

## The Next Revolution in Cell Therapy Leading Today, Creating Tomorrow

September 2020

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# Allogene: Leading the Future of AlloCAR T<sup>™</sup> Cell Therapy





## Why We Believe Allogeneic Cell Therapy Will Lead the Revolution

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#### Access

- Potential to treat all eligible patients
- Repeat dosing, if needed
- No need for complex logistics

#### Cost

• Scalable and efficient manufacturing

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- Potential to treat 100+ patients from a single manufacturing run
- Lower ancillary costs of care

### **Speed/Reliability**

- "Off the shelf" for on demand treatment
- Less product variability, made from healthy T cells

### Innovation

- Multiplex gene engineering/editing capabilities
- Opportunity for product optimization



# The AlloCAR T<sup>™</sup> Platform for Today and Tomorrow





# Defying Immunity: Overcoming GvHD and Graft Rejection



Allogeneic cell therapy engages the fundamental immunological process of Self vs. Non-Self recognition



ALLO-501: Two Gene Edits Directed at Controlling GvHD and Graft Rejection



1. TALEN-mediated TRAC KO eliminates TCRα expression to minimize risk of GvHD

2. TALEN-mediated CD52 KO allows selective lymphodepletion with ALLO-647

TALEN® is a Cellectis gene editing technology



# Deep AlloCAR T<sup>™</sup> Pipeline Targeting Vast Array of Tumor Types

CATEGORY	PROGRAM	PRE- CLINICAL PHASE 1		PHASE 2/3 <sup>1</sup>
	ALLO-501 (NHL) <sup>2 3</sup>			
CD19	ALLO-501A (NHL) <sup>2 3</sup>			
	UCART19 (ALL) <sup>2</sup>			
Hematological	ALLO-715 (MM)			
Malignancies Magazina	ALLO-715 + nirogacestat (MM) <sup>5</sup>			
	ALLO-605 (TurboCAR™/MM)			
	ALLO-316 (CD70/AML)			
	ALLO-819 (FLT3/AML)			
	ALLO-316 (CD70/RCC)			
Solid Tumors	DLL3 (SCLC)			
	Multiple Undisclosed Targets			
Lymphodepletion Agent	ALLO-647 (Anti-CD52 mAb) <sup>4</sup>			

- <sup>1</sup> Phase 3 may not be required if Phase 2 is registrational
- <sup>2</sup> Servier will hold ex-US commercial rights. Servier is the sponsor of the UCART19 trials
- <sup>3</sup> Allogene is the sponsor of the ALLO-501 and ALLO-501A trial
- <sup>4</sup> ALLO-647 intended to enable expansion and persistence of allogeneic CAR T product candidates
- <sup>5</sup> Allogene sponsored trial in combination with SpringWorks Therapeutics



## Pathways to Leverage CD19 & BCMA Clinical Expansion



### ALPHA Study (NCT03939026) Design and Endpoints Phase 1, Open-label, Multicenter Dose Escalation Study

#### **Primary Endpoints**

 Safety and dose-limiting toxicity of ALLO-647/Flu/Cy followed by ALLO-501

#### **Key Secondary Endpoints**

- Overall response rate
- ALLO-501 cell kinetics
- ALLO-647 PK

#### **Key Eligibility Criteria**

- R/R LBCL or FL
- At least 2 prior lines of therapy, including an anti-CD20 monoclonal antibody
- ECOG 0 or 1

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- Prior autologous CAR T allowed if tumor remains CD19+
- Patients with Donor Specific Antibodies and rituximab > 15ng/ml were excluded



- Lymphodepletion Regimens
  - LD1: Flu/Cy and ALLO-647 13 mg/d x 3 days
  - LD2/LD3: Flu/Cy and ALLO-647 30 mg/d x 3 days (concomitant/staggered)

Fludarabine (Flu): 30 mg/m2/d x 3 days Cyclophosphamide (Cy): 300 mg/m2/d x 3 days



