

## Developing Next Generation Programmed T Cell Therapies

January 2026

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# Autolus is positioned for value creation

Obe-cel product franchise supports multiple growth opportunities

## Initial Indication: Adult r/r B-ALL

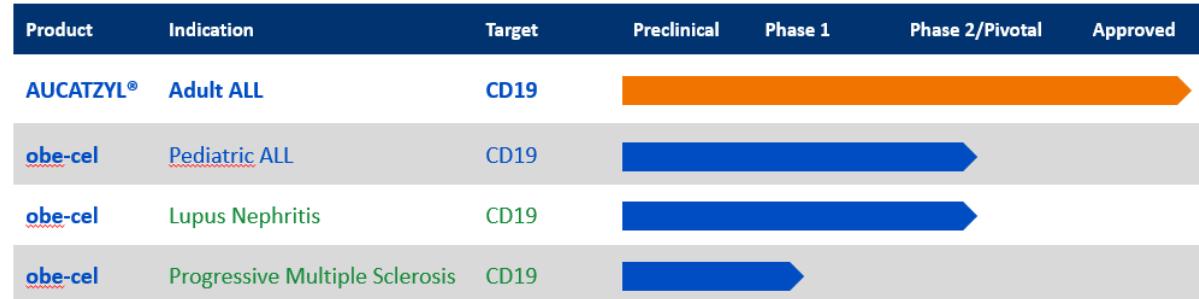
Strong Execution in First Year of Launch



**FY 2025 Net  
Product Revenue  
~\$75 million\***

-  Achieved CAR T market leadership in r/r B-ALL
-  Significant opportunity to grow overall CAR T market in adult r/r B-ALL
-  Physician interest to pursue investigator sponsored trials in 1<sup>st</sup> line ALL

## Pipeline expansion opportunities grow future commercial potential in new indications



 Opportunity to establish a **pipeline in a product** with recent data presentations supporting potentially pivotal Phase 2 clinical trials with obe-cel in lupus nephritis and pediatric ALL

**Commercial and pipeline opportunities supported by proven manufacturing and product delivery capabilities and established authorized treatment centers**

# Autolus is a leader in CAR T manufacturing & product delivery

**Executing on manufacturing and product delivery in the first year of launch:**

- ✓ Manufacturing success rate >90%
- ✓ Fast, reliable and consistent product delivery
- ✓ No capacity limitations



## Manufacturing Life Cycle Strategy: Opportunities for Innovation to Improve Margins

1 Optimizing the current manufacturing process and operating model

2 Enhancing automation opportunities on our existing process

3 Developing next-generation manufacturing platform with a step change in the cost and capacity profile



# AUTOLUS' FIRST APPROVED PRODUCT

# AUCATZYL®

## A potentially best-in-class, standalone CD19 CAR T cell therapy

# AUCATZYL® now approved in US, UK and EU

AUCATZYL indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (B-ALL)

- Highly active, fast off-rate CD19 CAR T therapy with a well managed safety profile<sup>1</sup> – approved in US, UK, EU
- First and currently only approved CAR T therapy with customized, tumor-burden guided dosing – no FDA REMS obligation
- Established infrastructure for manufacturing and commercialization
- Commercial presence in more than 60 US centers
- NICE determined AUCATZYL to be cost effective, UK\* launch initiated in December 2025
- Approval in EU<sup>†</sup> in 2025; pricing and reimbursement evaluation ongoing on a country-by-country basis



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukemia

# Strong first year of U.S. AUCATZYL® launch

## AUCATZYL Net Product Revenue

**Q4 2025:** ~\$24 Million\*

**FY 2025:** ~\$75 Million\*



## Strong initial launch based on:

- More than 60 treatment centers activated
- Positive physician and patient experience
- Reliable manufacture and delivery of product

## 2026 Expectations

**FY 2026 Net Product Revenue:**  
\$120-\$135 million

Shift to **positive gross margin in 2026** based on increasing volumes and improved manufacturing plant utilization

**Increase commercial footprint** in the US to more than 80 treatment centers and ongoing launch in the UK

# AUCATZYL geographic growth opportunities in ALL

UK Launch  
Q1 2026

## Expansion

- ✓ Conditional marketing authorization in the UK received April 2025
- ✓ Successful NICE pricing and reimbursement process Nov 2025
- ✓ AUCATZYL available in routine commissioning in NHS Dec 2025



