

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

July 2021

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Caution should be exercised when interpreting results from separate trials involving separate product candidates. There are differences in the clinical trial design, patient populations, and the product candidates themselves, and the results from the clinical trials of autologous products may have no interpretative value on our existing or future results.

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# Allogene: Leading the Field in Allogeneic Cell Therapy



# Rapidly Advancing Allogeneic Pipeline For Vast Array of Tumors

	CATEGORY	PROGRAM	PRE-CLINICAL	PHASE 1	PHASE 2/3 <sup>2</sup>	
	CD19	ALPHA: ALLO-501 (NHL) <sup>1</sup>				
	C	ALPHA2: ALLO-501A (NHL) <sup>1</sup>				
	Hematological d	UNIVERSAL: ALLO-715 (MM)				
	Malignancies	UNIVERSAL: ALLO-715 + nirogacestat (MM) <sup>3</sup>				
	۵	<i>IGNITE</i> : ALLO-605 (TurboCAR™/MM)				
C		ALLO-316 (CD70/AML)				
		ALLO-819 (FLT3/AML)				
-		TRAVERSE: ALLO-316 (CD70/RCC)				
	Solid Tumors	DLL3 (SCLC)				
		8 Undisclosed Targets				
	Lymphodepletion Agent	ALLO-647 (Anti-CD52 mAb) <sup>4</sup>				

 <sup>1</sup> Servier holds ex-US commercial rights
<sup>2</sup> Phase 3 may not be required if Phase 2 is registrational; Initiation for ALLO-501A Phase 2 trial expected 2H 2021

<sup>3</sup> Allogene Sponsored trial in combination with SpringWorks Therapeutics <sup>4</sup> ALLO-647 intended to enable expansion and persistence of allogeneic CAR T product candidates





## Innovating CAR T Therapies to Potentially Expand Access & Reduce Cost

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## Cost

- Scalable and efficient manufacturing
- Potential to treat 100+ patients from a single manufacturing run
- Opportunity to reduce ancillary cost of care associated with autologous therapy

## Access

- Potential to treat all eligible patients
- Re-dosing, if needed
- No need for complex logistics or bridging therapy

## Innovation

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



## Speed/Reliability

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



## Industrializing Allogeneic Cell Therapy Production: Strategy



Singularly focused AlloCAR T<sup>™</sup> platform development enables speed and minimizes cost



Ownership of manufacturing and testing allows improved process optimization, and control regulatory and compliance



Investment in partnerships with critical suppliers ensures availability of emergent, high-demand materials



ALLO-647 development and production, with dedicated ALLO oversight, preserves focus on AlloCAR T's



Leveraging QTPP framework for product understanding to improve process performance and supports comparability



COGM is shaped by infrastructure, and operationalization choices



celiable Product Deliver

## Industrializing Allogeneic Cell Therapy Production: Infrastructure





### Cell Forge 1 (Newark, CA)

- New state-of-the-art facility
- Designed for clinical and commercial manufacturing, analytical testing and distribution of cell therapies
- Construction complete in 2020, first GMP production planned for 2021

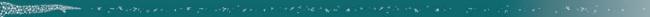
### **South San Francisco Facilities**

- Manufacturing process and product development
- Analytical methods for process and product understanding and release
- Quality Assurance and Quality Control

