

ASCO 2023 Cell Therapy Update May 31, 2023



### **Forward-Looking Statements**

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### Agenda

> Executive Summary

> Totality of Azer-cel Experience

> CAR T Relapse Setting Is Growing Area of High Unmet Need

> Potential First-In-Class: Azer-cel Clinical Update

> Potential Best-In-Class: 19B Stealth Cell Clinical Update

> Building On Precision's Cell Therapy Foundation

> Summary





### **Executive Summary**

#### Azer-cel: Potential First-In-Class Opportunity for CAR T Relapsed CD19+ DLBCL

#### Azer-cel is Precision's Lead CAR T Program Demonstrating Efficacy and Improved Safety Across Hematologic Malignancies

- Precision has amassed a robust data package (n = 84) for Azer-cel in NHL and ALL, with clinically meaningful efficacy and an acceptable safety profile
- Azer-cel data is most compelling in the Diffuse Large B Cell Lymphoma (DLBCL) CAR T relapse setting (n=18) with 83% ORR, 61% CR rates and 55% DoR ≥6 months<sup>1</sup>
- In latest cohort (n=7), Azer-cel safety profile ameliorated with 0% ≥ Grade 3 Allogeneic CAR T related AEs in fragile, relapse patient population

#### Next Step is Regulatory Guidance for Azer-cel Clinical Development Plan

- FDA meeting expected in June
- 500M Cells + FluCy750 established as viable Phase 2 dose for safety and efficacy
- Upcoming meeting objective to guide potential Phase 2 study; focus on trial design, size and endpoints

#### 19B Stealth Cell: Potential Best-In-Class Opportunity for Earlier Line CAR T Naïve CD19+ DLBCL

#### 19B Stealth Manufacturing Optimization Resulted in Phase I Efficacy and Safety on Par With Autologous CAR T in R/R NHL Setting

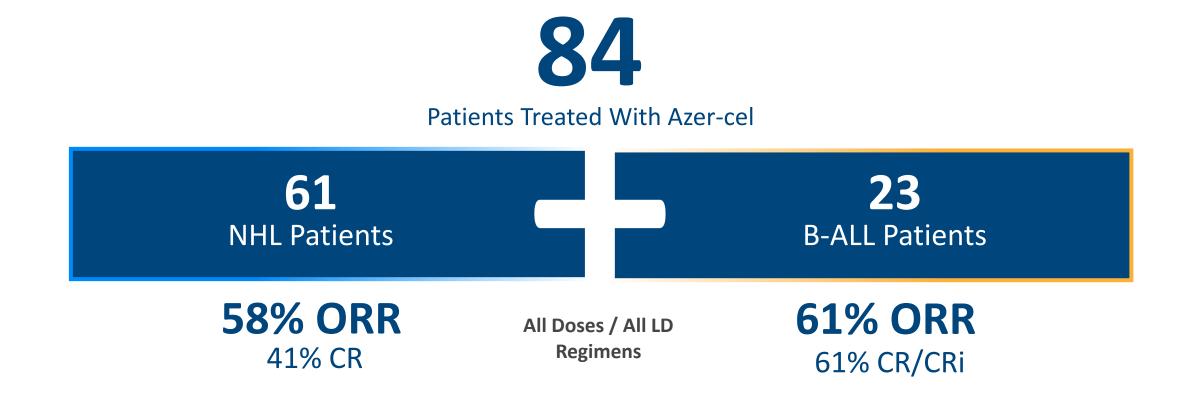
- Achieved 71% ORR with no Grade ≥3 Allogeneic CAR T related adverse events; Most compelling signal achieved in DLBCL patients with 80% ORR, and 60% CR (MRD-)
- 540M Cells + FluCy750 established as ongoing investigational dose based on Phase I therapeutic index
- 19B Stealth construct proof of concept achieved; enabling expansion and persistence by delaying host rejection through immune cloaking

#### **Building On Strong Cell Therapy Foundation**

- Optimization of manufacturing platform using ARCUS for CAR T insertion now clinically validated across two clinical candidates
- Precision CAR T platform has broad applicability beyond hematologic malignancies, including solid tumors and autoimmune diseases



### **Total Body of Evidence:** Azer-cel Has Meaningful Clinical Activity Across B Cell Malignancies

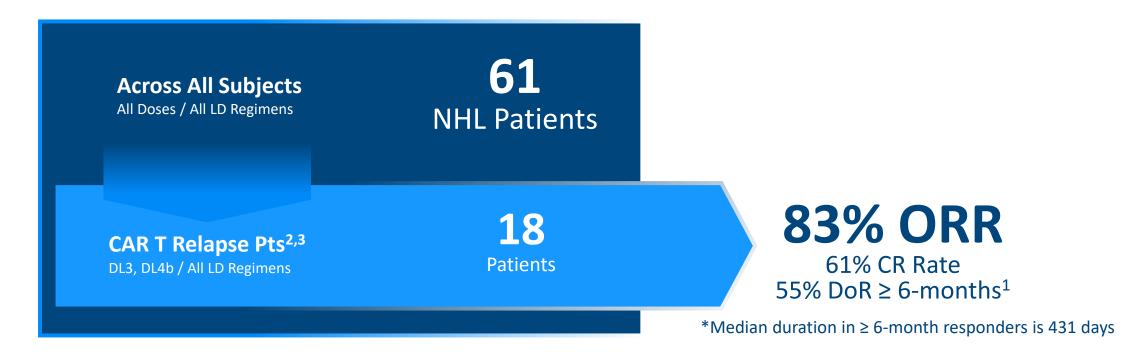


**★** Tailoring Azer-cel for the right patient, with right dose, right product attributes and right lymphodepletion



# Azer-cel is Active in CAR T Relapsed Patients:

Demonstrated High Response Rates and Durability



### \* Azer-cel has the potential to provide new standard of care for this high-risk population with unmet need



Note: Based on Patients Evaluable for Efficacy 1. N=11 patients evaluable for ≥ 6 months duration on response, 6 durable responders past 6 months or longer with 431 (> 1 year) median days on response; DoR measured from DO 2. N = 2 CAR T Relapse Patients patients were also treated at sLD and observed a 50% ORR 3. CAR T relapse Includes 17 NHL and 1 ALL patient from ASH Cohort; only sLD patients receiving optimized product attributes included

