# The Next Revolution in Cell Therapy

Leading Today, Creating Tomorrow

September 2023





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## Allogene: On a Mission for Patients

million

EE\$

Foundational platform technologies • AlloCAR T<sup>™</sup>

TurboCAR<sup>™</sup>

 Cloak<sup>™</sup> & Dagger<sup>™</sup> Cell Forge Alloy<sup>™</sup> manufacturing

PSC

>175

treated\* Data from nearly as many patients with AlloCAR T as from key competitors

\*Phase 1 trials

combined

-0

Patients

Resources focused

on defining the field

and writing the

allogeneic CAR T

playbook

singular focus on allogeneic cell therapy

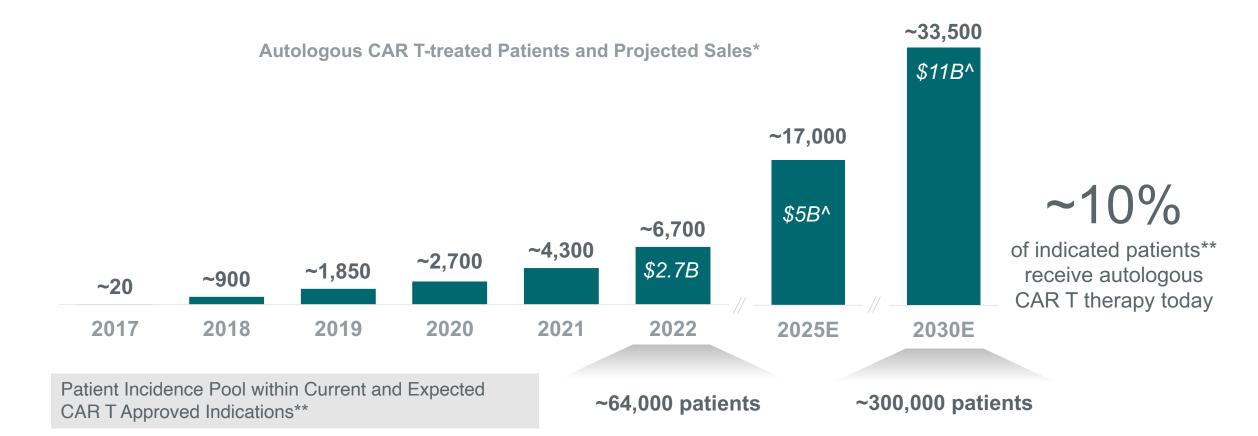
The industry's first Potentially **Pivotal Phase** 2 allogeneic CAR T trial

\$545

in cash, cash equivalents and investments as of June 30, 2023



### CAR T Sales Projected to Grow into an Expanding Market

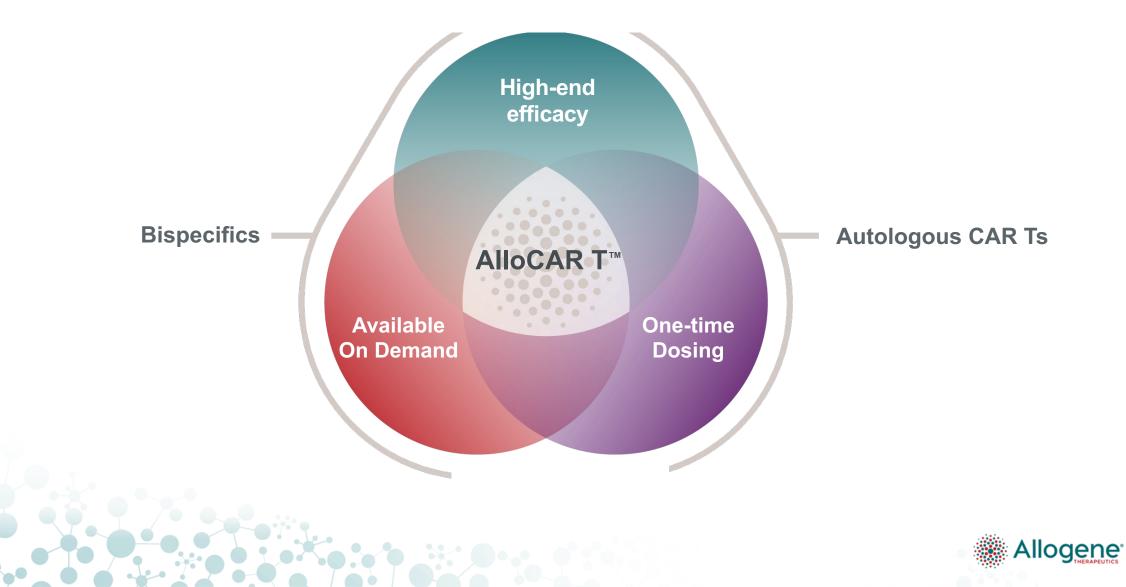


All Decision Resource Group-cited data © 2022 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission. \*2017-2022 estimated and rounded based on manufacturer-reported sales and average \$400K/patient assumption; 2025-2030 estimated and rounded based on Decision Resources Group sales and market share projections \*\*Decision Resources Group epidemiology for drug-treated incidence G7 markets, rounded and not necessarily reflecting specific medical eligibility criteria for autologous CAR T therapies; current indications defined as 2L/3L+ LBCL, 3L+ FL, r/r MCL, r/r Adult ALL, r/r/ Pediatric/Young Adult ALL, 5L+ MM; expected future indications represent Allogene assumptions on CAR T indications in 2030 and include 1L+ LBCL, 2L+ FL, r/r MCL, 1L+ MM ^ Decision Resources Group estimated autologous CAR T sales for 2L+ LBCL, 2L+ FL, 3L+ MCL and 3L+ MM in 2025 and 2L+ LBCL, 2L+ FL, 3L+ MCL, and 1L+ MM in 2030