### **External Network**

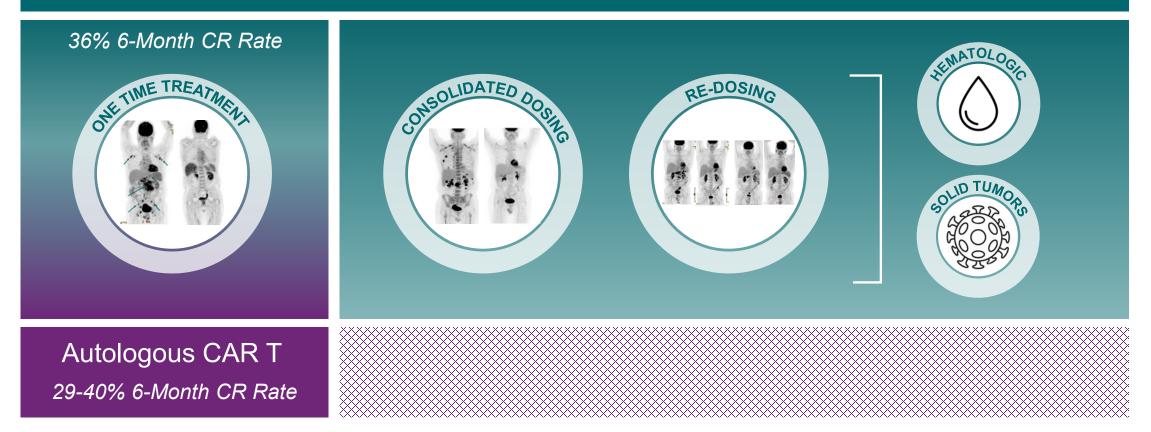
- Broad CMO and supplier network
- Incorporating external expertise for starting materials, drug substance and drug product manufacturing
- Packaging, labeling, logistics and clinical distribution





# Establishing a New Standard in CAR T Therapy





AlloCAR T<sup>TM</sup>: Interim results from Phase 1 ALPHA trial of ALLO-501 of autologous CAR T naïve patients with R/R LBCL; based on a data cutoff as of April 19, 2021 Autologous: Yescarta 6-month CR rate (Locke, AACR 2017); Kymriah 6-month CR rate (Schuster, 2019); Breyanzi 6-month CR rate estimated based on the Breyanzi USPI



## ALLO-501 Well Tolerated Safety in ALPHA Study

	ALLO-647 39 mg (N=11)			-647 60 mg ALL (N=6)		ALLO-647 90 mg (N=24)		All patients (N=41)	
n (%)	All Gr	Gr 3+	All Gr	Gr 3+	All Gr	Gr 3+	All Gr	Gr 3+	
IRR	5 (46)	-	3 (50)	-	18 (75)	1 (4)	26 (63)	1 (2)	
CRS	2 (18)	-	1 (17)	-	8 (33)	-	11 (27)	-	
ICANS	-	-	-	-	1 (4)	1 (4)	1 (2)	1 (2)	
GvHD	-	-	-	-	-	-	-	-	
Infection	7 (64)	1 (9)	1 (17)	1 (17)	17 (71)	8 (33)	25 (61)	10 (24)	
SAE-TEAE/ ALLO-501	1 (9)	-	-	-	-	3 (13)	4 (10)	4 (10)	

Data based on clinical database up through 19 Apr 2021.

Treatment emergent deaths without disease progression: fungal pneumonia (n=1); COVID-19, acquired in the community setting (n=2); arrythmia (n=1); stroke (n=1)

- No dose limiting toxicities or GvHD observed
- Only one (2%) Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- CRS was mild to moderate in severity and manageable with standard guidelines
- Infection rates similar to that observed in autologous CAR T trials



# ORR, CR and 6-Month CR on Par with Autologous CD19 CAR T

### Response Rate for Autologous CAR T Naïve by Disease Subtype (mITT)

	LBCL	FL	All patients	
	(N=11)	(N=21)	(N=32)	
ORR n (%)	7 (64)	17 (81)	24 (75)	
95% CI	31, 89	58, 95	57, 89	
CR n (%)	5 (46)	11 (52)	16 (50)	
95% CI	17, 77	30, 74	32, 68	

- ITT and mITT results were nearly identical
  - ITT for LBCL was 58% (ORR) and 42% (CR)
  - ITT for FL identical

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### 6 Month CR Rate

CAR T Naïve	mITT	ІТТ
LBCL (n=11/12)	4/11 (36%)	4/12 (33%)
FL (n=17/17)	4/17 (24%)	4/17 (24%)
FL and LBCL (n=28/29)	8/28 (29%)	8/29 (28%)

 LBCL 6-month CR rate after initial infusion similar to pivotal trials of autologous CAR T therapies (29% - 40%)\*

\*Autologous: Yescarta 6-month CR rate (Locke, AACR 2017); Kymriah 6month CR rate (Schuster, 2019); Breyanzi 6-month CR rate estimated based on the Breyanzi USPI