### Azer-cel Approach is Biologically Rational for CAR T Relapse Population



Azer-cel: Optimally Engineered and Manufactured

- Azer-cel from healthy donor may be more effective than an autologous product
- Autologous products made from cancer patients with impaired immune system may result in suboptimal product attributes<sup>1-4</sup>



1. Jacobson CA, et. al. J Clin Oncol 2020; 38:3095., Nastoupil LJ, et. al. J Clin Oncol 2020; 38:3119.

2. Das RK, et. al. Blood Adv 2020; 4: 4653.

3. T cell quantity and function impaired by prior therapy precluding generation of high-quality Auto CAR T product

4. Prior Chemotherapy adversely impacts surviving T cells and reduces early-lineage T cells necessary for CAR T cell expansion

### Majority of CAR T Relapse Patients Continue to Have CD19+ Disease

## **~85%** of patients<sup>1</sup> continue to have CD19+ disease



Patients

In our prospective data, patients continue to have antigen positive disease



Note: Retrospective Literature states that 12-28% of patients have antigen negative relapse (CD19-) 1. Precision Internal Clinical Data 2. Precision data; Spiegel US Consortium data

### CAR T Relapse Setting Has No Approved Standard of Care and Poor Prognosis

|                                  | CAR T Relapse Outcomes<br>U.S. Consortium Actual Data / RWD <sup>1,2,3</sup> | <u>Proposed</u> TPP For<br>CAR T Relapse Patients                           |
|----------------------------------|--|---|
| Overall Response Rate (ORR)      | ~20-30%  | > 50%   |
| Progression Free Survival (mPFS) | ~1.8 months  | > 3 months  |
| Overall Survival (mOS)           | Drug tx: 4-6 months<br>Palliative Care: <1 month                             | > 6 months  |
| Safety                           | Manageable safety profile in this fragile patient population                 | ★ No treatment related<br>Grade 5 events                                    |
| Potential Regulatory Path        | No therapy currently indicated/approved                                      | Single-arm study with<br>historical control<br>(e.g., U.S. Consortium Data) |

Notes: TPP = Target Product Profile

- 1. Barriers to enrollment in clinical trials of patients with aggressive.., Bezzera, E. Mayo Clinic, 2021
- 2. US CAR T Consortium Study https://pubmed.ncbi.nlm.nih.gov/33156925/



Note: Other therapies included targeted treatments such as venetoclax, brentuximab vedotin or ibrutinib, novel therapies, steroids, second CAR-T on clinical trial, and allogeneic stem cell transplant. In total, 8 patients proceeded to allogeneic stem cell transplant after axi-cel PD, 3 of whom remain in CR.

3. University of Washington study shows CAR T early relapsers only have mOS of 3.8 months; https://onlinelibrary.wiley.com/doi/10.1002/ajh.25505

### **CAR T Relapse Market is Large and Growing**







of patients currently treated with Auto CAR T will relapse<sup>1</sup>



★ By 2025, Global CAR T Relapse Patient Pool Is Expected To Grow ~4x as Auto CAR T Drugs become the SoC in 2L+
 → Estimate total Global G8 markets to be ~18k patients per year<sup>2</sup>

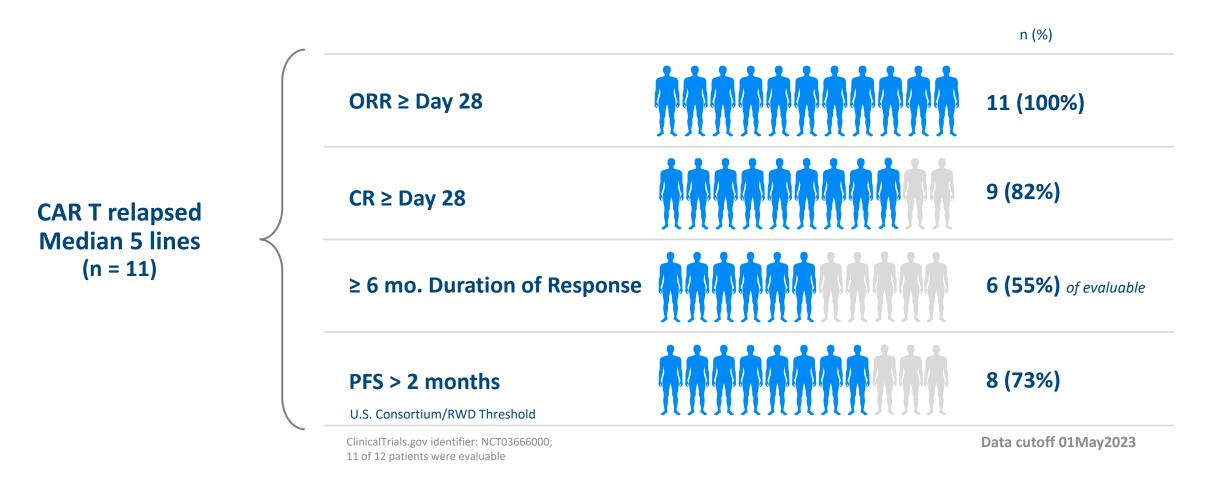


First-In-Class Opportunity

# Azer-cel: Allogeneic CAR T For CD19+ CAR T Relapsed Patients



Data Update



Despite compelling response and durability data

### Safety profile needed to be ameliorated given treatment related events



### **Significant Progress Made to Improve Azer-cel Therapeutic Index**



Optimized manufacturing process using ARCUS leading to improved product attributes resulting in improved potency and control