## ALPHA Phase 1 Patient Characteristics

	Number (%) of patients					
	40 x 10 <sup>6</sup> DL 1 (N=4)	120 x 10 <sup>6</sup> DL 2 (N=10)	360 x 10 <sup>6</sup> DL 3 (N=8)	All Patients (N=22)		
Median Age, years (range)	57 (42, 67)	70 (37, 73)	54 (34, 67)	63 (34, 73)		
Male	3 (75%)	8 (80%)	6 (75%)	17 (77%)		
Lymphoma Subtypes						
Diffuse Large B-cell Lymphoma <sup>+</sup>	3 (75%)	5 (50%)	6 (75%)	14 (64%)		
Follicular Lymphoma	1 (25%)	5 (50%)	2 (25%)	8 (36%)		
Current Disease Stage (per Lugano 2014) #						
Stage III	1 (25%)	5 (50%)	2 (25%)	8 (36%)		
Stage IV	2 (50%)	5 (50%)	6 (75%)	13 (59%)		
FL(IPI) Score 3-5	1 (25%)	6 (60%)	5 (63%)	12 (55%)		
Prior Treatments						
Median Number (range)	2 (2-4)	4 (3-4)	5 (3-8)	4 (2-8)		
Hematopoietic Stem Cell Transplant	2 (50%)	4 (40%)	3 (38%)	9 (41%)		
Autologous CAR T cell	-	1 (10%)	3 (38%)	4 (18%)		

\* Not otherwise specified, transformed FL, high-grade B cell lymphoma (double and triple hit), DLBCL coexistent with FL of any grade

" 1 patient with stage II disease treated at DL1

\* Defined as best outcome of SD or PD following last therapy, or progression within 12 months following Hematopoietic Stem Cell Transplant

- Heavily pretreated patients with advanced-stage disease
- 14 (64%) of patients were chemo refractory<sup>\*</sup>
- 4 patients received prior AutoCAR T
  - 2 had short-lasting PR as best response and 2 had PD as best response with AutoCAR T
- Analyses sets:
  - Efficacy: N=19
  - Safety: N=22

Data Cutoff Date: May 11, 2020



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# ALLO-501 and ALLO-647 Demonstrate Manageable Safety Profile

AE of Interest <sup>‡</sup>	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	All grades n (%)
Cytokine Release Syndrome *	2 (9%)	4 (18%)	1 (5%)	-	-	7 (32%)
ICANS *	7.7	1	-		-	
Graft-versus-Host Disease	<u>-</u> 1	2	_	-	-	-
Infection	5 (23%)	4 (18%)	2 (9%)†	-	-	11 (50%)
Infusion Reaction #	1 (5%)	9 (41%)	1 (5%)	-	-	11 (50%)
Neutropenia	-	1 (5%)	7 (32%)	7 (32%)	-	15 (68%)

- No DLT, GvHD
- Manageable CRS
- ALLO-501 toxicity not dose-proportional
- Median duration of hospitalization from D0: 7 days
- \* ASTCT Lee, 2019. ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome \* CMV reactivations and Rotavirus infection # attributed to ALLO-647

#### Serious Adverse Events (time to resolution) \*

- 4 patients (18%):
  - Gr2 pyrexia (2 days) and Gr2 CMV reactivation (6 days)
  - Gr3 rotavirus infection (15 days) and Gr3 hypokalemia (2 days)
  - Gr3 febrile neutropenia (2 days) and Gr3 hypotension (2 days)
  - Gr3 upper GI hemorrhage (<1 day) and Gr3 CMV reactivation (25 days)

<sup>‡</sup> Number of patients with AE regardless of attribution unless otherwise indicated, 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).

Data Cutoff Date: May 11, 2020



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## Phase 1 ALPHA Best Overall Response

Cell Dose	39mg ALLO-647			All 20mg	90mg ALLO-647		All 90mg	All Patients
and LD regimen	40 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=4)	120 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=4)	360 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=3)	ALLO-647 (N = 11)	120 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=6)	360 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=2)	ALLO-647 (N=8)	(N=19) Rate (95%Cl)
ORR, n (%)	3 (75%)	3 (75%)	1 (33%)	7 (64%)	4 (67%)	1 (50%)	5 (63%)	12/19 (63%) (38%, 84%)
CR , n (%)	1 (25%)	1 (25%)	1 (33%)	3 (27%)	4 (67%)	0 (0%)	4 (50%)	7/19 (37%) (16%, 62%)

Median follow-up time: 3.8 months (range: 0.7 - 6.1)



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## Reduction in Tumor Size Observed with ALLO-501



360 M 360 M 40 M 120 M 120 M 40 M 360 M 120 M 120 M 360 M 120 M 40 M 360 M 40 M 120 M 120

Patients (ALLO-501 / ALLO-647 dosing)

#### \* Received prior AutoCAR T

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Data Cutoff Date: May 11, 2020

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# Nine of Twelve Responders Remain in Response



# AlloCAR T Cell Expansion Is Associated with Clinical Response



Data Cutoff Date: May 11, 2020



# ALLO-647 Mediates Selective Lymphodepletion



• Median time to Platelet >=100K is 8 days for 90mg ALLO-647 dose cohort

Data Cutoff Date: May 11, 2020



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ALLO-647 (90 mg)