-4

## AlloCAR T Uniquely Positioned to Deliver Value to Patients



## Deep AlloCAR T Pipeline Opportunity

	Target	Program	Trial name	Study population	Discovery	IND- enabling	Phase 1	Phase 2 <sup>1</sup>	Approved	Designation	Next milestone
(	CD19	ALLO-501A	ALPHA2	3+ Line LBCL	•					FTD RMAT	Target enrollment completion 1H 2024
	CD19	ALLO-501A + ALLO-647 <sup>2</sup>	EXPAND	3+ Line LBCL	•						Initiated
gnanci	CD19	ALLO-501A	ALPHA3	Earlier Line LBCL	•	-**					Ph3 readiness in 2023
Mali	CD19	CD19 - Next Generation									
Hematologic Malignancies	BCMA	ALLO-715	UNIVERSAL	5+ Line MM	•					RMAT ODD	Reviewing Process Improvements
Hema	BCMA	ALLO-605 <sup>3</sup>	IGNITE	5+ Line MM	•					FTD ODD	Reviewing Process Improvements
(	CD70	ALLO-316		Heme Malignancies	•						
	FLT3	ALLO-819		AML							
(	CD70	ALLO-316	TRAVERSE	ccRCC	•					FTD	Cohort expansion 2023
	CD70	ALLO-316		Basket Study	•	-**					Determine histologies for inclusion
own	DLL3	ALLO-213		SCLC	•						
	Claudin 18.2	ALLO-182		Gastric & Pancreatic Cancer	•						
		7 undisclosed targets									

<sup>1</sup>Phase 3 may not be required if Phase 2 is registrational; <sup>2</sup>ALLO-647 (anti-CD52 mAb) is intended to enable expansion and persistence of allogeneic CAR T product candidates; <sup>3</sup>TurboCAR<sup>TM</sup>



# CD19 Program



# ALLO-501A: 1st Allogeneic CAR T to Enter Phase 2 Pivotal Study

#### **Program Optimization**



#### Dosing

- Lymphodepletion: Established ALLO-647 dose response relationship
- Cell Dosing: single 120M cell infusion

#### Manufacturing

 Alloy<sup>™</sup> material demonstrates robust performance

#### **Next Steps**

- Complete Phase 2 trial enrollment in r/r LBCL (1H 2024)
  - Earlier line Phase 3 readiness expected in 2023; initiation in 1H 2024

#### **ALPHA & ALPHA2 Trials**

#### Efficacy: Appears Comparable to Approved CD19 Autologous CAR Ts

- 67% ORR and 58% CR in r/r LBCL among the 12 patients treated with the Single Dose FCA90 regimen using Alloy<sup>™</sup> process material
- Robust durability with 6- and 12-month CR rates of 50%

#### Safety: Appears Similar or Slightly Better than Autologous CAR Ts

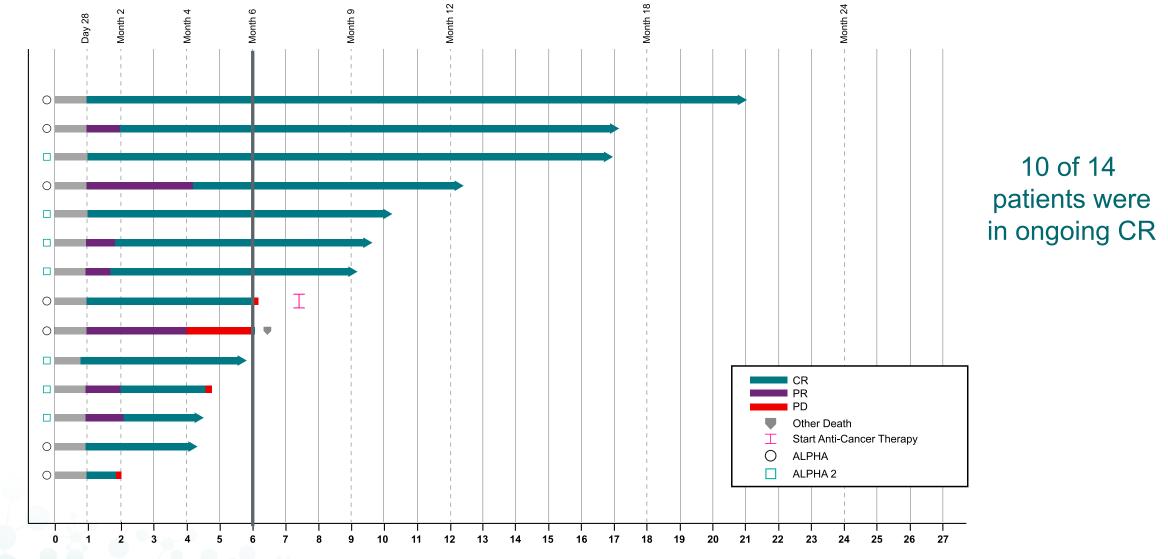
- No DLTs, GvHD or severe ICANS
- Low grade CRS
- 17% prolonged Gr3+ cytopenia
- Grade 3+ infection rates similar to autologous CAR T trials