Received favorable CMC feedback from the FDA for ongoing development path



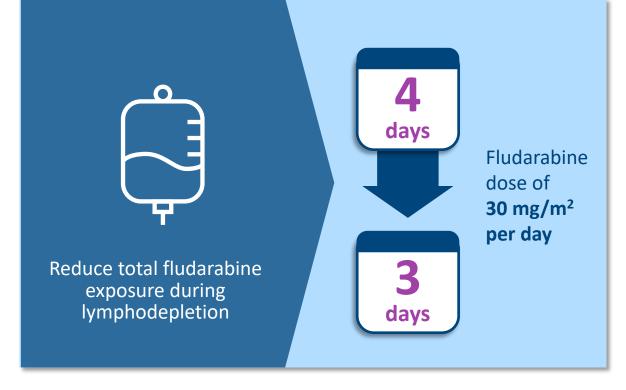
Reduced lymphodepletion dose intensity with goal to improve safety



### **Two Levers Designed to Improve Therapeutic Index**

1

**Reduced LD Dose Intensity:** Reducing the Fludarabine Dose in Lymphodepletion





**Potency with Control:** Improving Product Attributes

Process improvement led to improved fitness measured by non apoptotic cell fraction

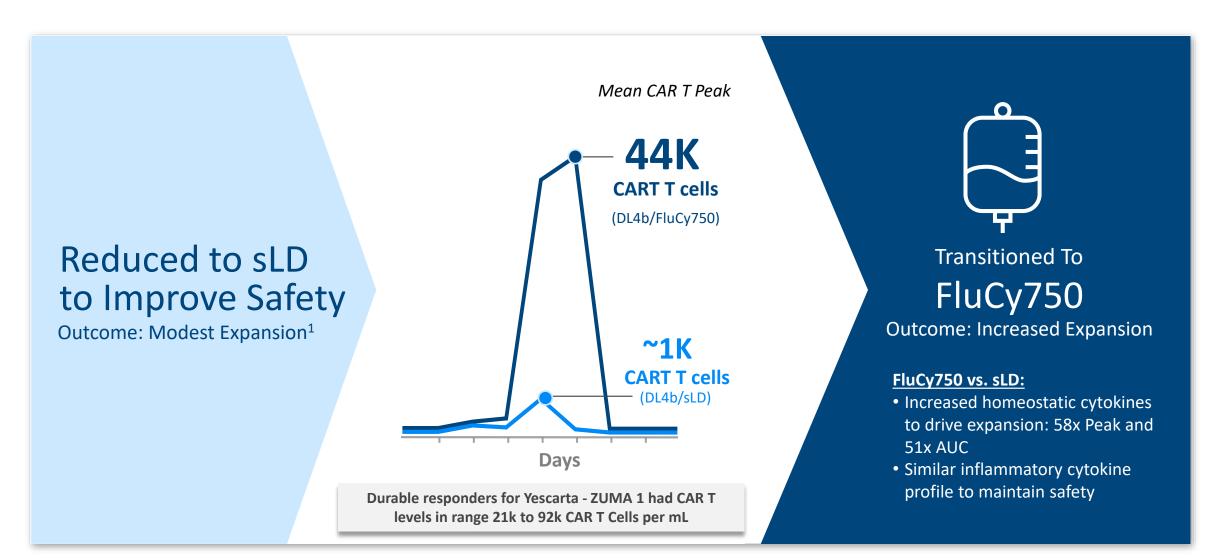
In optimized manufacturing process, reduced CD4+/CD8+ ratio to minimize inflammatory toxicities

 Total CD4+ CAR T effective cell dose is a key contributor of CD8+ CAR T cell peak expansion, inflammatory cytokines and inflammatory toxicities such as ICANS



### **Optimizing Lymphodepletion Regimen to Drive CAR T Expansion:**

An Important Factor to Drive Molecular Remission (MRD-)





First-In-Class Opportunity

# Azer-cel Safety Update CD19+ CAR T Relapsed Patients





### **Optimized Product Attributes and Reduced Fludarabine Exposure Significantly Improves Safety Profile**

Azer-cel

Data Update

| Number (%) of subjects experiencing events with max grade |               | <b>DL3a/eLD Cohort</b><br>(n=6) | DL4b/mLDCohort<br>(n=6) | Latest Cohort<br>(DL4b FluCy750 or sLD)<br>(n=7) | Latest Cohort<br>(DL4b FluCy750)<br>(n=5) |         |
|---|---------------|---------------------------------|-------------------------|--|---|---------|
| AE of special   | CRS           | Grade 1 or Grade 2              | 5 (83%)                 | 4 (67%)  | 4 (57%)                                   | 3 (60%) |
| interest <sup>1</sup>                                     |               | Grade 3 or higher               | 0                       | 0  | 0   | 0       |
|   | ICANS         | Grade 1 or Grade 2              | 2 (33%)                 | 1 (17%)  | 0   | 0       |
|   |               | Grade 3 or higher <sup>2</sup>  | 1 (17%)                 | 2 (33%)  | 0   | 0       |
|   | GvHD          |                                 | 0                       | 0  | 0   | 0       |
| Other   |               | Grade 1 or Grade 2              | 0                       | 1 (17%)  | 0   | 0       |
| notable AEs   | Infection     | Grade 3 or higher               | 4 (67%)                 | 2 (33%)  | 0   | 0       |
|   | Grade 5 event | s <sup>3</sup>                  | 2 (33%) <sup>3</sup>    | 3(50%) <sup>4</sup>                              | 0   | 0       |