# ALLO-501 Competes Favorably Compared with Autologous CAR T

	ALLO-501 (LBCL N=11) Phase 1 Dose Escalation	KYMRIAH® <sup>#</sup> Phase 2 Pivotal	YESCARTA®* Phase 2 Pivotal	BREYANZI® <sup>+</sup> Phase 2 Pivotal
ORR	64%	50% (label)	72% (label)	73% (label)
CR in LBCL (mITT)	46% (5/11)***	32% (label)	51% (label)	54% (label)
CR in LBCL (ITT)	42% (5/12)	26%	48%	43%
CR at 6 months in LBCL (mITT)	36%	29%	36%	~ 40%
% enrolled** or lymphodepleted^ but did not receive intended cell product	2% (1/42)****	33% (54/165)**	9% (10/111)**	36% (95/299)^
	ALLO-501 (FL and LBCL)			
CRS (Gr 3+, all FL and LBCL)	0%	22%	13%	4%
Neuro Events (Gr3+, all FL and LBCL)	3%	12%	31%	12%
Infection (Gr3+, all FL and LBCL)	24%	20%	23%	19%

# KYMRIAH USPI. Patient population in the label includes: 78% - primary DLBCL not otherwise specified (NOS); 22% DLBCL following transformation from Follicular Lymphoma
\*YESCARTA USPI & Schuster S et al NEJM 2019. Patient population in the label includes: 76% - DLBC; 16% - Transformed Follicular Lymphoma; 8% Primary Mediastinal Large B-cell Lymphoma.
\*BREYANZI USPI. 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

\*\*\*CAR T naïve patients (n=29); 11 DLBCL. For CR at 6 Month only 10 patients either reached Month 6 or discontinued/died or progressed. Safety population is N=38 (all patients, FL and DLBCL).

\*\*\*\*Percent enrolled is based on total number enrolled (includes FL and LBCL) regardless of prior CAR T therapy

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

^^ Kymriah: estimated from Shuster, 2019, Figure 3B., Breyanzi: Abramson, ASH 2019

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ALPHA Data Cutoff Date: April 19, 2021



## Consolidated Dosing: Exploring a Unique Allogeneic Attribute

### ORR for Autologous CAR Naïve Patients and Responders to Prior Autologous CAR Therapy

	DL2	Consolidation	All patients <sup>‡</sup>
	(N=4)	(N=5)	(N=9)
ORR n (%)	2 (50)	3 (60)	5 (56)
95% CI	7, 93	15, 95	21, 86
CR n (%)	2 (50)	3 (60)	5 (56)
95% CI	7, 93	15, 95	21, 86

### **Responses in Patients who Received Consolidation Across Studies**

Study/disease	Time from 1 <sup>st</sup> dose (months)	D28	D56	Month 4
ALPHA2/LBCL <sup>a</sup>	4.8	PD	PD	NA
ALPHA2/LBCL	4	PR	CR	CR
ALPHA2/LBCL <sup>b</sup>	3.7	PD	NA	NA
ALPHA2/LBCL	3	PR	CR	-
ALPHA2/LBCL	2	PR	CR <sup>^</sup>	-
ALPHA/FL	3	CR	CR	-
ALPHA/FL	2	PR	PR <sup>^</sup>	-
ALPHA/FL	2	PR	CR <sup>^</sup>	-

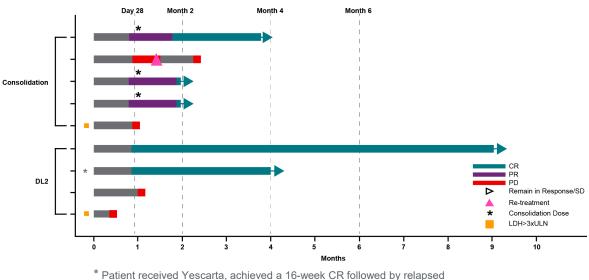
Dash (-) represents patients who have not yet reached the timepoint and only includes subjects that received their second consolidation dose

<sup>^</sup> Clinical database data cutoff of 19 Apr 2021; additional unaudited data up through 12 May 2021 are included.