#### **Delivery: Ability to Meet Current Demand & Grow Market**

- Scalable, optimized Alloy<sup>TM</sup> manufacturing process
- 100% of product in spec
- Treatment within 2-5 days of enrollment



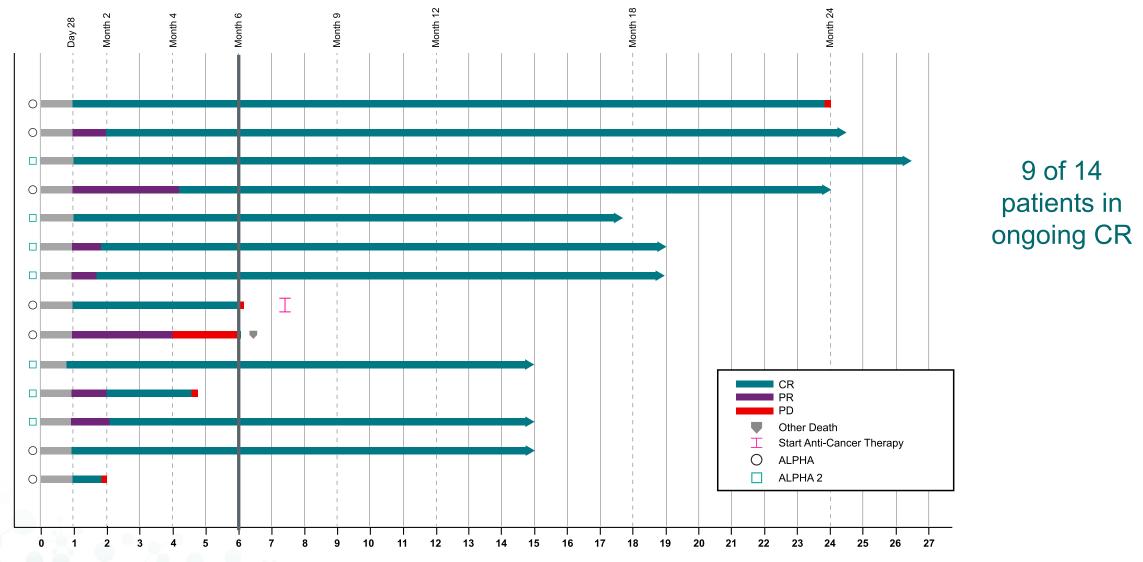
### ASH 2021: Status of LBCL Patients Who Achieved a Complete Response



Months



### Oct 2022 Update: Responses Remain Durable in LBCL with Additional Follow-Up



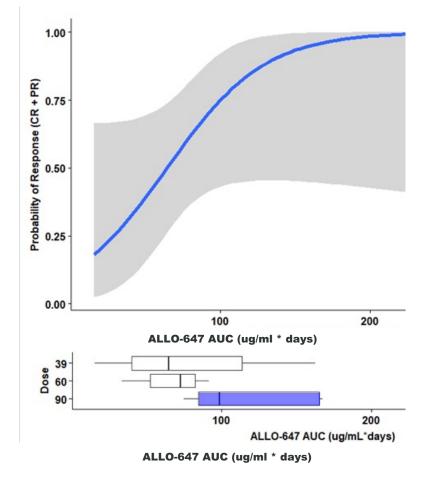
Months



## ALLO-647 Improves the Likelihood of Response

#### ALLO-647 (anti-CD52 mAb) Prevents Premature Rejection of Allogeneic CAR T Cells

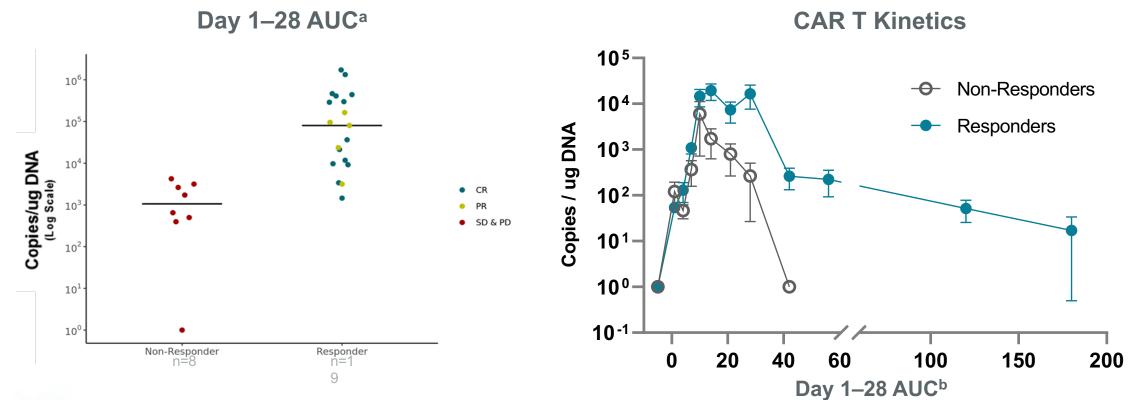
- AlloCAR T dosed with standard FC lymphodepletion results in limited response rate and durability
- ALLO-647 + FC (FCA) compared to FC alone\* leads to significant CAR T cell expansion
- Data demonstrate dose response relationship between ALLO-647 exposure and likelihood of response and cell expansion





\*ASH 2018 Benjamin, R Abstract # 612

### CAR T Cell Expansion Is Associated With Response



AUC = area under the curve; p = 0.0000554 by unpaired t-test. <sup>a</sup> 6 subjects excluded from AUC for having missing data. <sup>b</sup> Data shown for visits before, or without, consolidation or re-treatment. Data cutoff: April 20, 2023.



