



# The Next Revolution in Cell Therapy

Leading Today, Creating Tomorrow

November 2020

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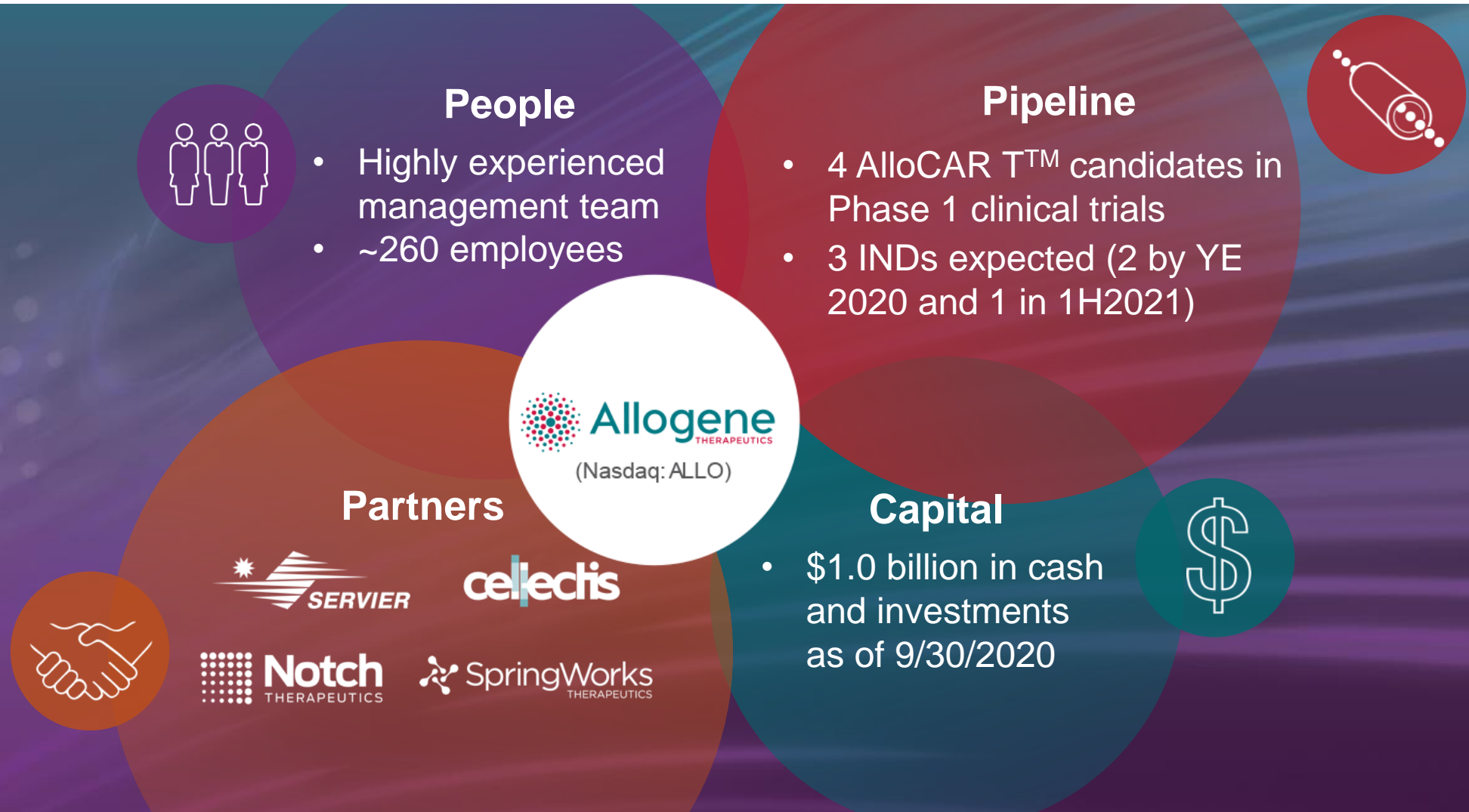
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# Allogene: Leading the Future of AlloCAR T™ Cell Therapy





# Why We Believe Allogeneic Cell Therapy Will Lead the Revolution



## Access

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



## Cost

- Scalable and efficient manufacturing
- 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

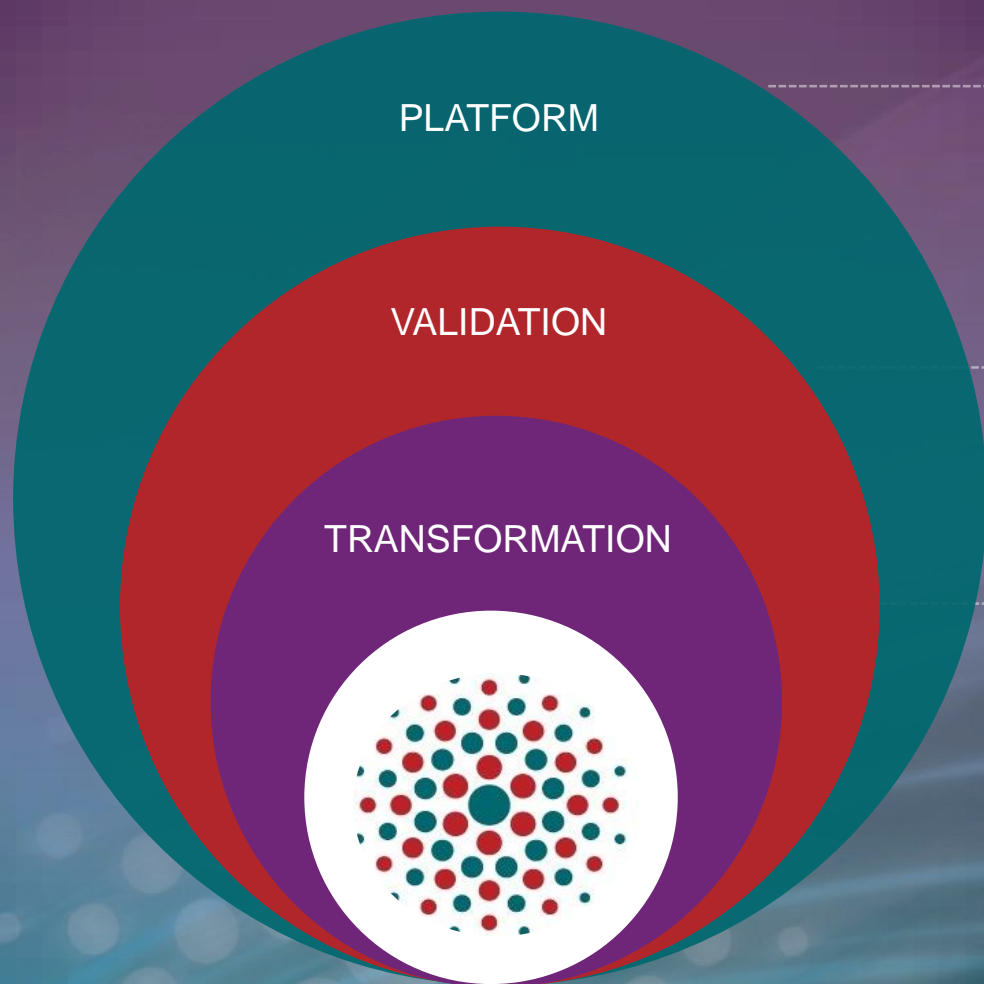


## Innovation

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



# The AlloCAR T™ Platform for Today and Tomorrow



## **Establish industry leading AlloCAR T platform**

- TALEN® gene editing technology
- Proprietary lymphodepletion
- State-of-the-art manufacturing

## **Rapid development across robust AlloCAR T portfolio**

- 4 Clinical & 16 Preclinical programs across both hematological and solid tumor indications

## **Pre-clinical next generation technologies**

- TurboCAR™: Improved T cell fitness
- Immune evasion: Enhanced expansion/persistence
- Solid tumors: CAR optimization and target selection
- iPSCs: Renewable cell source

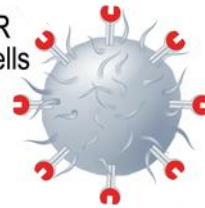


# Defying Immunity: Overcoming GvHD and Graft Rejection

## GvHD

Donor T cells view the recipient's body tissues as foreign and attack causing serious or fatal side effects