<sup>a</sup> Patient experienced PD at day 28 and underwent retreatment.

<sup>b</sup> Patient experienced PD and did not undergo further treatment with ALLO-501.

### Swimmer Plot of Tumor Response to Study Treatment



- 56% ORR and CR
- 75% ORR and 63% CR among patients (n=8) treated in the consolidation cohorts across ALPHA studies
- Re-expansion of CAR T cells seen after second CAR T dose



# CD19 Program: De-Risking AlloCAR T<sup>TM</sup> Therapy

- Highly Favorable ORR and CR rates of 75% and 50%, respectively in CAR T naïve patients
  - 36% of Large B Cell Lymphoma patients in CR at month 6 following a single infusion
  - Longest ongoing CR 15+ months
- ITT results nearly identical to mITT results reflecting ability to treat nearly every enrolled patient; Median/mean time of 5 days from enrollment to start of therapy.
- No dose limiting toxicities or graft-vs-host disease and limited Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and Cytokine Release Syndrome (CRS)
- Interim Phase 1 ALPHA2 Data Demonstrated Consistent Efficacy and Safety Profile for ALLO-501A Relative to ALLO-501
- Consolidation Dosing Shows Early Promise with Four Patients Converting from Partial Response to CR Following Second Dose of ALLO-501/A

## ALLO-501 Produced Deep and Durable Responses in Patients with R/R NHL

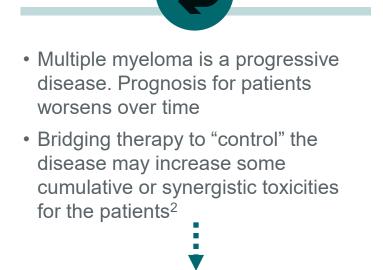


## Planning the Pivotal Study Pathway

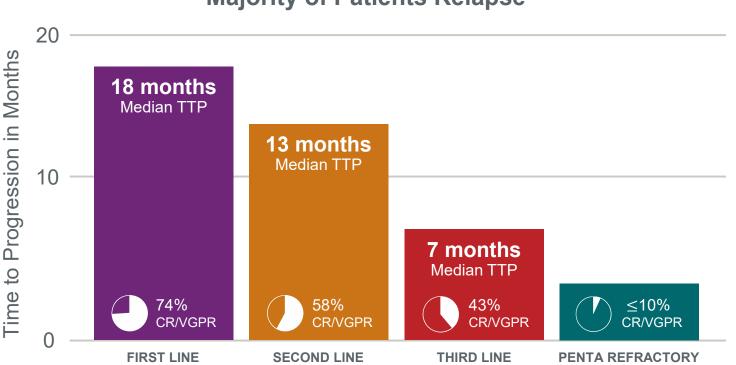
- Data provide strong support for advancing ALLO-501A into Phase 2 portion of ALPHA2
- Next Steps Include:
  - Collect additional data from consolidation arms of ALPHA and ALPHA2 studies
  - Finalize dose and schedule of ALLO-501A and lymphodepletion
  - Host regulatory discussions on trial design and conduct
- Pivotal strategy seeks to take advantage of unique aspects of AlloCAR T
  - Anticipate ability to deliver therapy to essentially all enrolled patients
  - Consider dosing in the outpatient setting
  - Potential to deploy a redosing strategy to increase number of patients who derive long-term benefit
  - Cell Forge 1 manufacturing to support Phase 2 trial