### CD19 AlloCAR T: Safety and Efficacy Highly Competitive with Auto CAR T

	All Alloy (n=33)	FCA90 Alloy (n=12)	KYMRIAH <sup>®1</sup> Phase 2 Pivotal	YESCARTA <sup>®2</sup> Phase 2 Pivotal	BREYANZI <sup>®3</sup> Phase 2 Pivotal
ORR	58%	67%	50% (label)	72% (label)	73% (label)
CR in LBCL (mITT)	42%	58%	32% (label)	51% (label)	54% (label)
CR at 6 months in LBCL (mITT)	31%	50%	29%	36%	~ 40%
CRS (Gr 3+)	0%	0%	22%	13%	4%
Neuro Events (Gr3+)	6%	0%	12%	31%	12%
Infection (Gr3+)	15%	8%	20%	23%	19%
n enrolled who did not receive intended cell product	n=3	n=1***	33%**	9%**	36%^

<sup>1</sup> KYMRIAH USPI and Schuster S et al NEJM 2019. Patient population in the label includes: 78% - primary DLBCL not otherwise specified (NOS); 22% DLBCL following transformation from Follicular Lymphoma

<sup>2</sup>YESCARTA USPI and Neelapu, NEJM 2017. Patient population in the label includes: 76% - DLBC; 16% - Transformed Follicular Lymphoma; 8% Primary Mediastinal Large B-cell Lymphoma.

<sup>3</sup> BREYANZI USPI and Abramson, Lancet, 2020. Patient population in label includes: 53% - de novo DLBCL; 25% DLBCL transformed from indolent Lymphoma; 14% high-grade B-cell Lymphoma; 7% Primary Mediastinal Large B-cell Lymphoma; 1% grade 3B Follicular Lymphoma \*\*Percent of patients who enrolled and did not receive intended cell product including out of spec products

\*\*\*After enrollment, one subject was found to have CNS involvement and was excluded

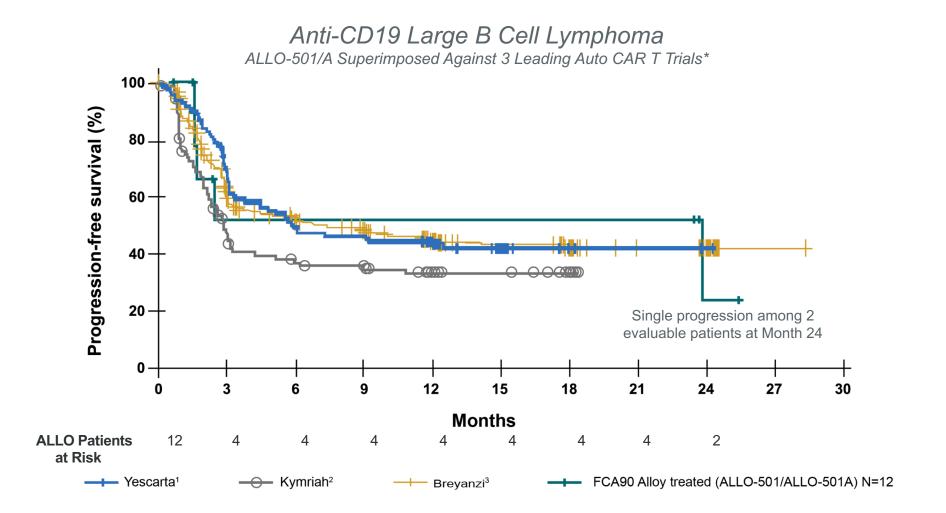
^Percent who underwent lymphodepletion but did not receive intended cell product including out of spec products

FOR ILLUSTRATIVE PURPOSES ONLY: no head-to-head clinical trial has been conducted. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.





### CD19 AlloCAR T: Only Allogeneic CAR T with PFS Tracking with Autologous CAR T



\* 1. Neelapu SS, et al. N Engl J Med. 2017;377:2531-44. 2. Schuster SJ, et al. N Engl J Med 2019;380:45-56. 3. Abramson JS, et al. Lancet 2020; 396: 839-52.



### 3L+ LBCL Program Intended for Approval of ALLO-501A & ALLO-647

tudy	ig/ ent	Lymphodepletion (d -5 to -3)	Treatment (d0)	Primary EPs	
ALPHA2 Phase 2 Stu (n=100)	Screenin Enrollme	<ul> <li>Flu 30 mg/m<sup>2</sup> IV x3</li> <li>Cy 300 mg/m<sup>2</sup> IV x3</li> <li>ALLO-647 90 mg IV</li> </ul>	ALLO-501A: single IV infusion of 120M CART cells on day 0	• ORR • CR	

t	Active Arm: Lymphodepletion (d -5 to -3)	Treatment (d0)	
ig/Enrollment	<ul> <li>Flu 30 mg/m<sup>2</sup> IV x3</li> <li>Cy 300 mg/m<sup>2</sup> IV x3</li> <li>ALLO-647 90 mg IV</li> </ul>	ALLO-501A: single IV infusion of 120M CART cells on day 0	<pre>Primary EP • PFS</pre>
Screening	Control Arm: Lymphodepletion (d -5 to -3)	Treatment (d0)	
Scre	<ul> <li>Flu 30 mg/m<sup>2</sup> IV x3</li> <li>Cy 300 mg/m<sup>2</sup> IV x3</li> </ul>	ALLO-501A: single IV infusion of 120M CART cells on day 0	