CAR  
T cells



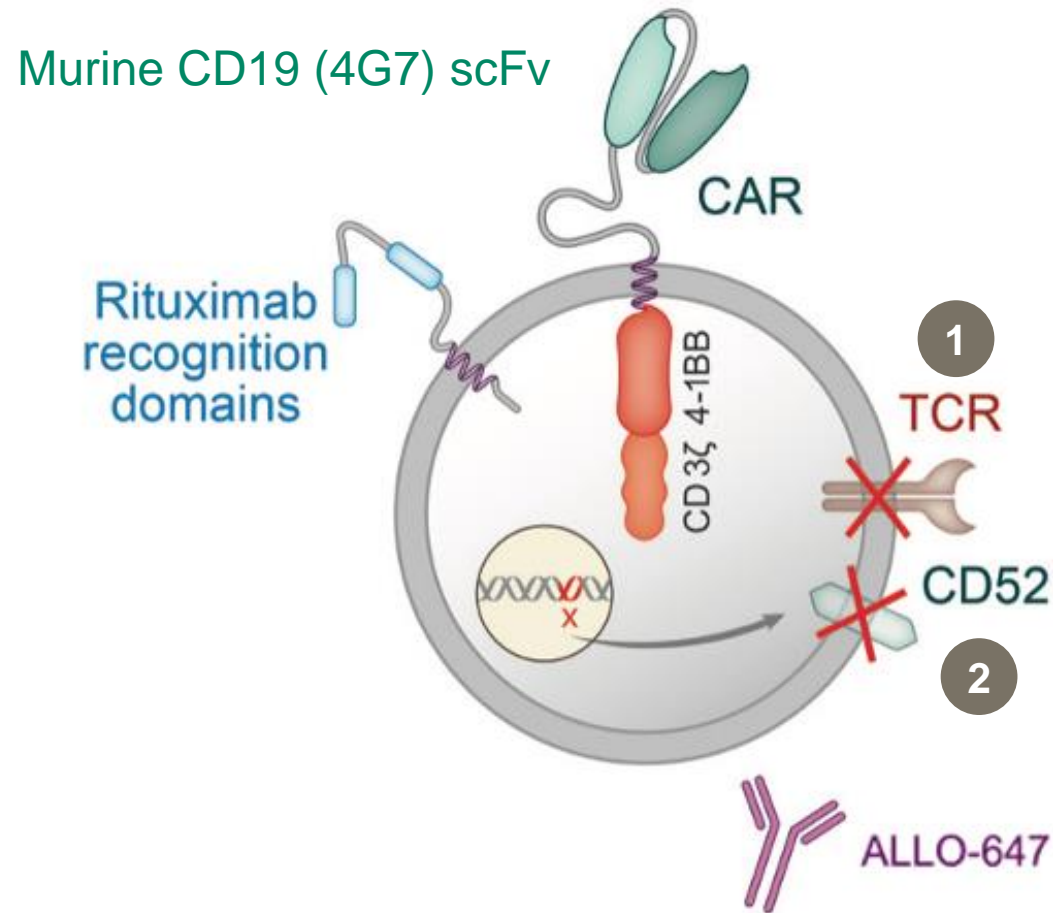
## Graft Rejection

Recipient's immune system detects donor T cells as foreign and kills donor T cells



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 Collectis gene editing technology



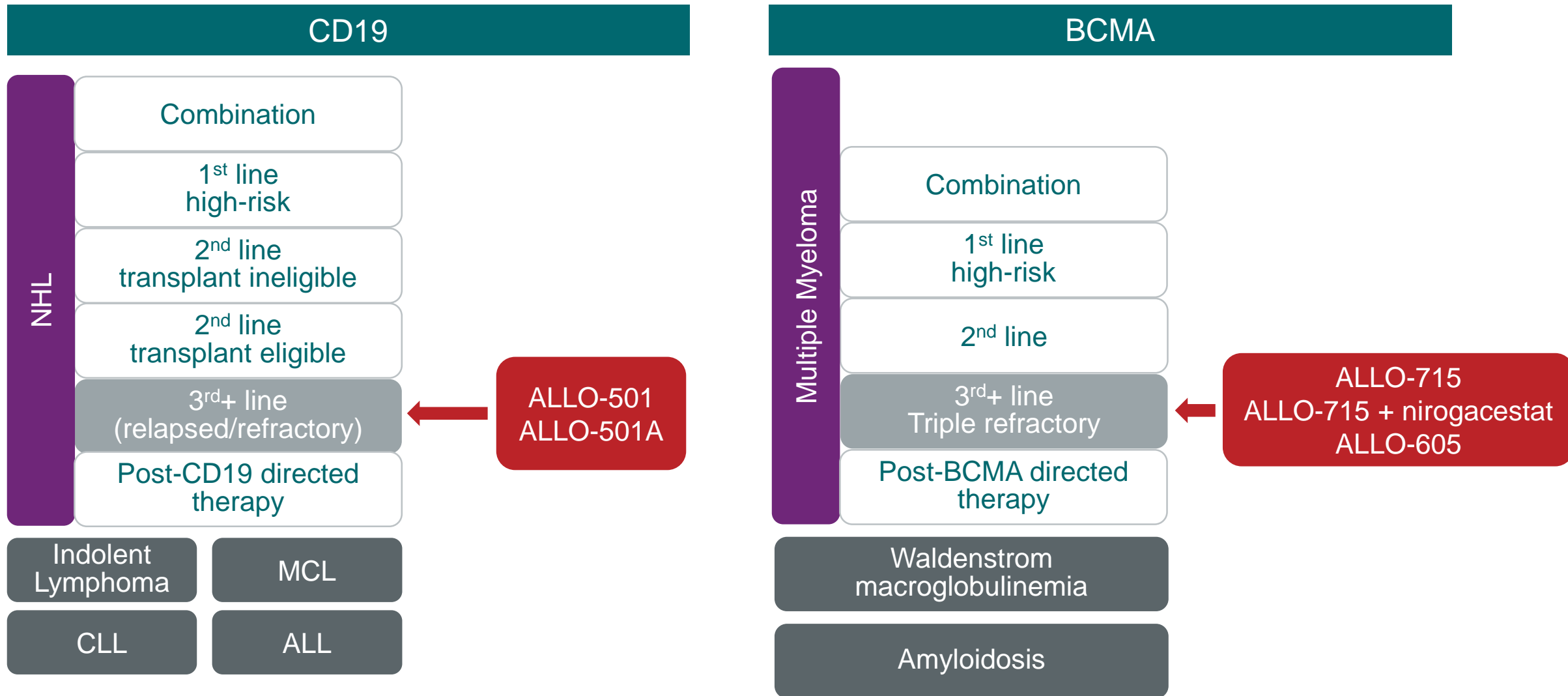
# Deep AlloCAR T™ Pipeline Targeting Vast Array of Tumor Types

CATEGORY	PROGRAM	PRE-CLINICAL	PHASE 1	PHASE 2/3 <sup>2</sup>
Hematological Malignancies	CD19	ALLO-501 (NHL) <sup>1</sup>		
	CD19	ALLO-501A (NHL) <sup>1</sup>		
	BCMA	ALLO-715 (MM)		<sup>1</sup> Servier holds ex-US commercial rights
		ALLO-715 + nirogacestat (MM) <sup>4</sup>		<sup>2</sup> Phase 3 may not be required if Phase 2 is registrational
		ALLO-605 (TurboCAR™/MM)		<sup>3</sup> ALLO-647 intended to enable expansion and persistence of allogeneic CAR T product candidates
		ALLO-316 (CD70/AML)		<sup>4</sup> Allogene Sponsored trial in combination with SpringWorks Therapeutics; Initiation expected 2021
		ALLO-819 (FLT3/AML)		
Solid Tumors		ALLO-316 (CD70/RCC)		
		DLL3 (SCLC)		
		Multiple Undisclosed Targets		
Lymphodepletion Agent		ALLO-647 (Anti-CD52 mAb) <sup>3</sup>		





# Pathways to Leverage CD19 & BCMA Clinical Expansion



# ALPHA Study (NCT03939026) Design and Endpoints

## Phase 1, Open-label, Multicenter Dose Escalation Study

### Primary Endpoints

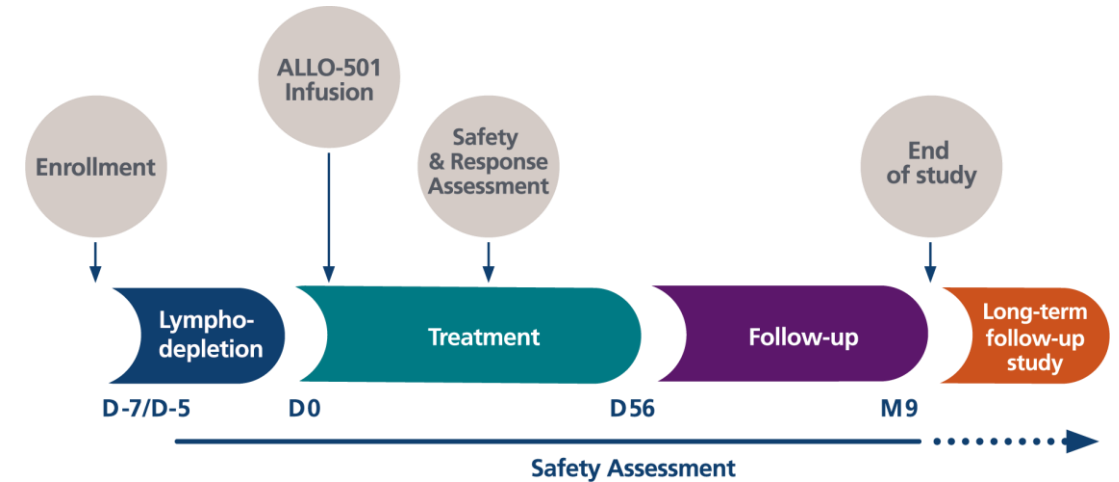
- Safety and dose-limiting toxicity of ALLO-647/Flu/Cy followed by ALLO-501

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



	DL1	DL2	DL3
Cell Dose	40 x 10 <sup>6</sup> CAR <sup>+</sup> T cells	120 x 10 <sup>6</sup> CAR <sup>+</sup> T cells	360 x 10 <sup>6</sup> CAR <sup>+</sup> T cells

- 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/m<sup>2</sup>/d x 3 days    Cyclophosphamide (Cy): 300 mg/m<sup>2</sup>/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%)
<b>Lymphoma Subtypes</b>				
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%)
<b>Current Disease Stage (per Lugano 2014) <sup>#</sup></b>				
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%)
<b>Prior Treatments</b>				
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%)

- Heavily pretreated patients with advanced-stage disease
- 14 (64%) of patients were chemo refractory\*
- 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

<sup>†</sup> Not otherwise specified, transformed FL, high-grade B cell lymphoma (double and triple hit), DLBCL coexistent with FL of any grade