## Initiation of Potential Pivotal Phase 2 Trial of ALLO-501A Planned for Late 2021

# Why Allogeneic Cell Therapy Matters in Multiple Myeloma



Time is of the essence for patients with rapid progression



Majority of Patients Relapse<sup>1</sup>

<sup>1</sup>Bird SA, Boyd K. Palliat Care Soc Pract. 2019;13:1-13

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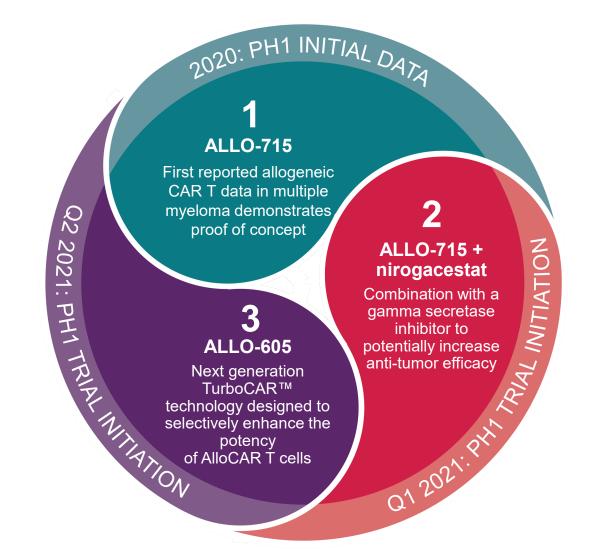
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<sup>2</sup>Zheng Ping-Pin, et al. Drug Discovery Today June 2018; 23:6; 1175-82

<sup>3</sup> Gandhi, et al., *Leukemia*. 2019 September ; 33(9): 2266–2275. doi:10.1038/s41375-019-0435-7; TTP based upon conditional mPFS reported, VGPR based on interpolated values



# Building an Anti-BCMA AlloCAR T<sup>™</sup> Franchise in Multiple Myeloma





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# ALLO-715: First AlloCAR T<sup>TM</sup> To Demonstrate Feasibility in Myeloma

### ALLO-715 UNIVERSAL Ph1 Trial: Initial Data Readout: ASH 2020 Next Steps: Explore combination with nirogacestat

### **Clear benefits associated with an off-the-shelf therapy:**

- ~90% of patients treated within 5 days of study enrollment
- Obviates need for bridging therapy prior to dosing

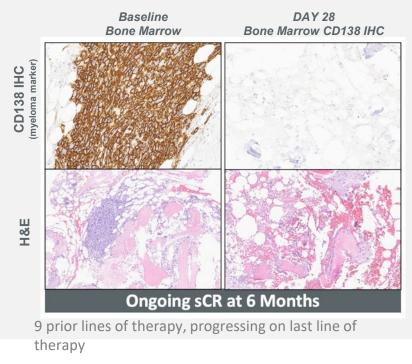
### Well tolerated across dose levels:

- No GVHD or neurotoxicity (ICANS); manageable grade 1 or 2 CRS
- Infection rate on par with other studies in advanced myeloma

# Dose dependent ALLO-715 activity observed in heavily pretreated, refractory patients

- ALLO-715 cell persistence observed through month 4
- 320M cell dose of ALLO-715 (DL3) with FCA lymphodepletion associated with a 60% Overall Response Rate (ORR)
- 5 of 6 VGPR+ patients assessed for MRD status; all were negative

### ALLO-715 Case Study: Ability to Achieve a Durable Deep Response







ASH 2020; image on file

## ALLO-715: Initial Data Creates Pathway for Allogeneic CAR T in MM

### **Initial Safety Compared to BCMA Directed Therapies**

	ALLO-715 Ph1 (N=31) <sup>1</sup>	lde-Cel 300/450M N=128 <sup>2</sup>	Orva-Cel 300/450/600M N=62 <sup>3</sup>	Cilta-Cel 0.75M/kg N=29 <sup>4</sup>
Cytokine Release Syndrome (CRS)	45%	84%	89%	93%
CRS (Grade ≥3)	0	5.5%	3%	7%
Neurologic Toxicity	0	18%	13%	10%
Neurologic Toxicity (Grade ≥3)*	0	3%	3%	3%
Infection (Grade ≥3)	16%	NR	13%	21%
Neutropenia (Grade ≥3)	52%	89%	90%	100%
Death from AEs	3%	3%	3%	8%