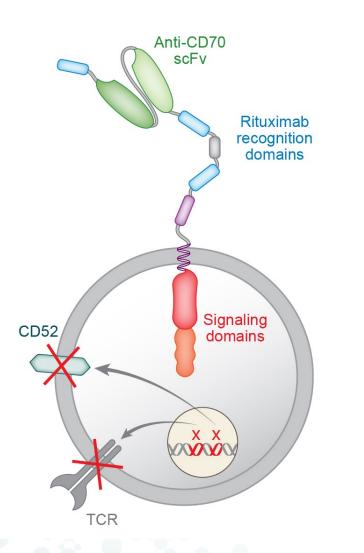


EXPAND Phase 2 Study (n=70)

# CD70 Program



## ALLO-316: A Potentially Best-In-Class Candidate for RCC



#### **ALLO-316 Engineered for Optimal Activity**

- "Masking" technology to avoid fratricide during manufacture and to eliminate need for CD70 knock out
- Dagger<sup>TM</sup> technology aimed at enhancing cell persistence and expansion
- Open field of unmet need
  - Tivozanib approved in 3L+ setting: ORR <20% and mPFS <6mo\*

\*Tivozanib Pl

#### **CD70 Target Selectively Expressed in RCC, Other Tumors**

Phase 1 ongoing in 3L+ RCC, a large indication with unmet need

#### **TRAVERSE** Phase 1 Shows Encouraging Activity in CD70+ RCC

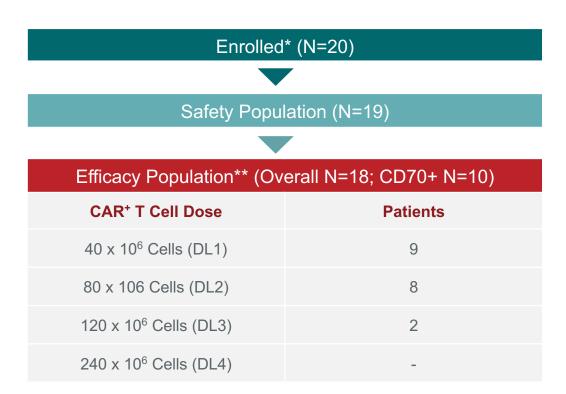
- 30% ORR, 100% DCR in patients with established CD70+ expression
- AE profile generally consistent with autologous CAR T therapies , no GvHD, 1 Grade 3 DLT

#### **Next Steps**

- Establish Phase 2 regimen in ongoing TRAVERSE trial
- Explore other solid tumor and hematologic indications or combination with other anticancer therapies such as immune checkpoint inhibitors



## ALLO-316 TRAVERSE Phase Trial: Patient Flow



\* One patient withdrew consent prior to treatment

\*\* Of the 19 patients dosed with ALLO-316, 18 had at least 1 tumor assessment

#### **Dose exploration continuing**

#### • Study enrolled patients with clear cell RCC

- Patients must have received a checkpoint inhibitor and a VEGF inhibitor in the advanced and/or metastatic setting
- Patients were heavily pretreated with a median of 3 prior lines of therapy
- HLA independent dosing (standard for AlloCAR T<sup>™</sup>)
- Median follow-up time: 7.8 months



## ALLO-316: Safety and Tolerability Consistent with Autologous CAR T

	Patients who received ALLO-316 (n=19)		
TEAEs of Interest <sup>b</sup>	All Grades n (%)	Grade 3+ n (%)	
Infusion-Related Reaction	1 (5)	0	
CRS	11 (58)	1 (5)	
ICANS	0	0	
GvHD	0	0	
Neurotoxicity <sup>c</sup>	13 (68)	2 (11)	
Infection <sup>d</sup>	8 (42)	4 (21)	
Prolonged Grade 3+ Cytopenia <sup>e</sup>	N/A	3 (16)	

 One DLT event (Gr 3 type 2 autoimmune hepatitis<sup>a</sup>) in DL2 FCA

- CRS was low grade (except 1 Gr 3) and responded to standard treatment
- No reports of ICANS; 2 patients were noted to have Gr 3 neurotoxicity (syncope and fatigue, respectively)
- No GvHD observed
- One patient had Gr 5 respiratory failure in the setting of COVID-19 infection deemed unrelated to study treatment
- Infections now managed with enhanced prophylaxis

<sup>a</sup> DLT initially reported as elevated AST/elevated ALT.

<sup>b</sup> Number of patients with AE occurring from the start of study drug up to subsequent anti-cancer therapy. For patients reporting more than one AE within a preferred term, only one AE with the maximum grade is reported.

<sup>c</sup> Neurotoxicity including ICANS: includes preferred terms (PT) from the Allogene MedDRA Query (AMQ) for Neurologic toxicities including ICANs, a broad search basket of over 200 PTs selected to identify the medical concept. The majority of neurotoxicities are fatigue and headache.