<sup>#</sup> 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

Data Cutoff Date: May 11, 2020



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

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

## 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)

\* ASTCT Lee, 2019. ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome

<sup>†</sup> CMV reactivations and Rotavirus infection

<sup>#</sup> attributed to ALLO-647

<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





# Phase 1 ALPHA Best Overall Response

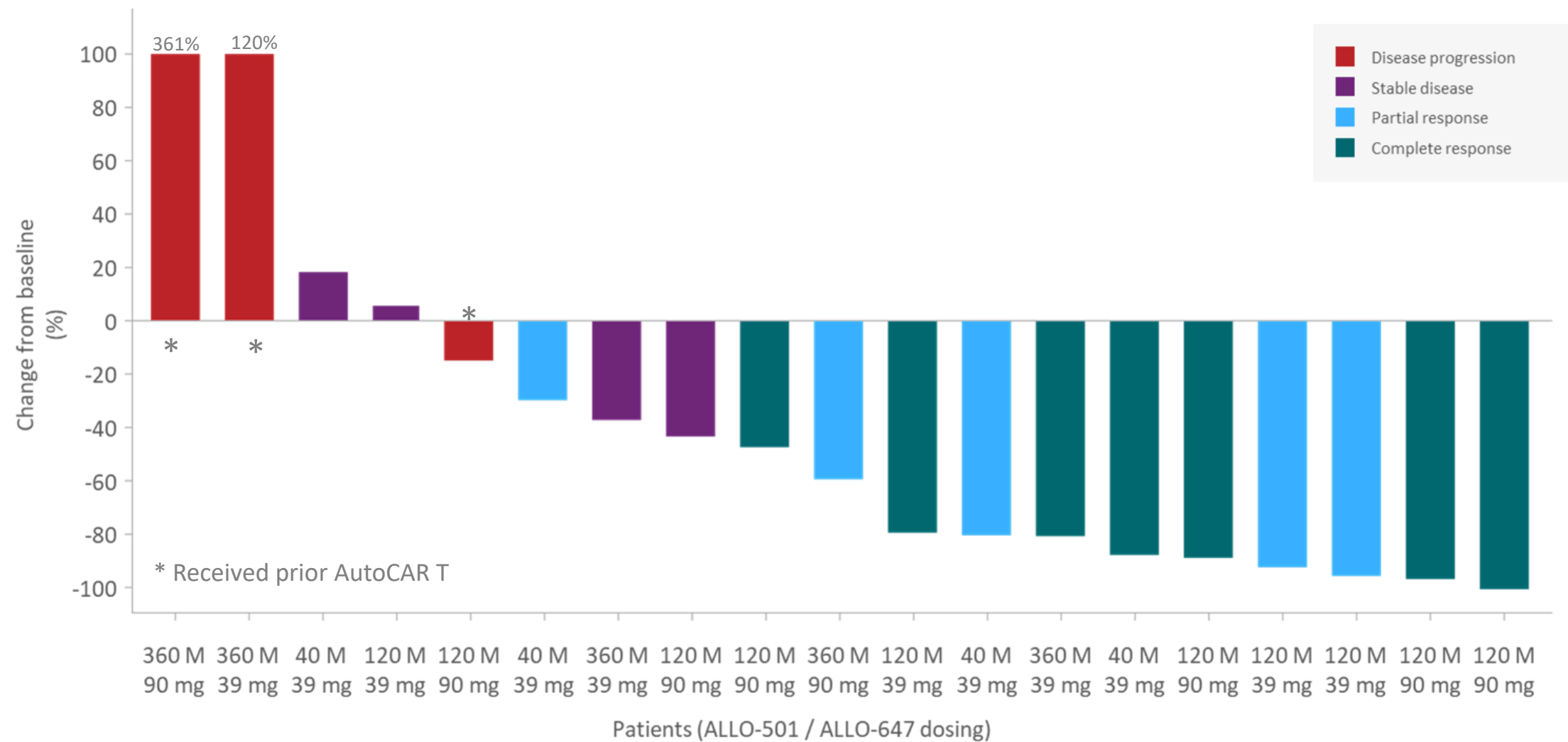
Cell Dose and LD regimen	39mg ALLO-647			ALL 39mg ALLO-647 (N = 11)	90mg ALLO-647		All 90mg ALLO-647 (N=8)	All Patients (N=19) Rate (95%CI)
	40 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=4)	120 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=4)	360 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=3)		120 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=6)	360 x 10 <sup>6</sup> CAR <sup>+</sup> cells (N=2)		
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)*