1 ASH 2020; 2 Munshi, ASCO 2020 (Ide-cel); 3 Mailankody, ASCO 2020 (Orva-cel); 4 Madduri, ASH 2020 Abstract

### **Initial Responses Compared to BCMA Directed Therapies**

Cell Dose & LD regimen	ALLO-715 320M & FCA (N=10) <sup>1</sup>	Ide-Cel (BB/BMS) 300/450M N=124 <sup>2</sup>	Orva-Cel (Juno/BMS) 300/450/600M N=62 <sup>3</sup>	Cilta-Cel (JNJ) 0.75M/kg N=97 <sup>4</sup>
ORR, %	60%	73%	92%	95%
VGPR+ Rate, %	40%	53%	68%	88%
MRD- Rate, % (N Evaluated)	100% (4/4)	78% (80/102)	84% (21/25)	94% (49/52)

1 ASH 2020; Responses included 2 subjects with only day 14 assessment and 1 subject who converted from a confirmed PR to VGPR (pending confirmation).; 2 Munshi, ASCO 2020 (Ide-cel); 3 Mailankody, ASCO 2020 (Orva-cel); 4 Madduri, ASH 2020 Abstract



# UNIVERSAL: ALLO-715 + Nirogacestat Cohort

### **Primary Endpoints**

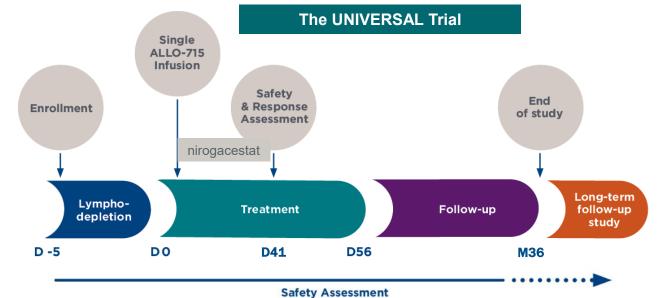
• Safety and tolerability of ALLO-715 in combination with nirogacestat

### **Secondary Endpoints**

- Anti-tumor activity and cellular kinetics of ALLO-715 in combination with nirogacestat
- ALLO-647 and nirogacestat pharmacokinetics
- Evaluate the expression of BCMA in bone marrow plasma cells with and without nirogacestat

### Key Eligibility Criteria

- Relapsed/Refractory Multiple Myeloma
- ≥ 3 prior therapies including IMiD, PI & anti-CD38
- Refractory to last prior therapy
- ECOG 0 or 1
- No donor-specific antibodies
- No bridging therapy allowed



### ALLO-715 Dose Escalation: 320 or 480 x 10<sup>6</sup> CAR<sup>+</sup> T cells

*IMiD: immunomodulatory imade drug PI: proteosome inhibitors* 



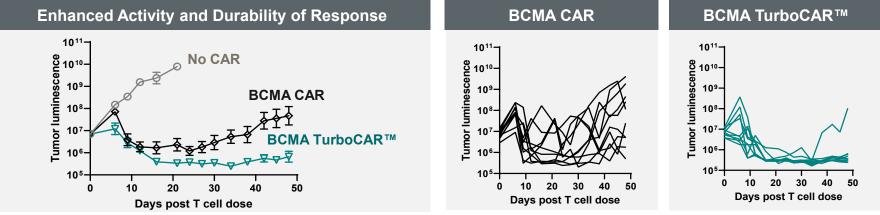
## ALLO-605: First TurboCAR<sup>™</sup> Investigational Candidate

### ALLO-605 IGNITE Trial Initiated; FTD Granted June 2021

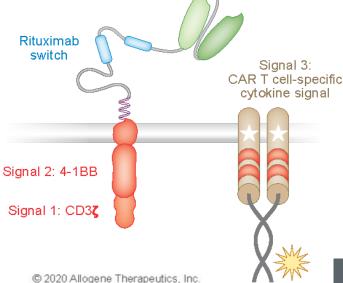


- Does not stimulate host immune cells which could cause systemic toxicity or reject CAR
- Delivers survival benefit selectively to CAR T cells
- Opportunities for development include:
  - Improving the efficacy of CAR T cells
  - Reducing CAR T cell dose requirement
  - Overcoming exhaustion to enable CAR T therapies for solid tumors