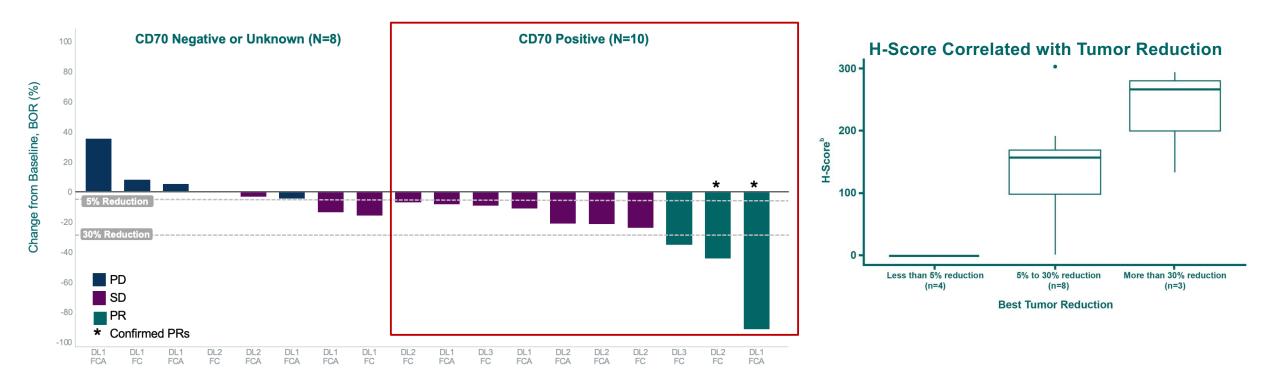
<sup>d</sup> The 4 Gr 3+ infections comprised 2 bacterial (PICC line infection and UTI), 1 fungal (bronchopulmonary aspergillosis) and 1 viral (Gr 5 respiratory failure in setting of COVID-19). At the time of data cut, one additional Gr 3 fungal sinusitis had not yet been recoded as disease progression.

e Prolonged Cytopenia at Day 28, includes Grade 3 or above neutropenia, thrombocytopenia, anaemia or pancytopenia which is present at Study Day 28.



## ALLO-316: Demonstrates Feasibility to Treat Solid Tumors

#### TRAVERSE continues to explore cell dose and lymphodepletion regimen in CD70+ RCC patients

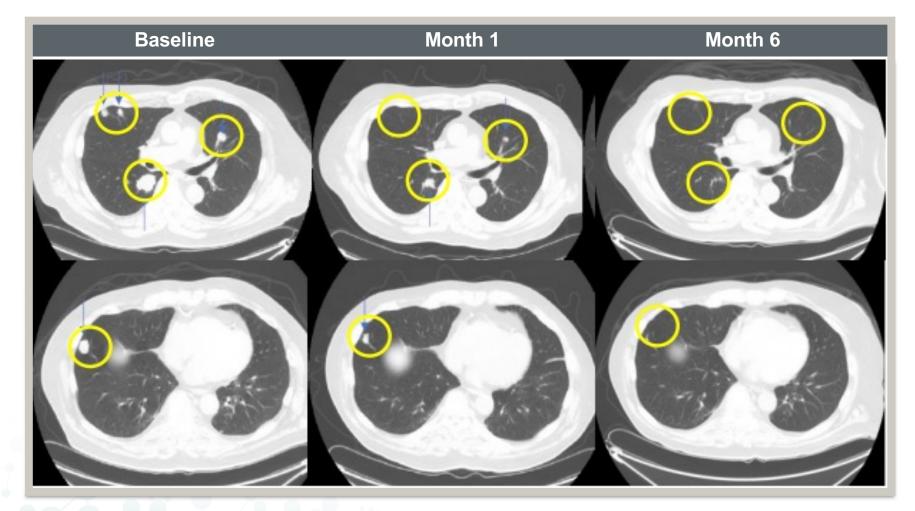


#### **Response Rates Correlate with CD70 Expression**

- All Patients Evaluable for Efficacy: 17% ORR and 89% disease control rate (DCR)
- CD70+ Patients: 30% ORR and 100% DCR



### ALLO-316 Case Study 1: Deepening Response After Lowest Tested Cell Dose

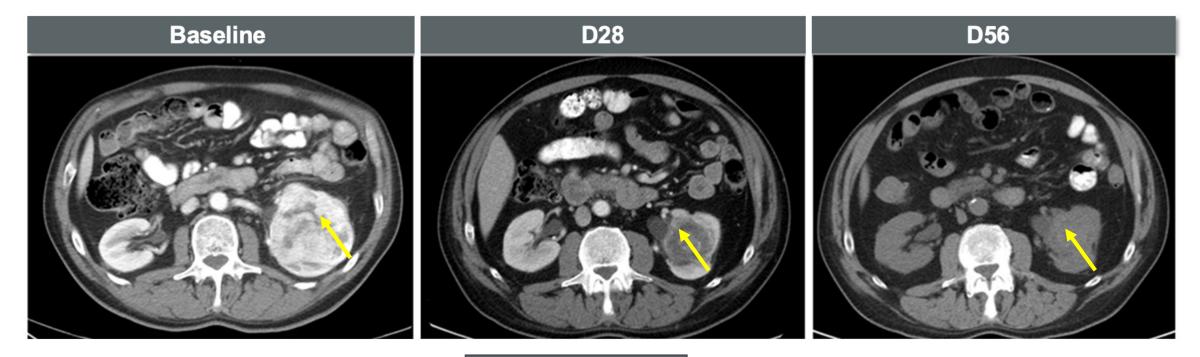


#### Partial Response

- 68-year-old man with metastatic RCC to the lungs, refractory to checkpoint blockade, angiogenesis inhibitors
- Treated with FCA and 40M CAR+ cells
- Responded with initial partial response at Month 1 that continued to deepen through Month 6
- Demonstrates durability of response with ALLO-316



# Case Study 2: ALLO-316 Can Target Primary Renal Tumors



#### Stable Disease

- 70-year-old male with RCC metastatic to adrenal and bone, refractory to axitinib and pembrolizumab
- Treated with FCA and 80M CAR+ cells
- Best Overall Response of Stable Disease with 45% decrease in size of primary left kidney tumor