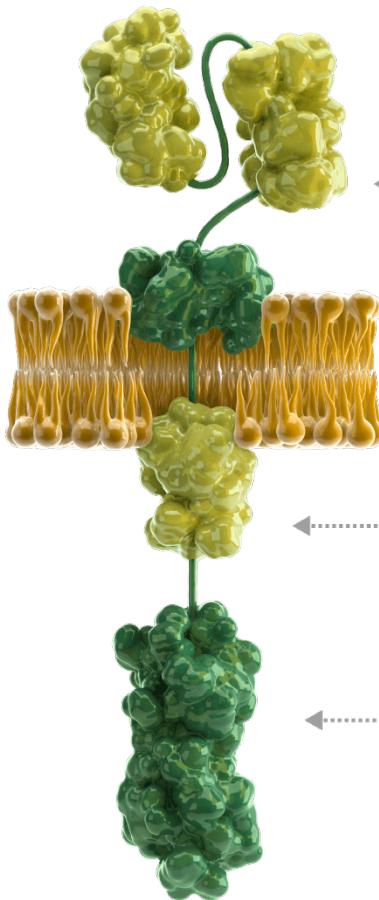
EU market  
access -  
pending

- ✓ European Commission (EC) conditional approval received July 2025
  - Ongoing country-by-country evaluation of pricing and reimbursement decisions to assess feasibility of market entry; no anticipated EU sales in 2026
  - Exploration of alternate market access mechanisms in 2026



# We believe AUCATZYL® has a unique mechanism of action

Clinical data show increased activity and reduced toxicity



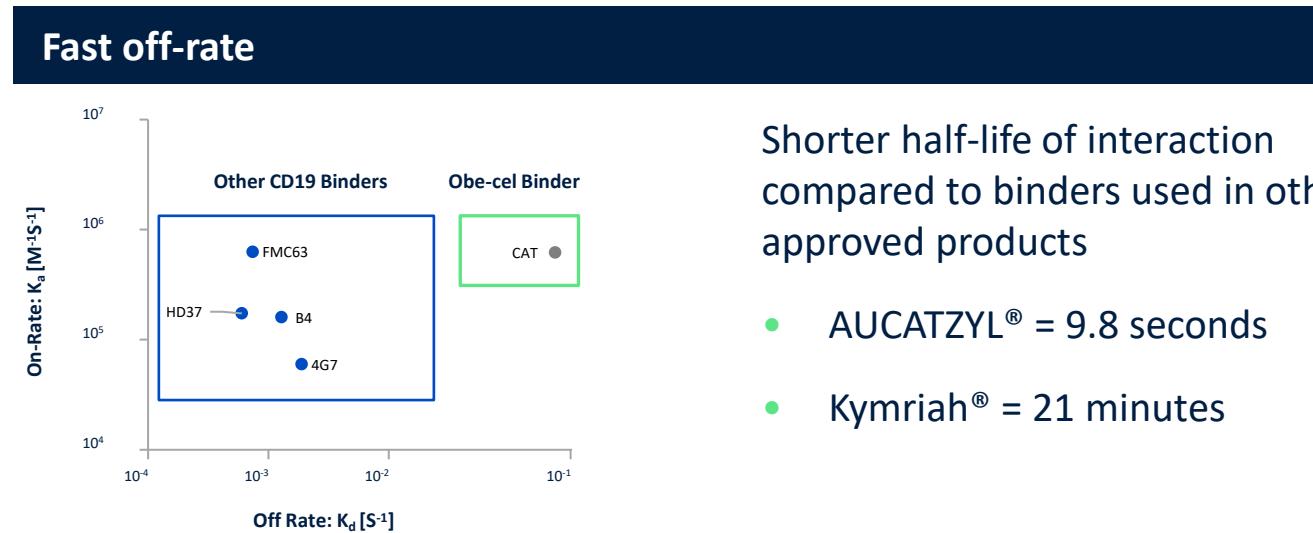
**CAT19 fast off-rate binder<sup>2</sup>**

**CD8-derived hinge region/  
transmembrane domain<sup>2</sup>**

**4-1BB co-stimulatory domain<sup>1,4</sup>**

Shown to enhance CAR T-cell expansion and reduce exhaustion compared with CD28 CARs in preclinical studies

**CD3ζ activation domain<sup>1</sup>**



Shorter half-life of interaction compared to binders used in other approved products

