. Rituximab, Cetuximab)
- Defective NK cell number & function has been linked to increased cancer risk and tumor development
- NK cell activity inversely correlated to relapse (anti-metastatic)
- NK cells infiltration predicts immune checkpoint blockade responsiveness



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**Study Design**: Randomized, double-blind, Placebo-controlled study in adults with 5 doses of 1/4<sup>th</sup> unit APPL (~ 37 million cells) over 8 weeks vs. Humira treatment.

Study Population: Moderate-to-Severe CD (CDAI score: 220-450) who are refractory to Corticosteroids

**Primary objective:** To assess the clinical efficacy by measuring response/remission rates during the induction phase as well as to explore durability of response during the maintenance phase in subjects with moderate to severe CD. Subjects shall be re-treated if a flare is developed during the 1-year.

**Secondary Objective:** The secondary objectives of this study are to assess clinical improvement by endoscopic measurements and quality of life assessments.

**Primary Endpoint:** To assess clinical efficacy, the modified Crohn's Disease Activity Index (CDAI) scoring system will be used to measure the following:

- Clinical Remission: Reduction of CDAI score to less than 150 points 4-6 weeks
- Clinical Remission: Reduction of CDAI score to less than 150 points 1-year

#### **Secondary Endpoints:**

- Clinical Response Rate: Reduction in CDAI score by 100 points to the baseline at 1-year
- Evaluation of mucosal healing as measured by Simple Endoscopic Score for Crohn's Disease (SES-CD) at week 4-6 and 1-year
- Patient-reported outcome of quality of life as measured by Inflammatory Bowel Disease Questionnaire (IBDQ)

Sample Size: 162 subjects in each arm (80% power and 10% drop out) involving APPL versus Humira with NI margin of 12%

#### **Timeline Estimate:**

- IND: 1H 2022