Lugano 2014; Data Cutoff Date: May 11, 2020

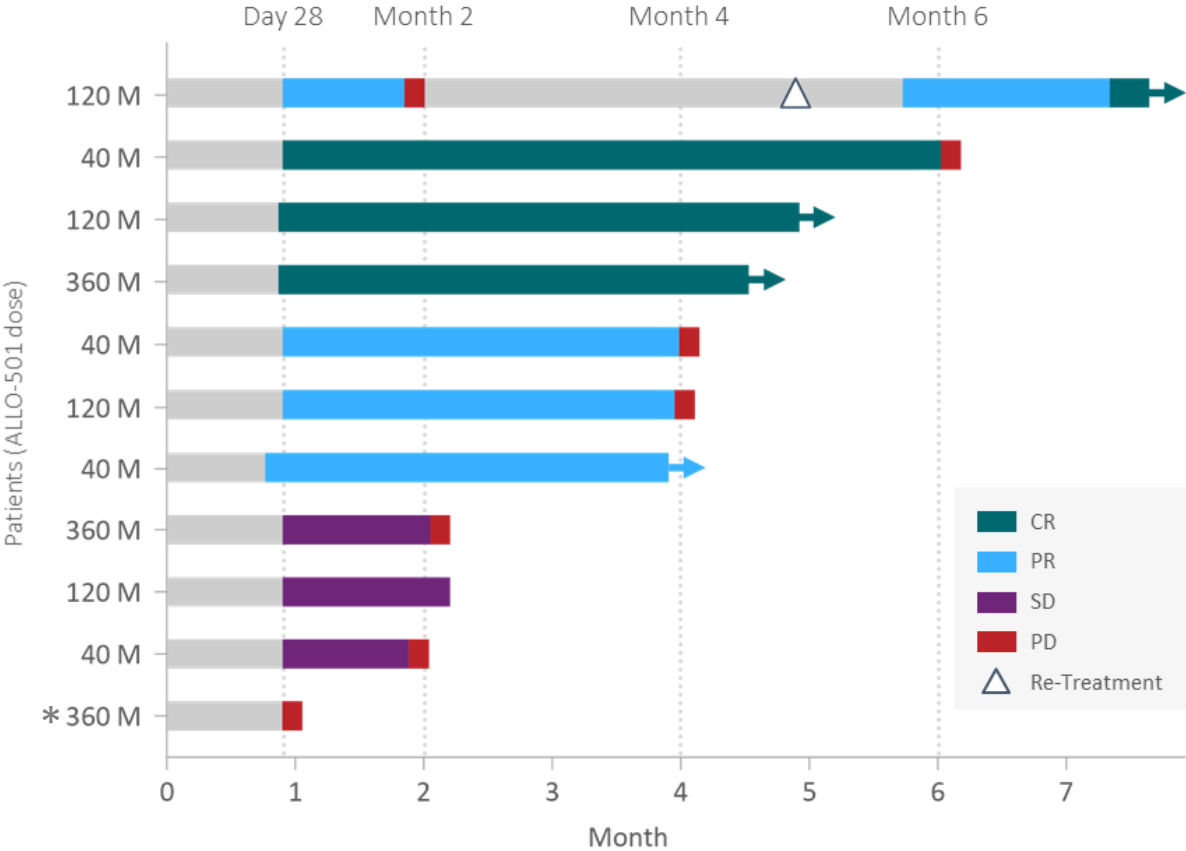


# Reduction in Tumor Size Observed with ALLO-501

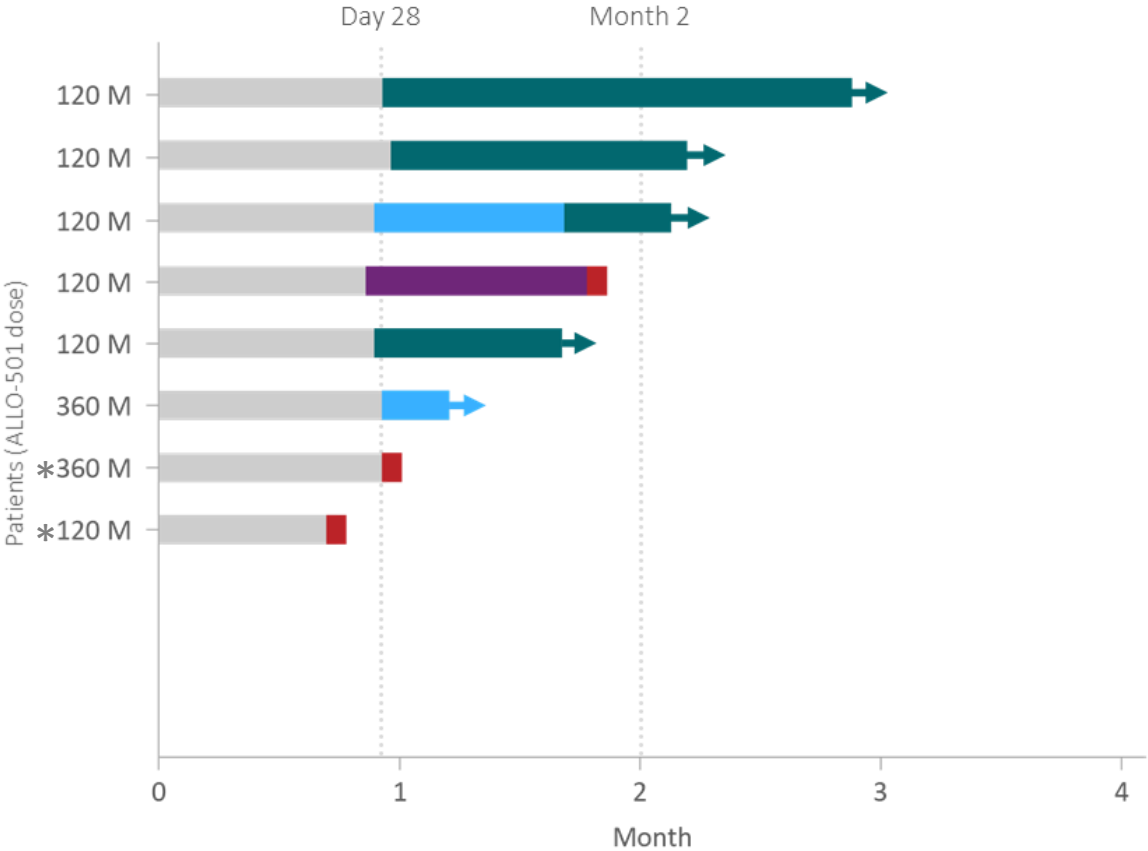


\* Received prior AutoCAR T

# Nine of Twelve Responders Remain in Response



**ALLO-647: 39 mg**  
Median follow up: 4.3 months (1.0, 6.1)



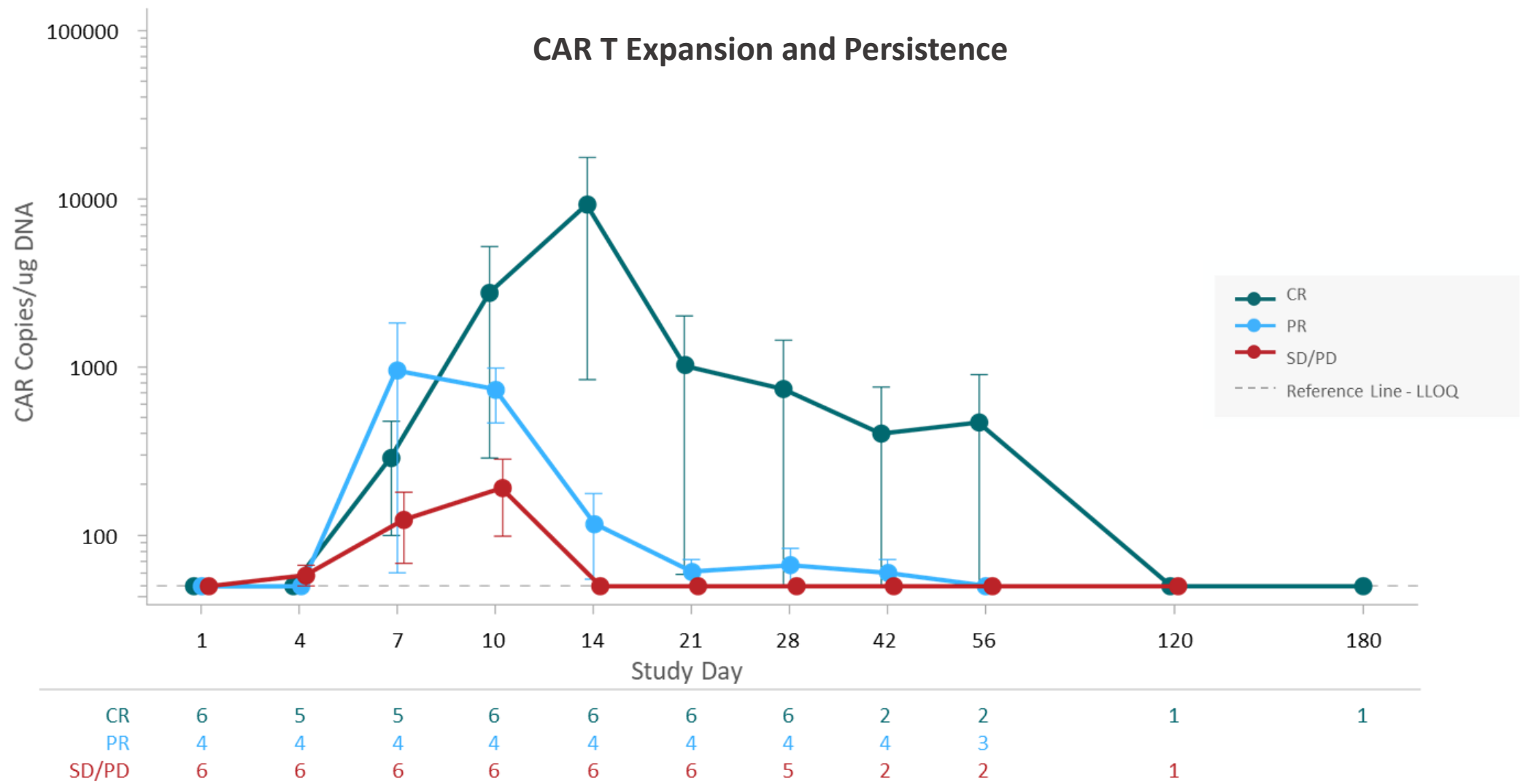
**ALLO-647: 90 mg**  
Median follow up: 1.9 months (0.7, 2.6)

*One patient who progressed after a PR was re-dosed with ALLO-501 (120 x 10<sup>6</sup> )  
and Flu/Cy/90mg ALLO-647 and achieved a CR*