- AUCATZYL® = 9.8 seconds
- Kymriah® = 21 minutes

### Potential for improved potency, reduced toxicity

Avoided over-activation of CAR T cells

→ Reduced toxicities

Increased CAR T peak expansion

→ Improved peak activity and persistence

Avoided exhaustion of CAR T-cells

→ Improved engraftment  
Improved persistence

# AUCATZYL was approved based on results from the FELIX trial

**FELIX 19**

**FELIX Phase 1b/2**

Cohort IA ≥5% BM blast	Cohort IIA ≥5% BM blast
Cohort IB <5% BM blast MRD+	Cohort IIB <5% BM blast MRD+
<b>Cohort IIC</b> Isolated EMD at screening	
<b>Patients (N)</b>	<b>Ph1b/2 pooled<sup>1</sup></b>
Enrolled	153
Infused	127

## Background

- Open-label, multinational, single-arm Phase 1b/2 trial in adult patients with R/R B-ALL<sup>1-2</sup>; largest CAR T cell therapy trial in R/R B-ALL to date (N=153 enrolled)
- Conducted during COVID-19 pandemic with highly immune compromised patients

## Summary of Trial Experience

- High ORR, encouraging EFS/OS and favorable tolerability with low levels of high-grade CRS and ICANS
- Timely and reliable clinical product supply and logistics despite COVID-19 pandemic restrictions
- Across all Phase 1b/2 cohorts, 40% of responders in ongoing remission without subsequent stem cell transplant/other therapy<sup>1</sup>
- Survival outcomes suggesting potential of long-term plateau<sup>1</sup>

# FELIX trial published in New England Journal of Medicine<sup>1</sup>

Favourable response rate and tolerability, despite challenging patient population

## High overall response rate with deep molecular responses

- Durable responses, particularly in patients with a low-to-intermediate bone marrow burden

## Excellent tolerability profile

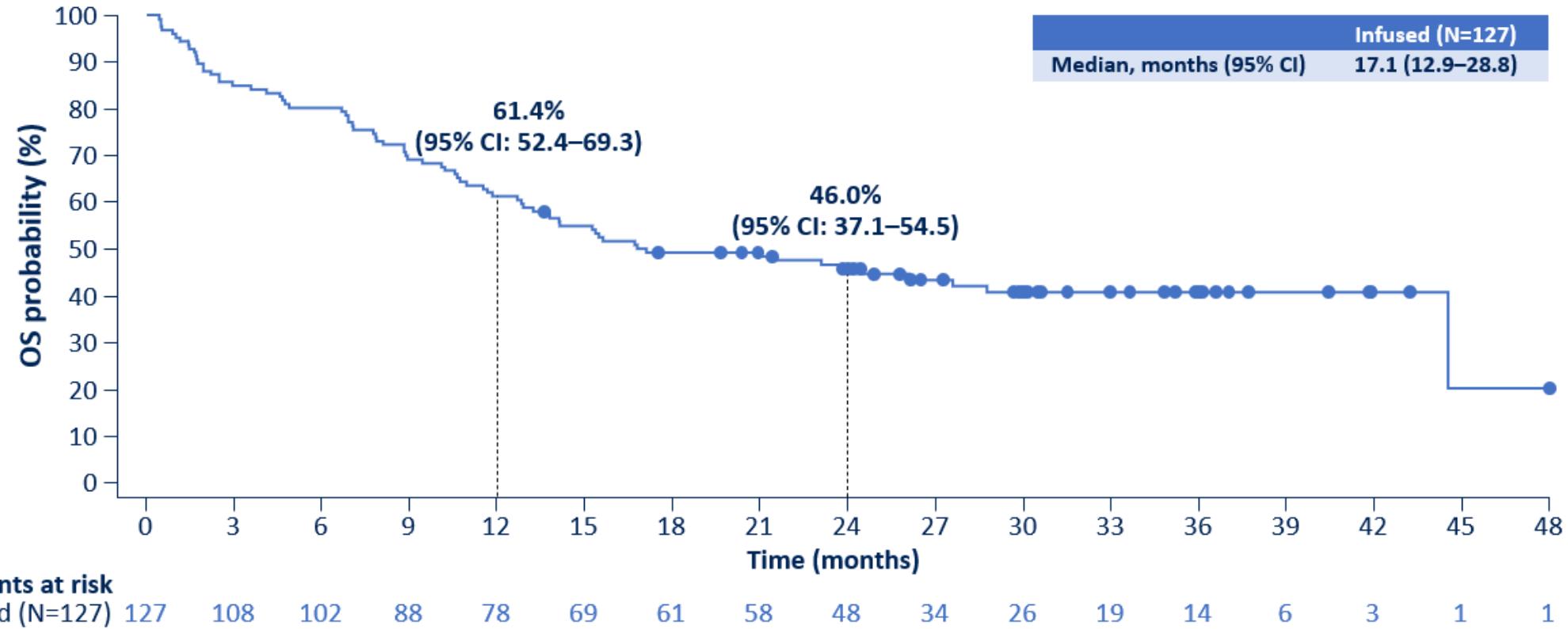
- Very low rates of high-grade immunotoxicities
- No high-grade events in low disease burden patients