Note: In Latest cohort, 500M cells is DL4b

1. AESI-Adverse Events of Special Interest

2 Median duration of Grade 3 ICANS was 4 days (2-24days)

3. Two deaths in the DL3a/ eLD Cohort related to infections and suspected fludarabine associated neurotoxicity

4. Three deaths in DL4b/ mLD Cohort were suspected fludarabine associated neurotoxicity

# In Latest Cohort, n = 5, Azer-cel CAR T Specific AE Profile is Comparable to Approved Autologous CAR T

Azer-cel Data Update

|   |                   |                                     | Autologous CAR T                    |                                     |  | Allogeneic CAR T |
|---|-------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|------------------|
| Number (%) of subjects experiencing events with max grade |                   | Yescarta <sup>1</sup><br>(r/r LBCL) | Kymriah <sup>2</sup><br>(r/r DLBCL) | Breyanzi <sup>3</sup><br>(r/r LBCL) | <b>Azer-cel</b> <sup>(n=5)</sup><br>(CAR T Relapse DLBCL)<br>(500M Cells + FluCy750) |                  |
| AE of<br>special<br>interest                              | CRS               | Grade 1 or Grade 2                  | 84%                                 | 51%                                 | 43%  | 60%              |
| Neurologic<br>toxicities<br>(including<br>ICANS)          | Grade 3 or higher | 9%                                  | 23%                                 | 3%                                  | 0  |                  |
|   | toxicities        | Grade 1 or Grade 2                  | 56%                                 | 41%                                 | 23%  | 0                |
|   |                   | Grade 3 or higher                   | 31%                                 | 19%                                 | 10%  | 0                |

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



Note: In Latest cohort, 500M cells is DL4b

- 1. https://www.yescartatecartusrems.com/
- 2. https://www.hcp.novartis.com/products/kymriah/diffuse-large-b-cell-lymphoma-adults/safety-profile/

3. https://www.breyanzi.com/receiving-breyanzi

4. Allogene 2023 10K

First-In-Class Opportunity

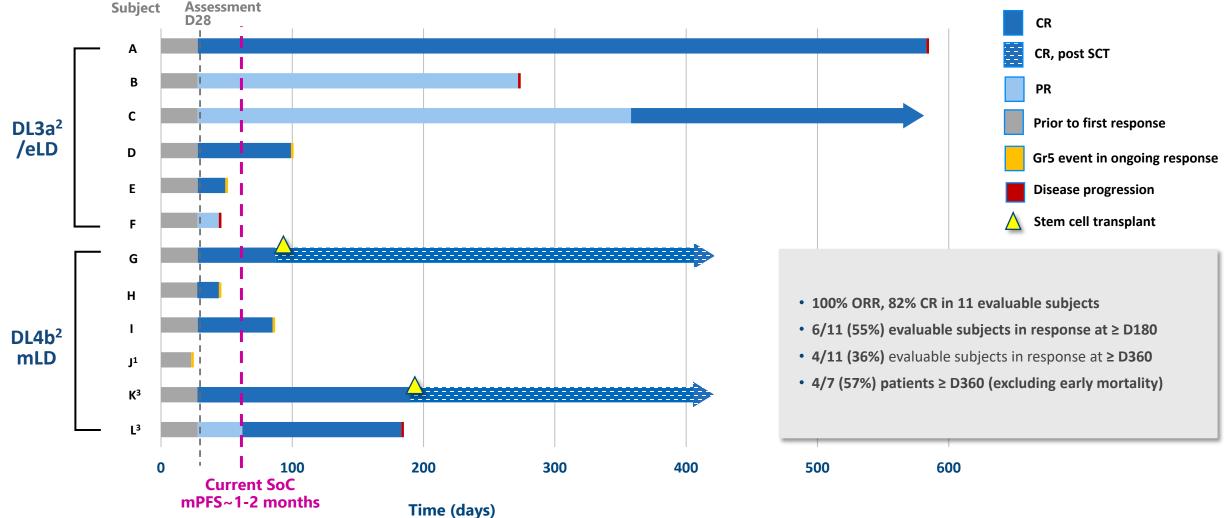
# Azer-cel Efficacy Update

Durability and Molecular Response Update from ASCO '22, n = 11 patients





# Update Since ASCO 2022 Data: Durability Favorable vs. Current Treatment Azer-cel Current Treatment Defined in U.S. Consortium Data/RWD Data Update