### Improved Engraftment and Persistence, and Delayed Exhaustion seen in preclinical studies







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## ALLO-605: IGNITE Study Utilizing First TurboCAR<sup>™</sup> to Target BCMA Phase 1/2, Open-label, Multicenter Dose Escalation and Dose Expansion Study

### **Primary Endpoints (Phase 1)**

Safety and tolerability of ALLO-605

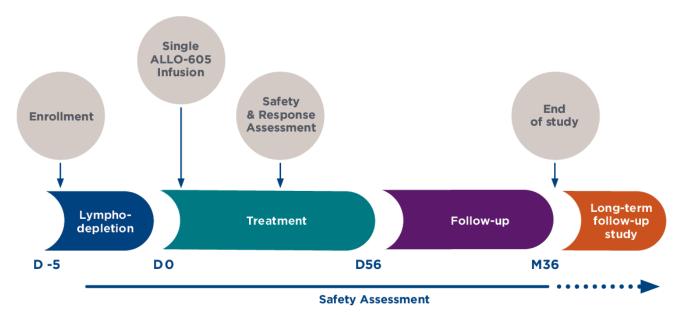
### Secondary Endpoints (Phase 1)

- Anti-tumor activity and cellular kinetics of ALLO-605
- ALLO-647 pharmacokinetics
- Evaluate immunogenicity against ALLO-605 and ALLO-647
- Evaluate responses in subjects with previous treatment with an anti-BCMA targeted therapy

## Key Eligibility Criteria

- Relapsed/Refractory Multiple Myeloma
- $\geq$  3 prior therapies including IMiD, PI & anti-CD38
- Refractory to last prior therapy
- FCOG 0 or 1

- No donor-specific antibodies
- No bridging therapy
- Adequate hematologic, renal liver, pulmonary and cardiac functions



Treatment:

Initial Dose Escalation: 80, 120, 360 X 10<sup>6</sup> CAR+ cells

### Lymphodepletion:

- ALLO-647: 20 to 24 mg x 2 days (staggered from FC)  $30 \text{ mg/m}^2/\text{d x} 3 \text{ days}$
- Fludarabine:
- Cyclophosphamide: 300 mg/m<sup>2</sup>/d x 3 days



# Translating CAR T Success in Hematologic Cancers to Solid Tumors

### **Target Selection/Validation**

- CAR optimization
- Multi-targeting CARs

### Solid Tumors Malignancies 179,000 1,600,000 504,000 Worldwide Market for Oncology Drugs in 2018\*

\*IQVIA

• All drug spend = \$1.2 trillion

Incidence

Deaths

22

- Total cancer drug spend  $\approx$  \$150 billion
- Hematologic cancer drugs  $\approx$  \$31.3 billion

**2020 American Cancer Society Statistics** 

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57,000

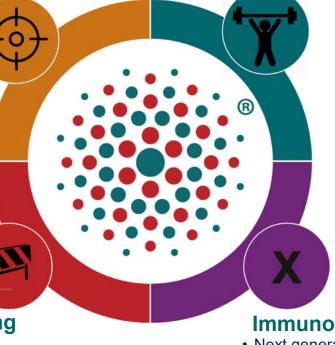
Significant opportunity to expand benefits of CAR T therapy into largest area of unmet need

**Tumor Trafficking** 

- Combinations
- CAR T engineering

### **T Cell Fitness**

- CAR signaling/ TurboCARs<sup>™</sup>
- Manufacturing improvements



### Immunosuppressive TME

- Next generation TurboCARs<sup>™</sup>
- Enhanced/flexible lymphodepletion
- CAR T cell doses, frequencies and administration of cells