\* Received prior AutoCAR T

Data Cutoff Date: May 11, 2020

# AlloCAR T Cell Expansion Is Associated with Clinical Response

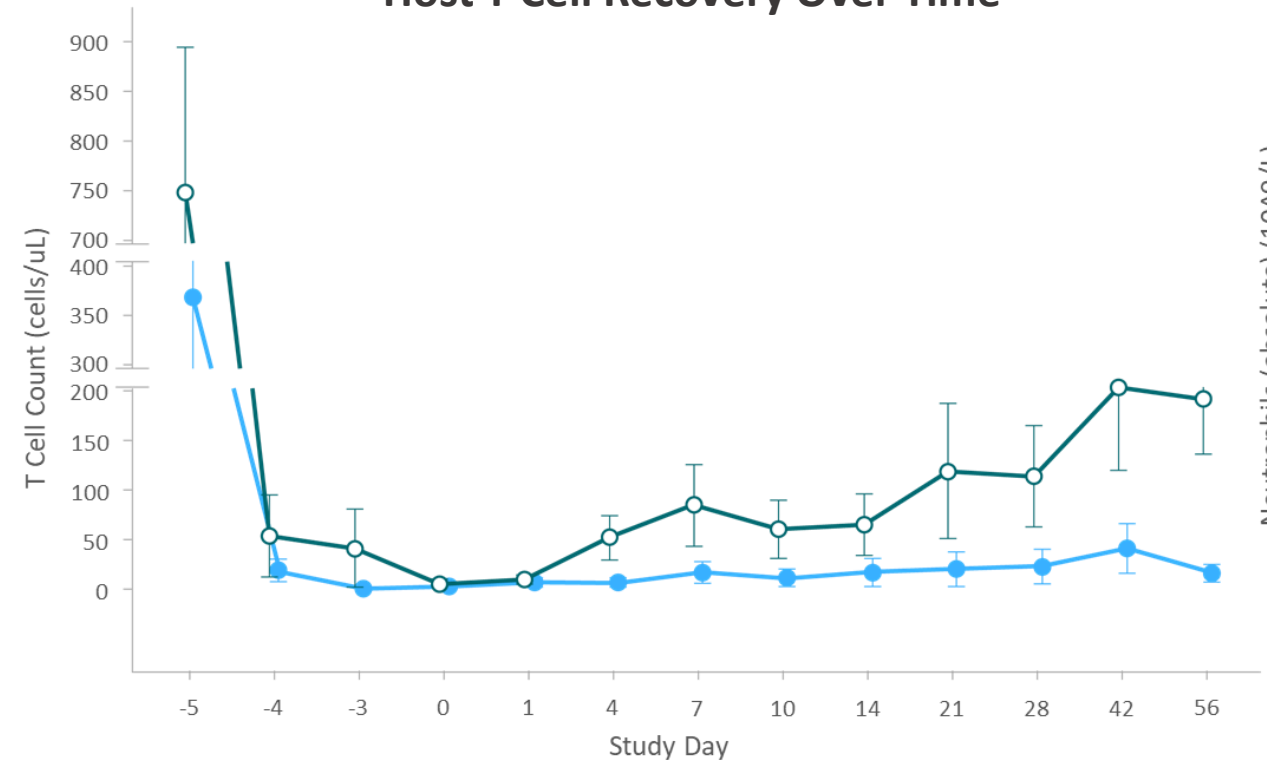


Data Cutoff Date: May 11, 2020



# ALLO-647 Mediates Selective Lymphodepletion

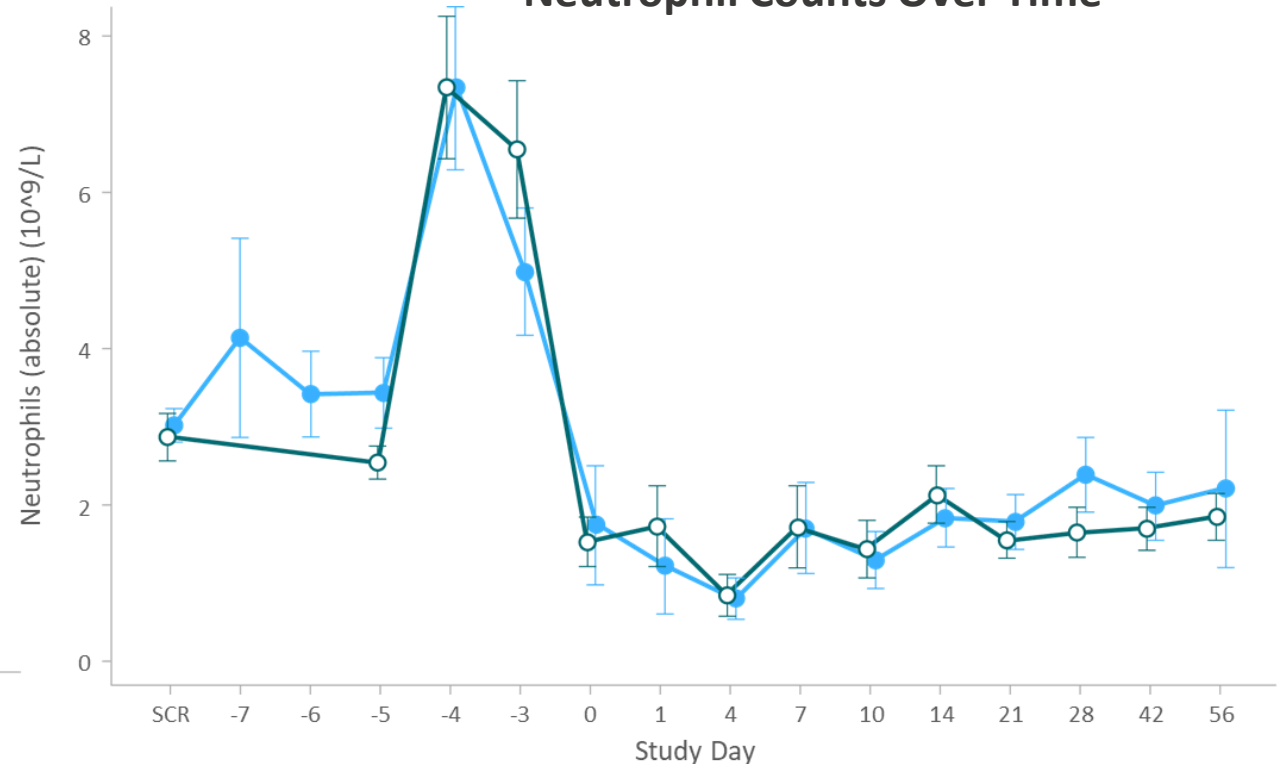
Host T Cell Recovery Over Time



11	11	11	11	11	11	11	11	11	11	9	10
8	10	9	10	9	8	8	8	8	6	3	2

- ALLO-647 (39 mg)
- ALLO-647 (90 mg)

Neutrophil Counts Over Time



11			11	11	11	11	10	10	11	2	11	11	11	10	10
10	5	5	11	11	11	10	7	8	10	10	9	8	6	4	3

- No difference in neutrophil kinetics between ALLO-647 treatment groups
- Median time to Platelet  $\geq 100K$  is 8 days for 90mg ALLO-647 dose cohort