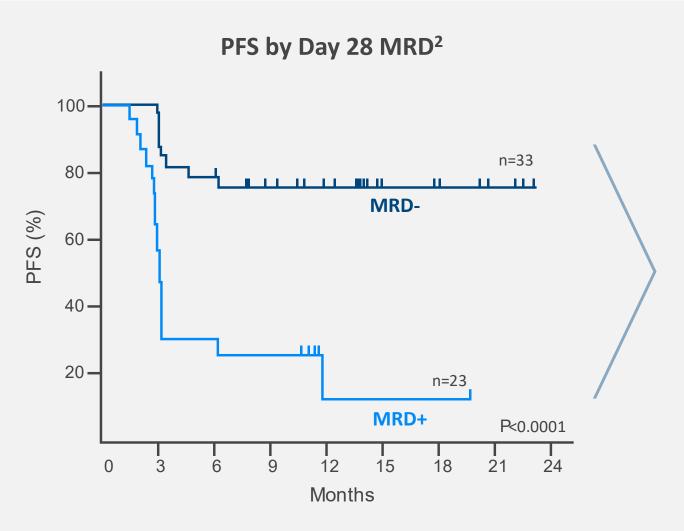




Subject J was non-evaluable for efficacy at Day 28 assessment due to death from suspected fludarabine (Flu)-associated neurotoxicity on Day 23.
 DL3a dose – 3 x 10<sup>6</sup> CAR T cells/kg; DL4b dose – 500 x 10<sup>6</sup> CAR T cells/flat dose.
 Subject K relaysed after Allo CAR T. Original response: K – CR for 150 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L relaysed after Allo CAR T. Original response: L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days before PD. Subject L - PR for 14 days befo

3. Subject K relapsed after Allo CAR T. Original response: K – CR for 150 days before PD. Subject L relapsed after Allo CAR T. Original response: L- PR for 14 days before PD. Note: DoR calculated from Day 0 onwards

### **Molecular Remission (MRD-) Key Predictor of Durability**



- Early Clearance of Circulating Tumor DNA (MRD-) measured by ClonoSEQ is Predictive for Relapse Free Interval After CAR T Treatment (per ZUMA-1)<sup>1</sup>
- PFS is Strongly Correlated with MRD Negative Status
- Molecular Remission (MRD-) is Predictive of Durable Response

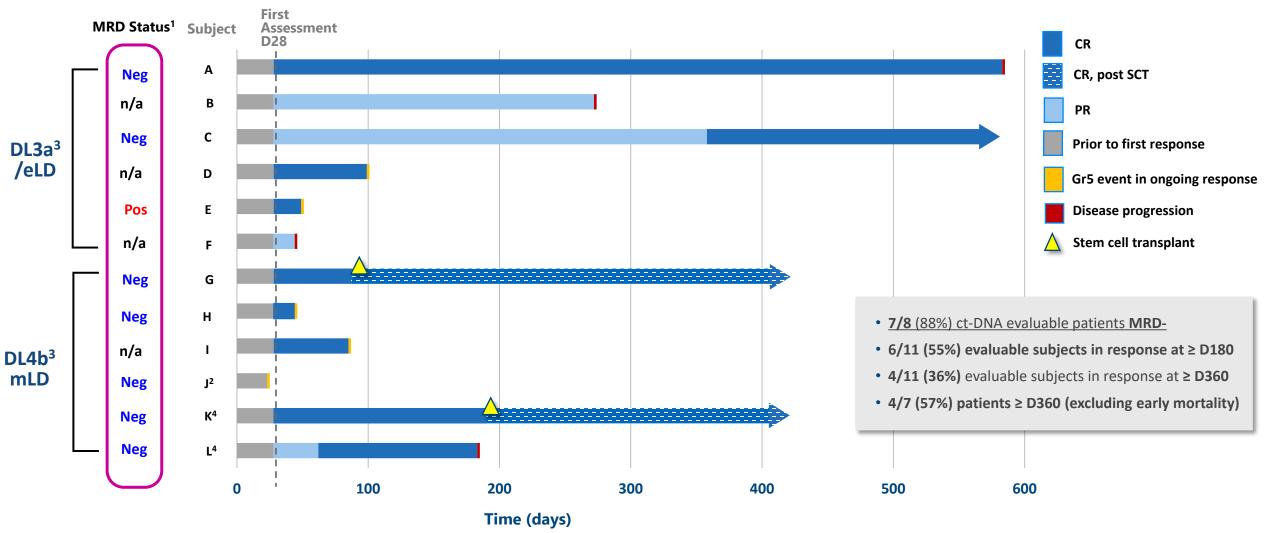
 MRD was evaluated via NGS-MRD assay to assess for ctDNA in plasma. Any detectable ctDNA was considered MRD-positive. ctDNA - circulating tumor DNA,; MRD – measurable (minimal) residual disease; NGS – next-generation sequencing; PET-CT – positron emission tomography-computed tomography; PFS – progression-free survival

2. Frank MJ et al., J Clin Oncol. 2021 Jun 16 ; JCO2100377.

### Update Since ASCO 2022: MRD Negativity Correlated With Durability

Azer-cel

Data Update



- 1. MRD determination for subjects C, E, G, H, K, and L using clonoSEQ<sup>®</sup>MRD Detection Assay (Adaptive Biotechnologies) at D28. Assessment for subject J was on D14. MRD determination for subject A was performed using a flow-based MRD assay.
- 2. Subject J was non-evaluable for efficacy at Day 28 assessment due to death from suspected fludarabine (Flu)-associated neurotoxicity on Day 23.
- 3. DL3a dose 3 x 10<sup>6</sup> CAR T cells/kg; DL4b dose 500 x 10<sup>6</sup> CAR T cells/flat dose.