### ALLO-501 Patient Case Study

- 120 x 10<sup>6</sup> CAR<sup>+</sup> T cells after Flu/Cy + 39mg ALLO-647
- 70-year-old male with follicular lymphoma
- FLIPI 4, stage 4 (bone marrow infiltration), splenic involvement
- Primary refractory with 4 prior lines of therapy (best outcome)
  - 1. R-Benda x 4 cycles (PD)
  - 2. R-CHOP x 2 cycles (SD)
  - 3. R-Len x 2 cycles (PD)
  - 4. Copanlisib x 2 cycles (SD)
- Safety:
  - ALLO-647-related: Gr1 pyrexia

### Patient remains in CR at Month 4

Data Cutoff Date: May 11, 2020

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#### Courtesy of Sattva Neelapu





## ALLO-501 Patient Case Study 2: Redosing after Disease Progression

#### First ALLO-501 Treatment



#### Month 2 PD: ALLO-501 Redosing



Courtesy of Sattva Neelapu



Data Cutoff Date: May 11, 2020



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## ALLO-501 ALPHA Phase 1 CAR T Naïve Efficacy Data Initial Responses Comparable to Autologous CAR T Therapies

Cell Dose and LD regimen	ALLO-501 ALLO-647 39mg Patients (N=10)	ALLO-501 ALLO-647 90mg Patients (N=6)	All ALLO-501 Ph1 (N=16)	Autologous Ph1 Trials in NHL*	Autologous Ph2 Trials in NHL**
ORR, n (%)	7 (70%)	5 (83%)	12 (75)%	64-80%	50-73%
CR, n (%)	3 (30%)	4 (67%)	7 (44%)	56-60%	32-53%

\* Kymriah and liso-cel trials include FL and MCL patients; ASH 2015; Schuster, NEJM, 2019; Abramson, ASH 2019

\*\* Yescarta, Kymriah FDA labeling information and Abramson ASH 2019; Based upon mITT analyses

ALPHA Data Cutoff Date: May 11, 2020



- Contractor

# Initial ALPHA Safety Data Compare Favorably to Autologous Therapies\*

AE of Interest (≧Gr3)	ALLO-501 Ph1 (N=22)	axi-cel Ph2* (N=101)	tisa-cel Ph2* (N=111)	liso-cel Ph2* (N=269)
Cytokine Release Syndrome	5%	13%	23%	2%
ICANS	-			
Neurologic Events		31%	18%	10%
Graft-versus-Host Disease	-	-	-	-
Infection	9%	23%	25%	12%
Neutropenia	64%	93%	81%	60%
Infusion Reaction	5%**	-	-	-

#### ALLO-501 safety profile increases potential outpatient opportunity

- \* Neelapu NEJM 2017, Schuster NEJM 2019, and Abramson ASH 2019
- \*\* Attributed to ALLO-647

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ALPHA Data Cutoff Date: May 11, 2020



## ALLO-501 Compares Favorably Across Other Criteria

Study	ALLO-501	Autologous Therapies*			
Product manufactured for all patients	100%	1-7% manufacturing failure			
		axi-cel	tisa-cel	liso-cel	
Time to Treatment	<b>5 days</b> Enrollment to treatment	17 days Leukapheresis to cell delivery	54 days Enrollment to treatment	Not reported	
Patients not treated	4%	9%	34%	Not reported	
Ease of re-dosing	Yes	May require re-manufacturing			

#### Almost all enrolled patients were treated with ALLO-501

\* Neelapu NEJM 2017, Schuster NEJM 2019, and Abramson ASH 2019

ALPHA Data Cutoff Date: May 11, 2020



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# Key Questions for the ALLO-501 ALPHA Study

Can ALLO-501 be successfully manufactured?

- Can ALLO-501 be safely administered without causing clinically relevant Graft vs. Host Disease?
- Can ALLO-647 be safely administered and allow a sufficient window of lymphodepletion to allow ALLO-501 expansion and persistence?
- ☑ Can ALLO-501 provide complete responses across multiple histologies?

**ONGOING** Can ALLO-501 provide durable responses?



# Path to a Pivotal Trial: Next Generation ALLO-501A in R/R NHL

### • ALLO-501A

- Next generation anti-CD19 AlloCAR T intended for Phase 2 Development
- Eliminates the rituximab recognition domains in ALLO-501, which we believe will allow for use in a broader patient population, including those NHL patients with recent rituximab exposure
- Abbreviated Phase 1 Trial initiated in Q2 2020



Servier holds ex-US rights to ALLO-501A



## Bringing AlloCAR T to Patients with Multiple Myeloma





# ALLO-715: UNIVERSAL Study Targeting BCMA in R/R MM

- Primary Objective:
  - Safety and tolerability
- Key Secondary Objectives:
  - Recommended P2 dose for ALLO-715 and lymphodepletion regimen
  - Anti-tumor activity
- Key Eligibility Criteria:
  - Relapsed/refractory multiple myeloma
  - At least 3 prior lines of MM therapy, including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 antibody
- Initial P1 data expected Q4 2020