Data Cutoff Date: May 11, 2020

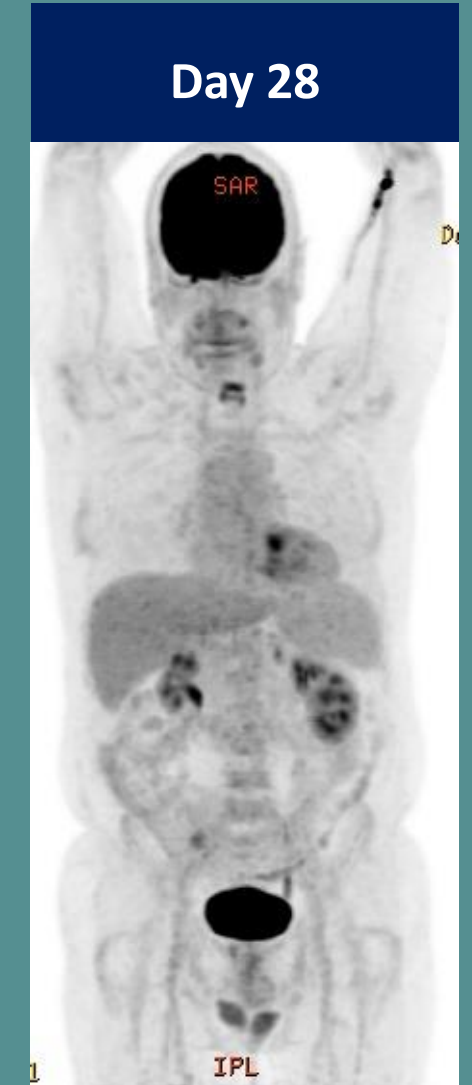


# ALLO-501 Patient Case Study

- **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

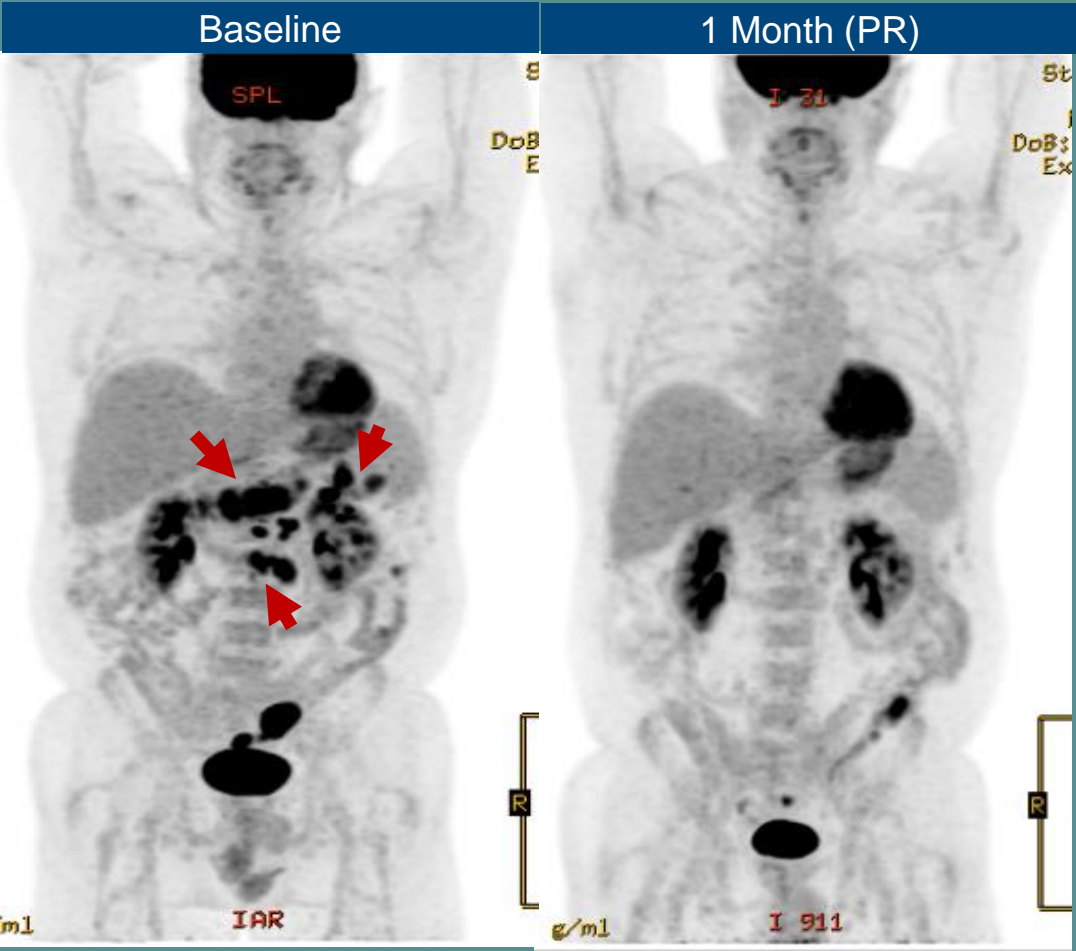


Courtesy of Sattva Neelapu

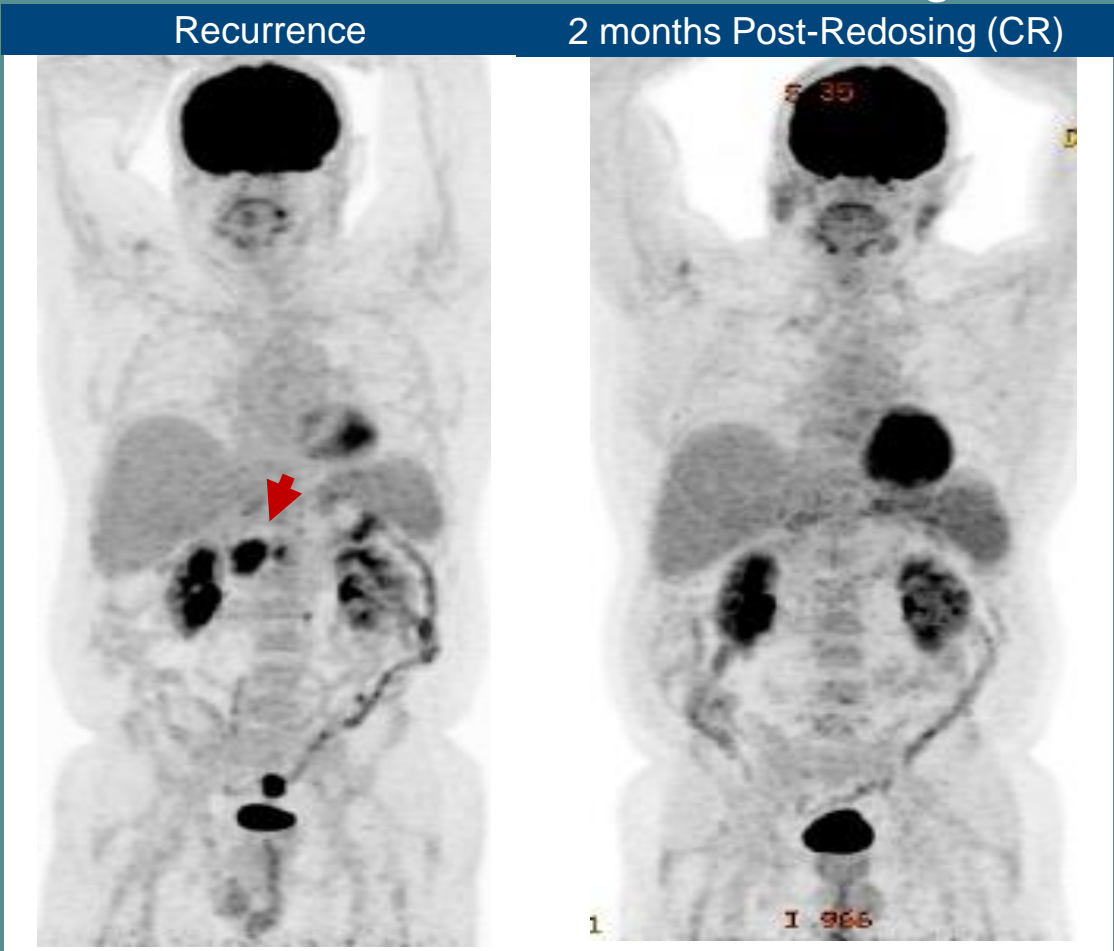


# ALLO-501 Patient Case Study 2: Redosing after Disease Progression

## First ALLO-501 Treatment



## Month 2 PD: ALLO-501 Redosing



Data Cutoff Date: May 11, 2020

Courtesy of Sattva Neelapu



# 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





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

AE of Interest ( $\geq$ 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

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		
Time to Treatment	5 days <i>Enrollment to treatment</i>	axi-cel	tisa-cel	liso-cel
		17 days <i>Leukapheresis to cell delivery</i>	54 days <i>Enrollment to treatment</i>	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



# 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

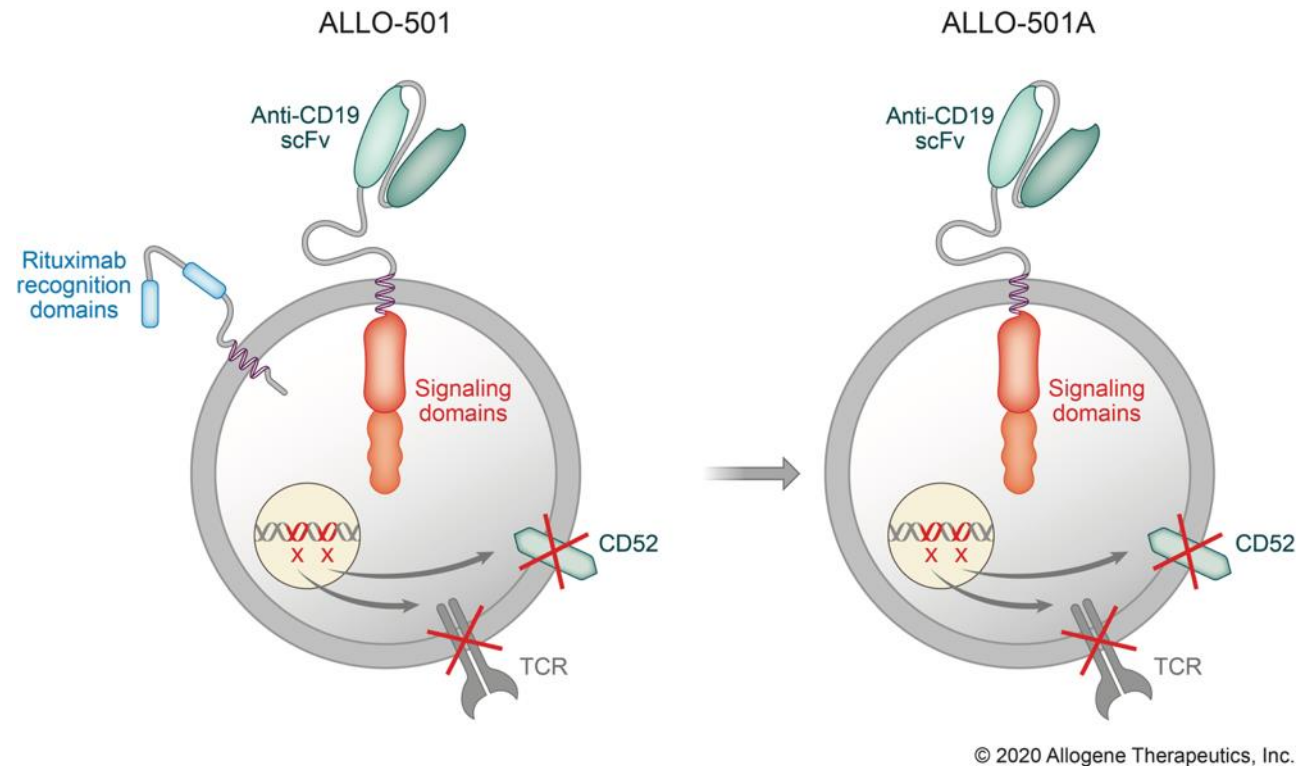
Can ALLO-501 provide durable responses?



# 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
- Initial data expected 1H2021



*Servier holds ex-US rights to ALLO-501A*



# Bringing AlloCAR T to Patients with Multiple Myeloma

- Anti-BCMA platform therapy
- Initial data from UNIVERSAL trial in R/R MM at ASH Q4 2020

**ALLO-715**

**ALLO-715 +  
nirogacestat**

**ALLO-605**

**Anti-  
BCMA**

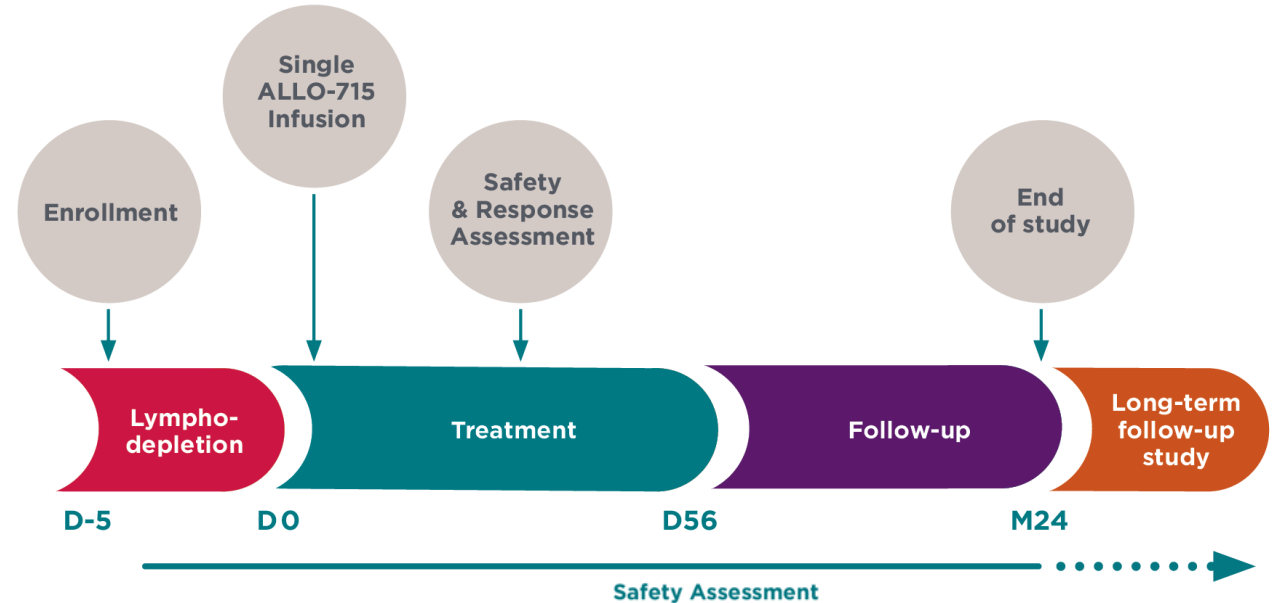
- IND submission expected 2H 2020
- Potential Increase Anti-Tumor Efficacy

TurboCAR™ is designed to recapitulate cytokine signaling selectively in CAR T cells and turbocharge potency and durability of engineered cells