4. Subject K relapsed after Allo CAR T. Original response: K – CR for 150 days before PD. Subject L relapsed after Allo CAR T. Original response: L- PR for 14 days before PD. Note: DoR calculated as response from Day 0 onwards



First-In-Class Opportunity

# Latest Azer-cel Cohort

Additional Safety and Efficacy Data Supports Potential Phase 2 Recommended Dose

500M CAR T Cells (DL4b) + FluCy750



 $FluCy750 = 30 \text{ mg/m}^2 \text{ Flu} \times 3 \text{ days} + 750 \text{ mg/m}^2 \text{ Cy} \times 3 \text{ days}$ 

### **Azer-cel + FluCy750 Preliminary Evidence of Efficacy:**

Overall Response Rate with Molecular Remissions in CAR T Relapse Setting

| Patient<br>ID | Cell Dose <sup>1</sup> | LD Type <sup>1</sup> | MRD<br>Status <sup>2</sup> | D28<br>Response <sup>3</sup> | Durability                 |
|---------------|------------------------|----------------------|----------------------------|------------------------------|----------------------------|
| 0             | 500M                   | FluCy750             | Neg                        | CR                           | PD (D90)<br>Antigen Escape |
| Р             | 500M                   | FluCy750             | Neg                        | PR                           | D90+                       |
| Q             | 500M                   | FluCy750             | Pending                    | PR                           | D28+                       |
| R             | 500M                   | FluCy750             | Pos                        | SD                           | D28+                       |
| S             | 500M                   | FluCy750             | n/a                        | PD                           | n/a                        |

Data Update

# **60% ORR** 66% MRD-(of evaluable n= 3)

### **★** Latest cohort maintained efficacy with an <u>ameliorated safety profile</u>

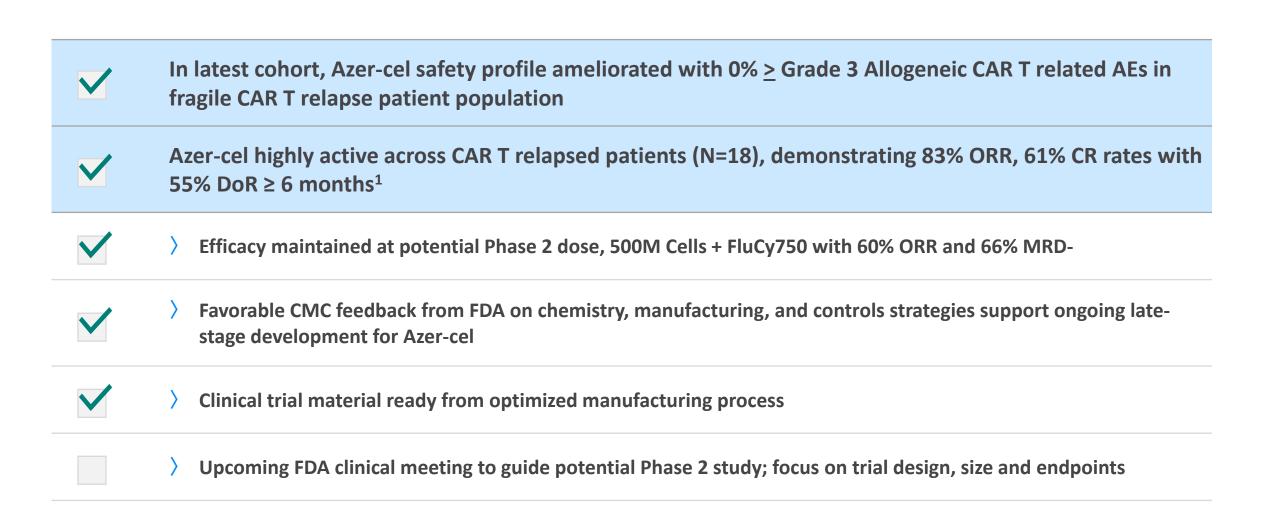


DL4b dose - 500 x 10<sup>6</sup> CAR T cells/flat dose (500M Cells). FluCy750= 30 mg/m<sup>2</sup> Flu × 3 days + 750 mg/m<sup>2</sup> Cy × 3 days.
 MRD determination using clonoSEQ<sup>®</sup>MRD Detection Assay (Adaptive Biotechnologies) at D28. Neg = negative, Pos = positive
 N = 2 CAR T Relapse Patients were also treated at sLD and observed a 50% ORR

### Established Endpoints of Key Significance for Single Arm Hematologic Oncology Trials

|  |                                    | Proposed Endpoints For<br>CAR T Relapse Patients                            | Azer-cel (500M cells + FluCy750)<br>Interim Product Profile |
|--|------------------------------------|---|---|
| Potential<br>Endpoints for<br>FDA approval | <b>Overall Response Rate (ORR)</b> | > 50%   | $\checkmark$  |
|  | 2°<br>Duration of Response (DoR)   | > 50% @ 3 months  | Not yet fully evaluable<br>66% MRD-                         |
|  | 2°<br>Safety Profile               | ★ No Treatment Related<br>Grade 5 Events                                    | $\checkmark$  |
|  | Potential Regulatory Path          | Single-arm study with<br>historical control<br>(e.g., U.S. Consortium Data) | Next step to be<br>discussed with FDA                       |







Azer-ce

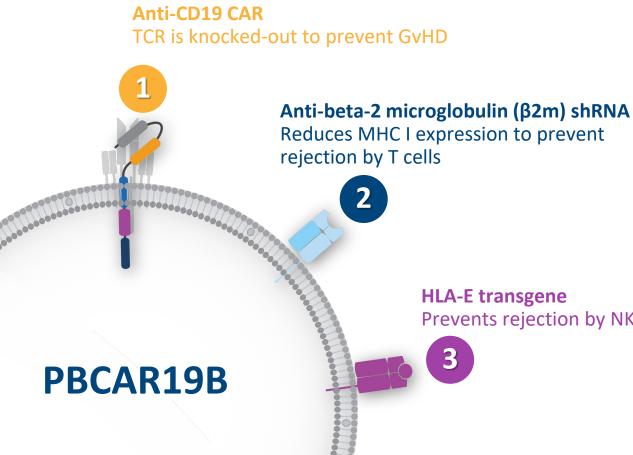
Best-In-Class Opportunity

# PBCAR19B Stealth Cell: Anti-CD19 Allogeneic CAR T

Cloaked Design to Evade Immune Rejection and Potentially Displace 2<sup>nd</sup> Line Auto CAR T in CD19+ CAR T Naïve Patients