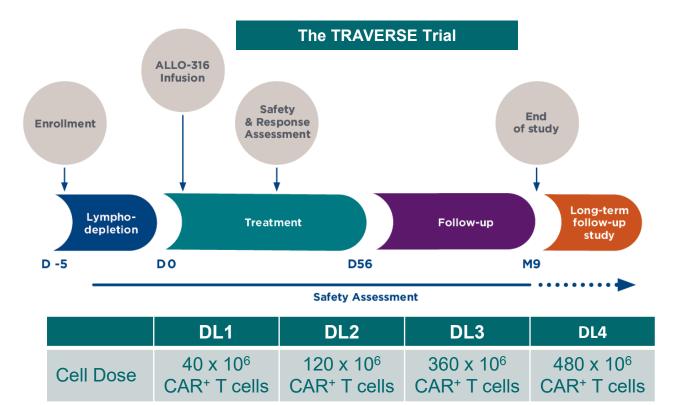
## ALLO-316: Investigating an AlloCAR T<sup>™</sup> in Renal Cell Carcinoma First of Several Solid Tumor Candidates Planned for Clinical Development

# CD70 target selectively expressed in several cancers<sup>1</sup>:

- RCC (80-100% of tumors)
  - High prevalence with limited 'off tumor' expression
- AML (96% of tumors)

## IND cleared for anti-CD70 candidate ALLO-316:

- ALLO-316 is associated with minimal or no fratricide
- Phase I TRAVERSE trial in RCC began in 1H 2021
  - Primary endpoints: Safety and tolerability
  - Secondary endpoints: Anti-tumor efficacy, PK/PD
- Potential second indication in AML targeted for 2021/2022



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



## Partnerships: Accelerating Development and Positioning for the Future



Global development partner for CD19 with ex-US commercialization rights



Established Allogene Overland Biopharm joint venture to develop and commercialize AlloCAR T™ cell therapies in greater China





Induced pluripotent stem cells (iPSC)



Enhanced manufacturing efficiency



Preclinical and clinical investigation of AlloCAR T candidates across Allogene's broad portfolio of hematologic and solid tumors



Clinical collaboration to evaluate ALLO-715 in combination with Nirogacestat

**GLOBAL EXPANSION** 

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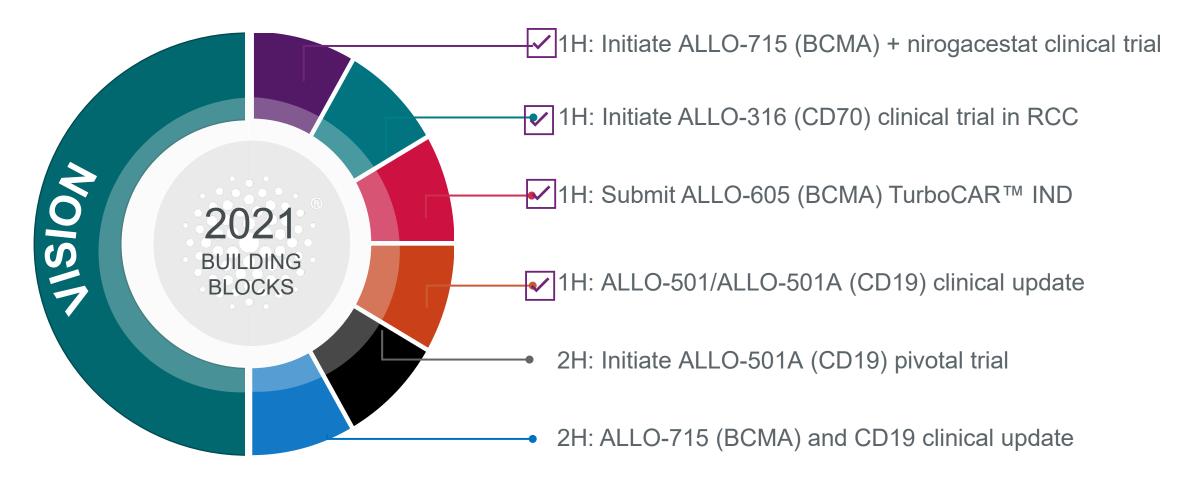
**TECHNOLOGIES** 

RESEARCH



## 2021 Building Blocks to the Allogene Vision

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Create and lead the next revolution in cancer treatment by delivering to patients the first AlloCAR T<sup>™</sup> therapies for blood cancers and solid tumors.





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

Allogene therapies utilize TALEN® 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. while Servier retains exclusive rights for all other countries. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA, FLT3, DLL3 and CD70.