Treatment:

• Initial Dose Escalation: 40, 120, 320 X 10<sup>6</sup> CAR+ cells

#### Lymphodepletion:

- ALLO-647: 39 to 90 mg
- Fludarabine: 30 mg/m²/d x 3 days
- Cyclophosphamide: 300 mg/m²/d x 3 days



# TurboCAR™: Turbocharging CAR T Cells

- Cytokine stimulation can increase the potency and durability of engineered T cells
- TurboCAR<sup>™</sup> is designed to recapitulate cytokine signaling selectively in CAR T cells
  - Minimizes systemic toxicity
  - Does not stimulate host immune cells which could reject CAR
  - Delivers survival benefit selectively to CAR T cells
- Opportunities for development include
  - Improving the efficacy of CAR T cells
  - Reducing CAR T cell dose requirement
  - Overcoming exhaustion to enable CAR T therapies for solid tumors
- ALLO-605 will be first TurboCAR candidate with IND expected in 2021





# ALLO-316 (anti-CD70): The Next AlloCAR T Clinical Candidate

- ALLO-316 is an anti-CD70 AlloCAR T candidate for renal cell carcinoma (RCC) as well as several hematological malignancies
- CD70 expression<sup>1</sup>:
  - RCC (80-100%)
  - AML (96%)
  - DLBCL (71%), MM (63%), CLL (50%)
  - GBM (35%)
  - CD70 is also expressed on activated T cells
- CD70 in RCC:

- High prevalence with limited 'off tumor' expression
- Good expression in metastatic disease
- ALLO-316 is associated with minimal or no fratricide
- IND Submission expected 2H 2020

<sup>1</sup> Expert Opin Ther Targets. 2008 Mar; 12(3): 341–351. doi: 10.1517/14728222.12.3.341





## iPSCs: The Road to a Renewable Cell Source

### Notch Therapeutics Collaboration



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- We believe the Notch proprietary platform supports scalable, feeder cell-free manufacturing of mature T cells and CAR T engineered cells
- Induced pluripotent stem cells (iPSC) cells can be engineered at the stem cell stage and clonal cell bank can be created

- Exclusive worldwide license agreement to develop iPSC AlloCAR<sup>™</sup> products for initial application in NHL, leukemia and MM
- Notch is a recognized leader in the differentiation of iPSCs into T Cells
- Allogene has 25% equity position in Notch



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## Creating State-of-the-Art AlloCAR T Manufacturing Capabilities



#### **Current South San Francisco Facility**

- Manufacturing process development & optimization
- Analytic methods for in-process characterization & improvement
- Quality Assurance and Quality Control support

### East Bay Area Facility (Newark, CA)

- In-house manufacturing capability build underway:
  GMP manufacturing expected to be ready in 2021
- Potential supply for commercial launch upon approval

### **Current CMO Support**

- Dedicated purpose built GMP suite
- Clinical supply manufacturing, formulation & release



# Allogene is Creating The AlloCAR T<sup>™</sup> Platform for Tomorrow

#### Improving T Cell Fitness

- TurboCARs<sup>™</sup>
- Manufacturing improvement
- Site-specific integration

#### Induced Pluripotent Stem Cells (iPSCs)\*

- Potential renewable starting cell source
- Master cell bank of engineered iPSCs
- Proprietary T cell differentiation technology



### **Preventing Graft Rejection**

- Enhanced lymphodepletion
- Immune evasion

### **Expanding Target Repertoire**

- Target selection/validation
- CAR optimization
- Multi-targeting CARs

\*In collaboration with Notch Therapeutics

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2020 Clinical Milestone Progress





### Allogene: Leading Today, Creating Tomorrow in Allogeneic Cell Therapy

Portfolio Rapid development of robust and expanding AlloCAR T<sup>™</sup> • portfolio Experience

Highly experienced cell therapy management team

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### Capability

Fully integrated, in-house capability for discovery & translational research, development and cell manufacturing

### **Scientific Leadership**

Vast knowledge and understanding of autologous and allogeneic similarities and differences



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## The Next Revolution in Cell Therapy Leading Today, Creating Tomorrow

ALLO-501 is an anti-CD19 allogeneic CAR T (AlloCAR T<sup>™</sup>) therapy being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. ALLO-501 uses Cellectis technologies. Servier grants to Allogene exclusive rights to ALLO-501 in the U.S. while Servier retains exclusive rights for all other countries.