### PBCAR19B Stealth Cell: Anti-CD19 Allogeneic CAR T Cloaked to Evade **Immune Rejection**



### **Tx Goal/ Patient Population**

**Displace 2<sup>nd</sup> Line Auto CAR T in CD19+ CAR T Naïve Patients** 

**Key Feature** 

### **PBCAR19B Stealth Cell**

Cloaked To Overcome Rejection by T Cells and NK Cells

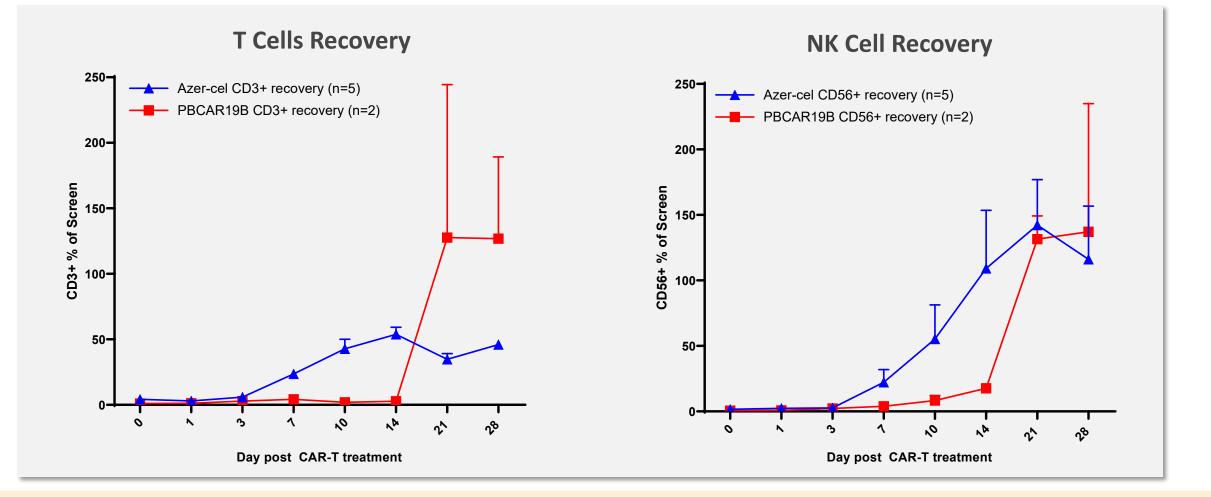
**HLA-E transgene** Prevents rejection by NK cells

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### Delayed Immune Response By T Cells and NK Cells Demonstrates Proof of Principle For Stealth Construct in DLBCL

# Ex Vivo





#### ★ This strategy may further enhance efficacy profile to displace autologous CAR T in early line DLBCL



PBCAR19B Data Update

| Number (%) of subjects experiencing events with max grade |                |                    | 540M Cells +<br>sLD<br>Cohort<br>(n=3) | 540M Cells +<br>FluCy750<br>Cohort<br>(n=4) |
|---|----------------|--------------------|--|---|
| AE of special   | CRS            | Grade 1 or Grade 2 | 1 (33%)                                | 1 (25%)                                     |
| interest  |                | Grade 3 or higher  | 0                                      | 0   |
|   | ICANS          | Grade 1 or Grade 2 | 1 (33%)                                | 0   |
|   |                | Grade 3 or higher  | 0                                      | 0   |
|   | GvHD           |                    | 0                                      | 0   |
| Other<br>notable AEs                                      | Infection      | Grade 1 or Grade 2 | 0                                      | 0   |
|   | Infection      | Grade 3 or higher  | 0                                      | 0   |
|   | Grade 5 events |                    | 0                                      | 0   |

\*Data cutoff 01May2023



# PBCAR19B Stealth Cell Dosed at 540M Cells Achieved 71% ORR with No Grade ≥3 Allogeneic CAR T Related Adverse Events

| Patient ID | Disease | LD Type <sup>1</sup> | MRD Status <sup>2</sup> | D28 Response | Durability |
|------------|---------|----------------------|-------------------------|--------------|------------|
| 1          | DLBCL   | sLD                  | Pos                     | PR           | PD (D60)   |
| 2          | DLBCL   | sLD                  | Neg                     | CR           | D150+      |
| 3          | DLBCL   | sLD                  | Pos                     | PD           | n/a        |
| 4          | DLBCL   | FluCy750             | Neg                     | CR           | D60+       |
| 5          | DLBCL   | FluCy750             | Neg                     | CR           | D28+       |
| 6          | MCL     | FluCy750             | n/a                     | PR           | D28+       |
| 7          | MCL     | FluCy750             | Pos                     | PD           | n/a        |

★ Most Compelling Signal: In <u>DLBCL patients</u>, 80% ORR with 60% CR (MRD-)

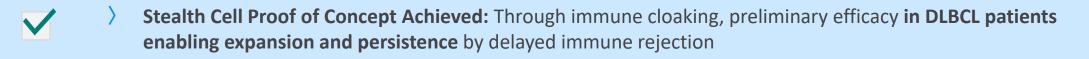


Note: In DL1, 270M Cells, 1 PR out of 3 subjects treated 1. DL2 dose – 540 x 10<sup>6</sup> CAR T cells/flat dose, sLD = 30 mg/m<sup>2</sup> Flu × 3 days + 500 mg/m<sup>2</sup> Cy × 3 days, FluCy750 = 30 mg/m<sup>2</sup> Flu × 3 days + 750 mg/m<sup>2</sup> Cy × 3 days 2. MRD determination using clonoSEQ<sup>®</sup>MRD Detection Assay (Adaptive Biotechnologies) at D28