# CD70 Dagger™ Technology



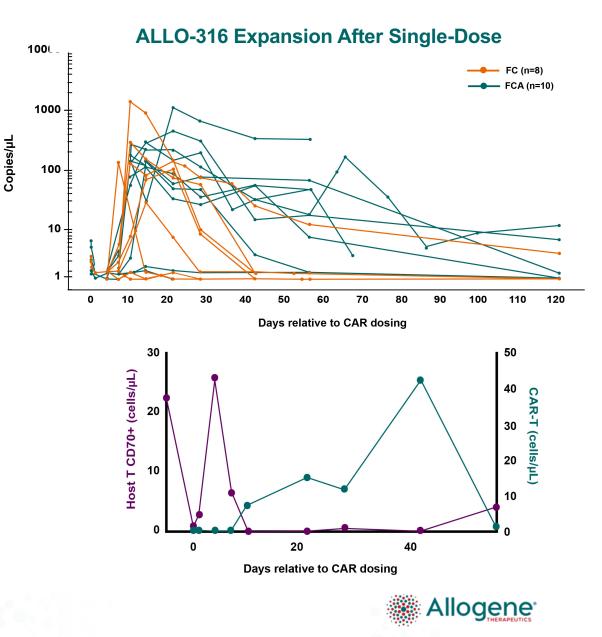
### Dagger™: A Next-Gen Approach for Improved Cell Expansion

#### Potentially Foundational CD70 Dagger™ Technology Platform Designed To Control Immune Rejection

- Dagger<sup>™</sup> Platform takes advantage of CD70 on activated host T cells to enhance CAR T cell expansion and persistence
- CAR T cells armed with Dagger<sup>™</sup> receptors can eradicate alloreactive host T cells *in vitro*, and may reduce host rejection *in vivo*

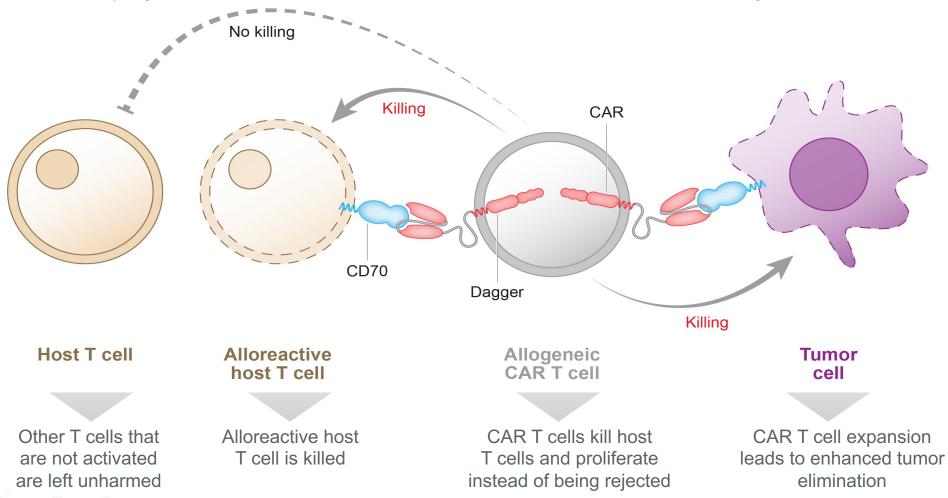
#### ALLO-316 Phase 1 Data Provides Proof-of-Concept

- Robust CAR T expansion observed in TRAVERSE study
  - Following ALLO-316 infusion, alloreactive host T cells upregulate CD70 by Day 4
  - ALLO-316 expands by Day 10 and eliminates CD70+ host T cells while CD70- host T cells are spared
  - Host CD70+ T cells recover as ALLO-316 contracts



### Dagger<sup>™</sup> Mechanism Specifically Targets Alloreactive Host T Cells

Deploys Anti-CD70 to Protect AlloCAR T Cells from Immune Rejection





# **BCMA** Program



### ALLO-715: First & Only Allogeneic CAR T Study to Establish Proof-of-Concept in MM

#### **BCMA Program Evolution**

#### **Established Proof-of-Concept**

 First AlloCAR T to establish responses in myeloma comparable to an approved autologous CAR T therapy

#### Manufacturing

 Reviewing opportunity to improve manufacturing processes across BCMA candidates for optimal performance



#### **Next Steps**

- ALLO-715 Phase 1 complete
  - Data published in Nature Medicine
  - Manufacturing process optimization underway
- ALLO-605 TurboCAR<sup>™</sup> in process optimization (IGNITE trial)

#### **ALLO-715 UNIVERSAL Trial**

#### **Expansion Cohort Demonstrated Deep and Durable Responses**

- Single Infusion of 320M CAR+ cells with FCA60 Lymphodepletion Resulted in 67% ORR and 42% VGPR+
  - 100% of VGPR+ Patients Minimal Residual Disease
  - Median DOR of 9.2 months