# 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 at ASH Q4 2020



## Treatment:

- Initial Dose Escalation: 40, 160, 320 X  $10^6$  CAR+ cells

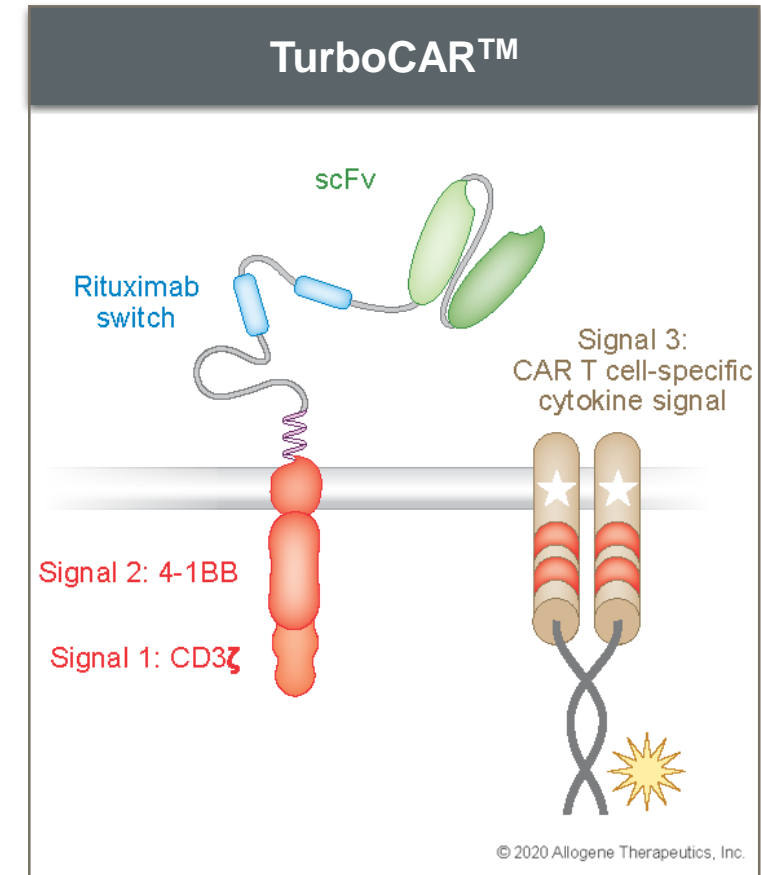
## Lymphodepletion:

- ALLO-647: 39 to 90 mg
- Fludarabine: 30 mg/m<sup>2</sup>/d x 3 days
- Cyclophosphamide: 300 mg/m<sup>2</sup>/d x 3 days



# TurboCAR™: Turbocharging CAR T Cells

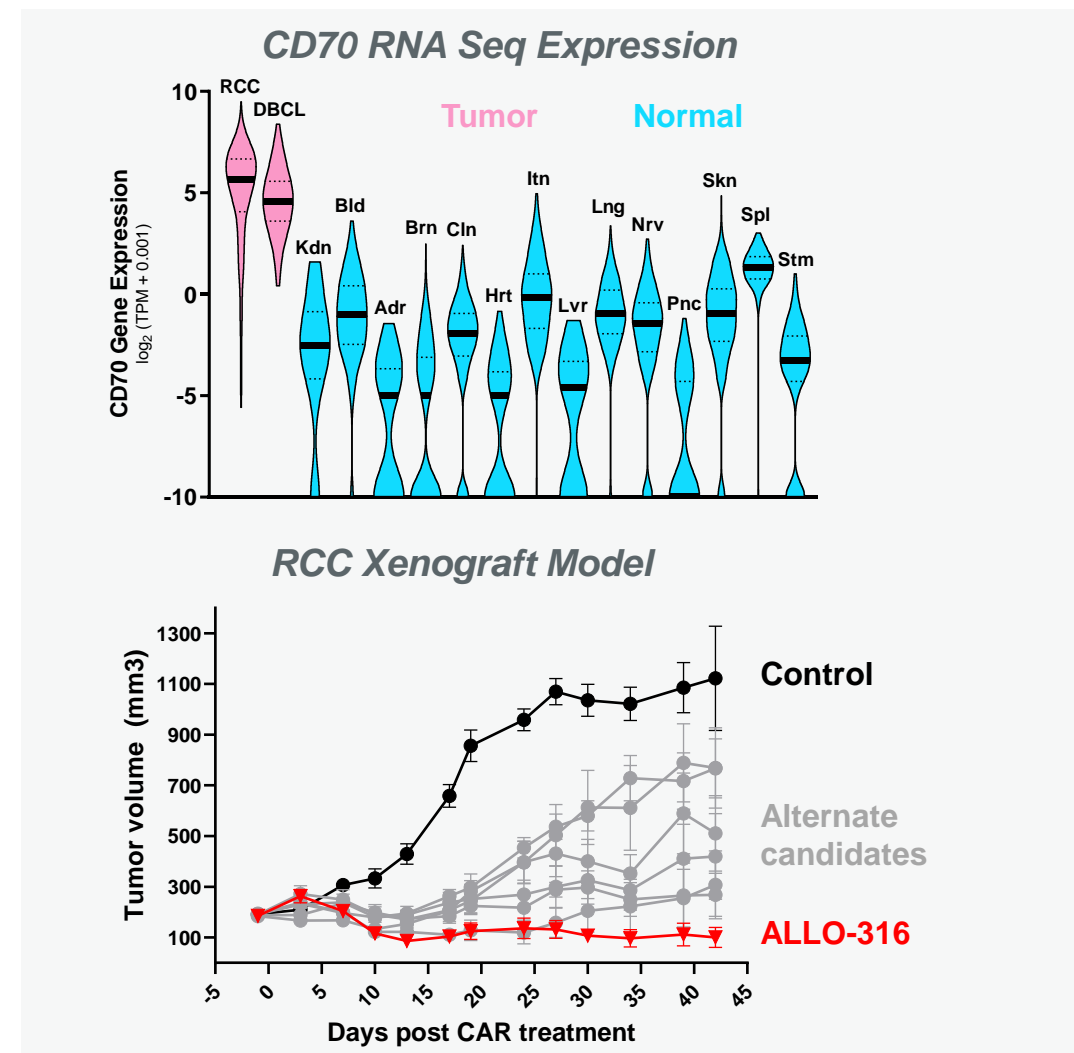
- Cytokine stimulation can increase the potency and durability of engineered T cells
- TurboCAR™ is designed to recapitulate cytokine signaling selectively in CAR T cells
  - Minimizes systemic toxicity
  - Does not stimulate host immune cells which could reject CAR
  - Delivers survival benefit selectively 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 1H 2021



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

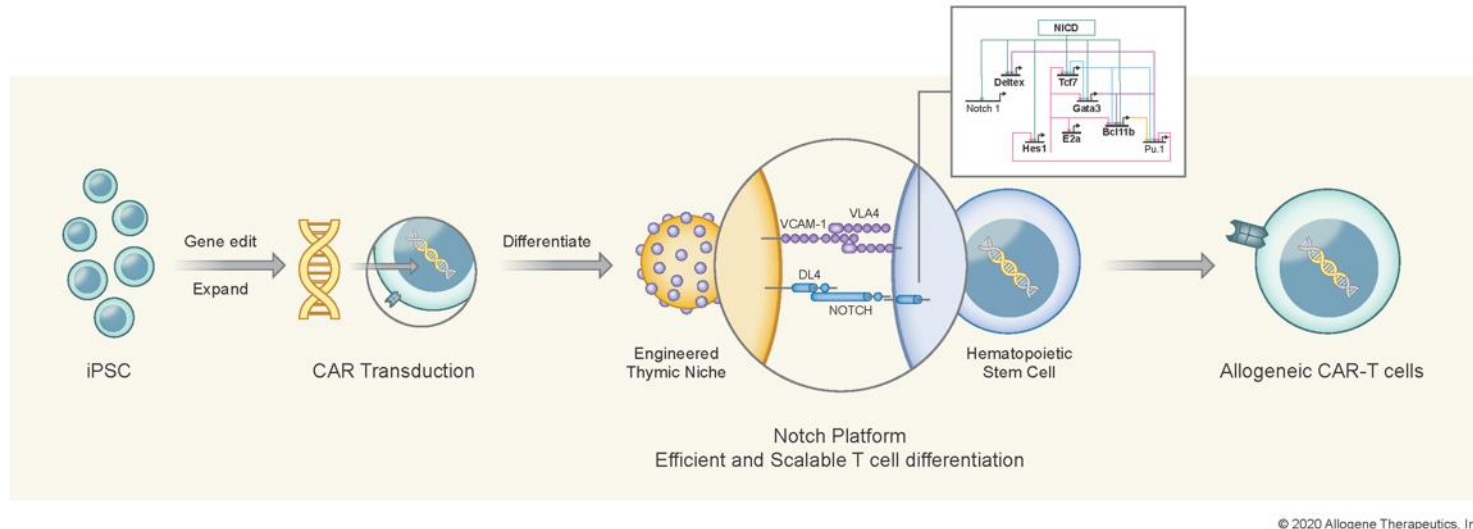
- ALLO-316 is an anti-CD70 AlloCAR T candidate for renal cell carcinoma (RCC) as well as several hematological malignancies
- CD70 expression<sup>1</sup>:
  - RCC (80-100%)
  - AML (96%)
  - DLBCL (71%), MM (63%), CLL (50%)
  - GBM (35%)
  - CD70 is also expressed on activated T cells
- CD70 in RCC: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



- 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™ 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