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\*Data cutoff 01May2023

### PBCAR19B Stealth Cell Potential Best-In-Class Allogeneic Therapy For CAR T Naïve Patients



#### Total Experience at 540M Cells:

- > Treatment with PBCAR19B 540M Cells showed encouraging safety profile with no ≥ Grade 3 Allogeneic CAR T related AEs
- > PBCAR19B showed high ORR (71%) and CR rate (43%) in subjects with evidence of molecular remission (MRD-) and preliminary durability

#### **Compelling Signal of Interest:**

- Compelling signal in DLBCL patients, 80% ORR with 60% CR (MRD-); Long-term durability to be confirmed once evaluable
- 540M Cells + FluCy750 established dose for continued investigation in DLBCL patients

#### \* Results achieved with new optimized manufacturing process further validate Precision's Cell Therapy Platform



Building On Strong Foundation

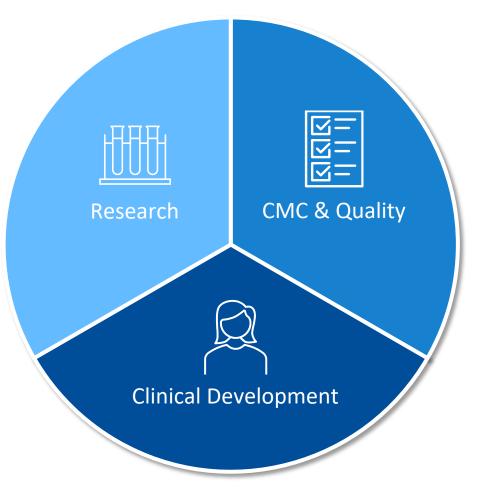
# Going Beyond Our Leading Clinical CAR T Assets

Next Generation Research Toolkit





### **Precision BioSciences Cell Therapy End-to-End Capabilities**



### Precision has built an engine for rapid discovery and earlydevelopment of donor-derived allogeneic cancer cell therapies

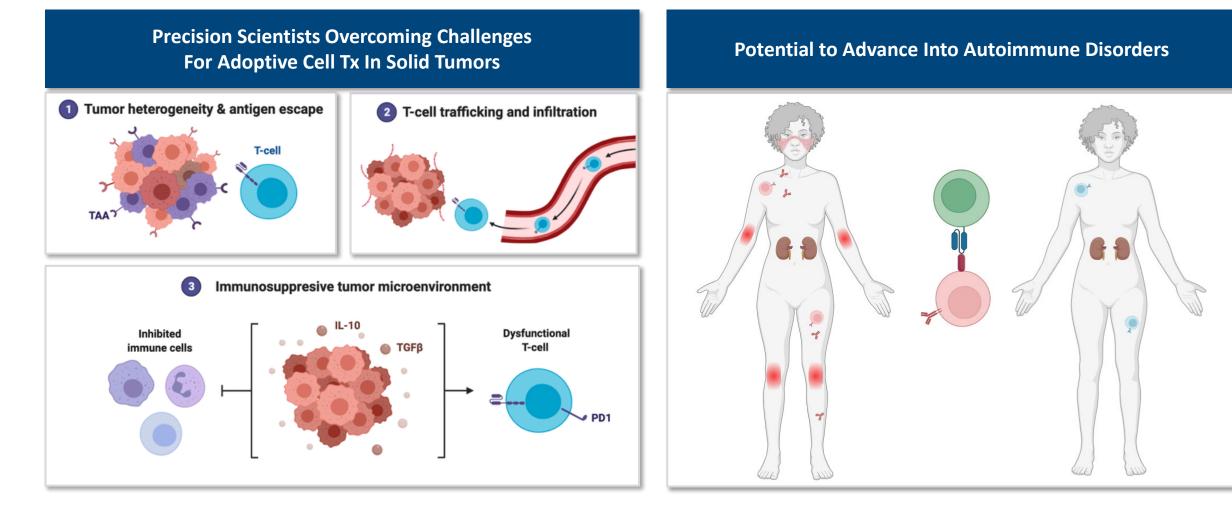
- Process development and CMC team continually iterate on improvements to the platform and next generation products
- Research rapidly designs and tests new constructs in the donor-derived allogeneic cell therapy platform
- Rapid pathway to IND due to platform synergies and regulator familiarity as well as close cross-functional team interactions
  - Experienced clinical operations team and infrastructure; currently in the clinic for later stage development

Proven cell therapy research, process development, manufacturing, quality, and clinical teams



### Solid Tumor & Autoimmune Opportunities For Precision's CAR T Platform

Ex Vivo Capabilities





### **Precision BioSciences' Leading CAR T Platform**

### **★** Precision has validated its proprietary cell therapy platform using ARCUS

Azer-cel is active with acceptable safety profile in CAR T relapse setting; Next step for Azer-cel is clinical meeting with FDA

PBCAR19B Stealth Cell construct demonstrated acceptable safety profile and preliminary efficacy in Phase 1; compelling signal in DLBCL ready for validation in next stage of development; seeking partnership opportunity

Precision's platform wide manufacturing optimizations and high CAR T insertion efficiency with ARCUS are the foundation for improved product potency and control

Precision's state of the art cell therapy capabilities support potential collaborations in hematological malignancies, solid tumors and autoimmune disorders





# PRECISION BIOSCIENCES

# End of Presentation- THANK YOU Question and Answer Session...