#### Manageable Safety Profile Across All Doses:

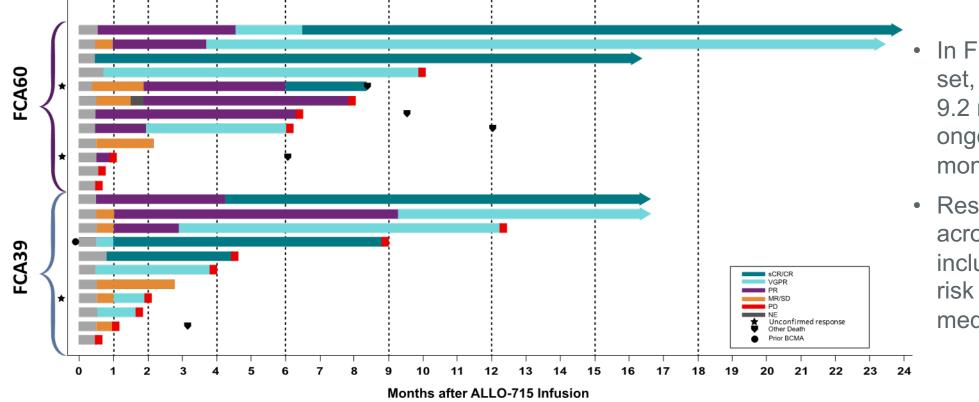
- No GvHD
- Low-grade and reversible neurotoxicity; one Gr 2 ICANS
- Low-grade CRS with only one Gr 3
- Low use of tocilizumab (32%) and steroids (25%)

#### **Treatment within 5 Days of Enrollment; No Bridging Therapy**

- 92% of enrolled patients received product
- 100% of infused product manufactured & released per product specifications



## ALLO-715 Expansion Cohort Shows Durable Responses



- In FCA60 efficacy evaluable set, the median DOR was 9.2 months with the longest ongoing response at 24 months
- Responses were seen across all subgroups including patients with highrisk cytogenetics and extra medullary disease

\* Two subjects had responses of PR which were never confirmed; one of them is categorized as best response PD and the other as best response SD. One subject had a response of VGPR which was never confirmed and is categorized as a best response of PR.



### A Single Dose of ALLO-715 Has Potential to Address Patient Need

Treatment Administration and Efficacy (mITT)	ALLO-715 (320M & FCA60) n=12 <sup>1</sup>	Tecvayli (teclistamab)²	Abecma® (Ide-cel) <sup>3</sup>	Carvykti (Cilta-cel) <sup>4</sup>
ORR (mITT)	67%	62%	72%	98%
VGPR+ Rate (mITT)	42%	57%	53%	95%
CR/sCR Rate (mITT)	17%	28%	28%	78%
MRD <sup>5</sup> - in VGPR+	100%	69%	75%	92%
Duration of Response (median)	9.2 mo <sup>6</sup>	Not reached	11.0 mo	21.8 mo
CRS (Gr3+)	0%	< 1%	9%	5%
Neurologic Toxicity (Gr3+)	0%	2.4%	4%	11%
Infection (Gr3+)	35%	39.2%	26%	27%
Grade 5 Adverse Events	6%	5%	6%	9%
% enrolled who did not receive intended cell product <sup>7</sup>	11%	Discontinuation (AE) 1.2% Dose interruption (AE) 73%	26%	29%
Days to treatment initiation <sup>8</sup>	5	Not reported	33	32
Required bridging therapy	0%	NA	87%	75%

<sup>1</sup> data through 11 Oct 2022; <sup>2</sup> Tecvalyi USPI and Usmani, 2021; <sup>3</sup> Abecma USMI and Munshi, 2021; <sup>4</sup> USPI and Berdeja, 2021; <sup>5</sup> For UNIVERSAL, MRD status is evaluated in subjects with VGPR+; for Tecvayli, MRD is reported in 26 subjects with CR or better; for Abecma, MRD is reported among subjects with CR or sCR; <sup>6</sup> 5 subjects remain in response between 17 and 24 months; <sup>7</sup> cell product that is successfully manufactured and meets release specifications; for Abecma 11 patients did not receive treatment and 24 patients received out of specification product; for Carvykti, 16 patients did not receive Carvykti due to progressive disease and 17 patients received out-of-specification product; <sup>8</sup> for ALLO-715, time from enrollment to start of lymphodepletion. Two patients were not treated due to rapidly progressing disease; for Abecma, time from apheresis to cell product availability (includes 87% of patients who received bridging therapy)

FOR ILLUSTRATIVE PURPOSES ONLY: no head-to-head clinical trial has been conducted. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.





### Realizing the Potential of Allogeneic CAR T through Innovation and Execution

#### Our goal is to make CAR T available to <u>all</u> patients in need



Best & First-in-Class Profile

#### **ALLO-501A**

- First potentially pivotal Ph2 trial
- 67% ORR and 58% CR rate with single dose and FCA90 lymphodepletion
- · Durability moves the field beyond proofof-concept and validates Allogene's platform



BCMA Potential First-in-Class

#### **ALLO-715**

- First & only allogeneic CAR T trial to demonstrate potential in MM
- Expansion cohorts deliver response rates that support advancement
- Reviewing manufacturing process improvements across BCMA candidates for optimal performance

**CD70** *Expanding into Solid Tumors* 

#### **ALLO-316**

- Demonstrates feasibility of an allogeneic CAR T to treat RCC
- Induced Anti-Tumor Activity in Patients with CD70 Expressing RCC with **Deepening Responses Over Time**



CD19 Data Cutoff Date: October 25, 2022; ALLO-715 Data Cutoff Date:



# The Next Revolution in Cell Therapy

### Leading the Revolution from CAR T Therapies to CAR T Products

Allogene therapies utilize TALEN<sup>®</sup> gene-editing technology pioneered and owned by Cellectis. ALLO-501 and ALLO-501A are anti-CD19 AlloCAR T<sup>™</sup> therapies being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA, FLT3, DLL3, CD70 and Claudin 18.2.