# 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)**

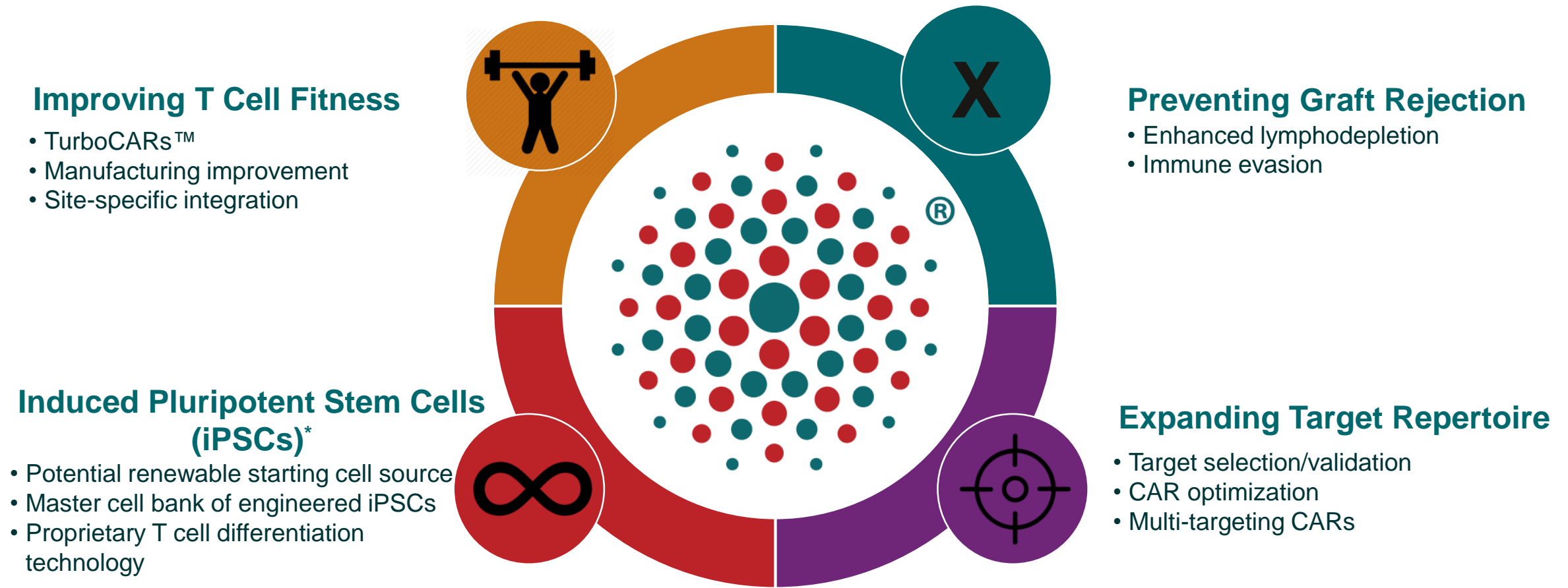
- In-house manufacturing capability build underway:
  - GMP manufacturing expected to be ready in 2021
- Potential supply for commercial launch upon approval

## **Current CMO Support**

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

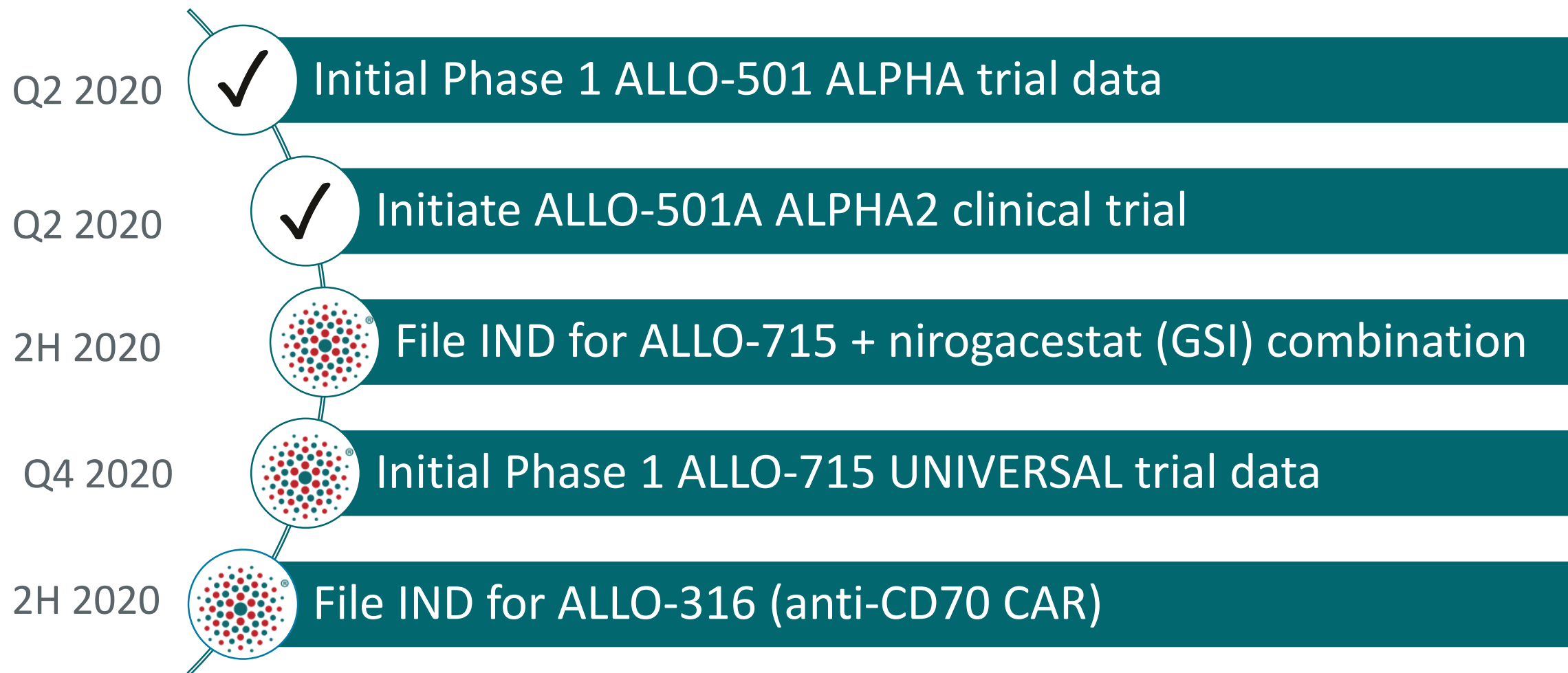


# Allogene is Creating The AlloCAR T™ Platform for Tomorrow

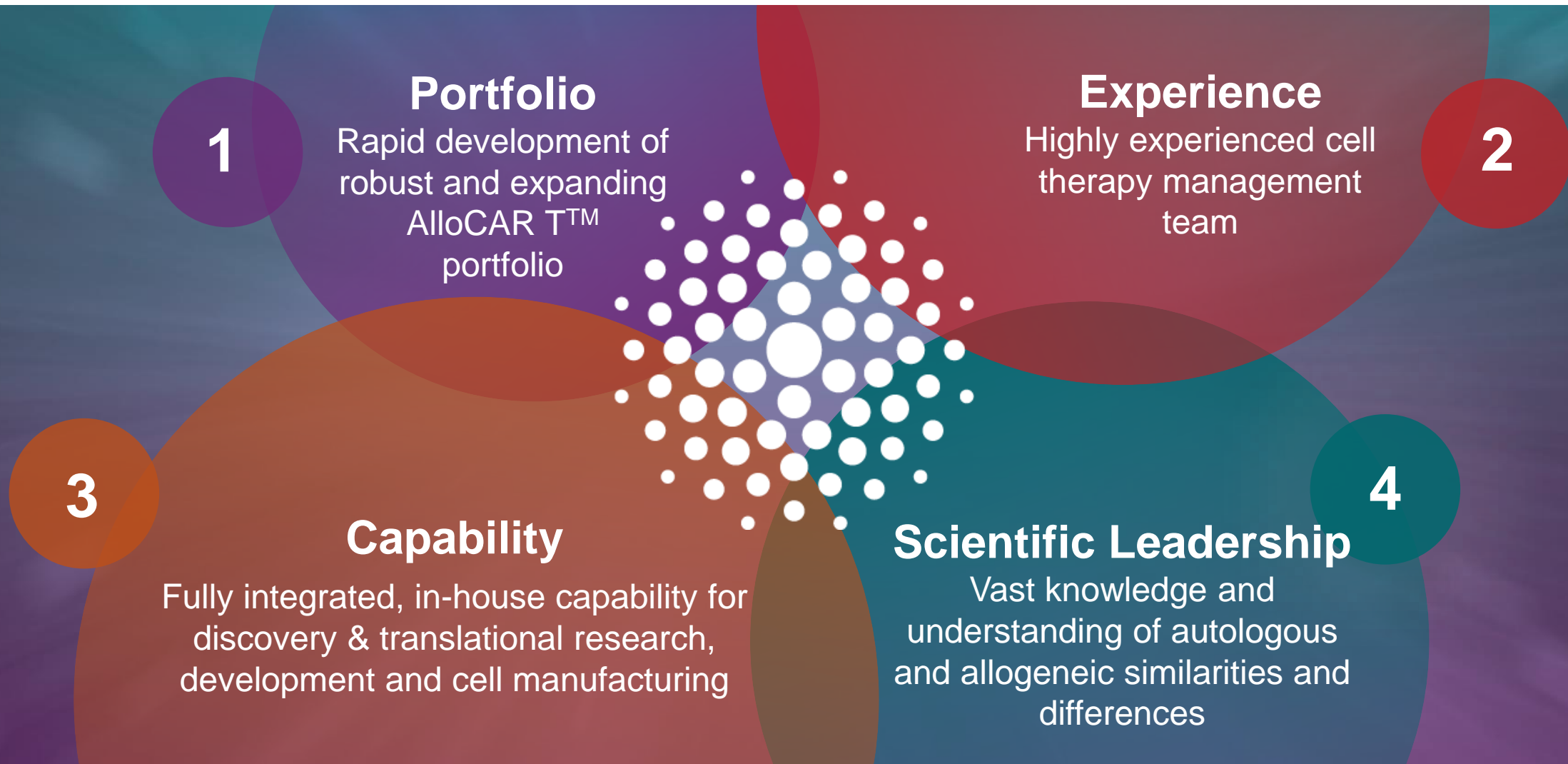


*\*In collaboration with Notch Therapeutics*

## 2020 Clinical Milestone Progress



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







# The Next Revolution in Cell Therapy

## Leading Today, Creating Tomorrow

*ALLO-501 is an anti-CD19 allogeneic CAR T (AlloCAR T™) 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.*