Response by disease status at lymphodepletion	Overall Remission Rate (CR/CRI)
All patients (n=127)	77%
Morphological disease (n=91)	75%
Measurable residual disease (n=29)	96%
Isolated extramedullary disease (n=7)	71%

Safety by disease burden at lymphodepletion	Grade ≥3 CRS	Grade ≥3 ICANS
All patients (n=127)	2%	7%
>75% Blasts (n=40)	2%	12%
5-75% Blasts (n=51)	4%	8%
<5% Blasts (n=36)	0%	0%

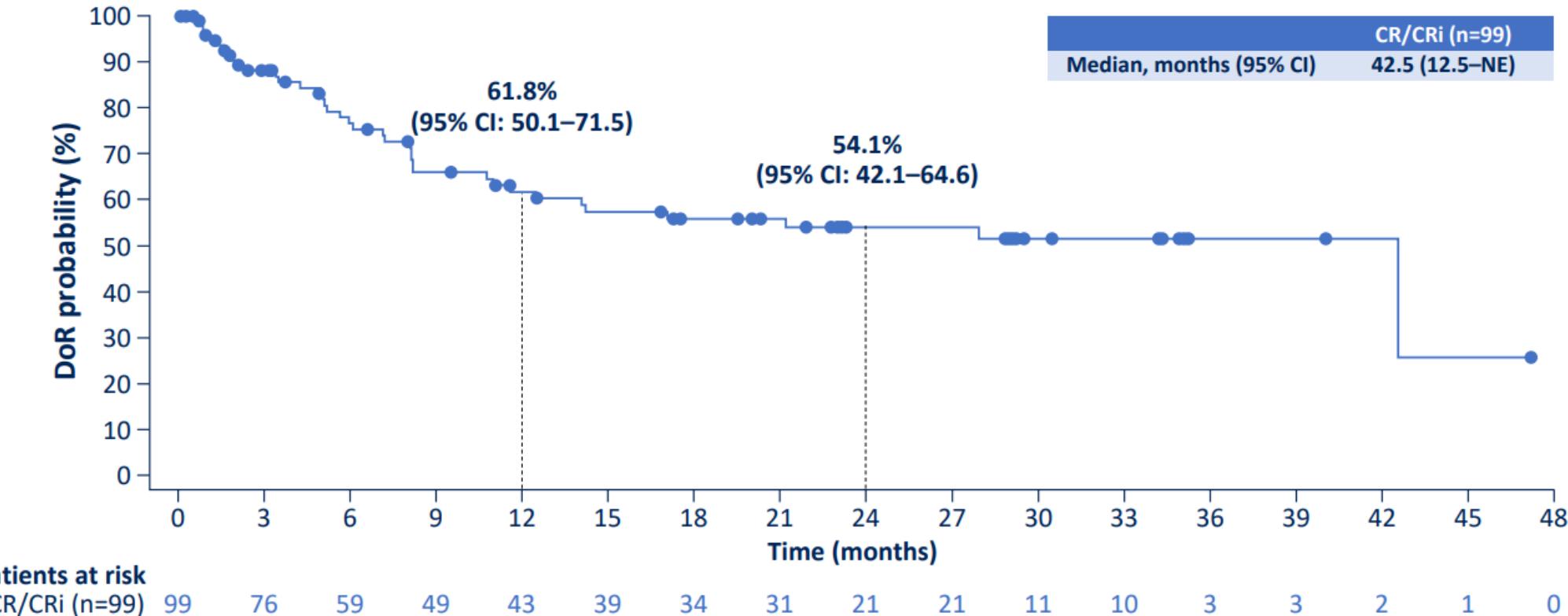
# Data continue to show long term remissions in r/r adult B-ALL

At 24 months, overall survival probability was 46.0%



# Duration of response: median 42.6 months at last data cut

More than half of patients still in remission at 24 months



# Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

# Pipeline supports growth with multiple development opportunities

## Near-Term Growth Drivers

Product	Indication	Target	Preclinical	Phase 1	Phase 2/Pivotal	Approved	Status
AUCATZYL® (obe-cel)	Adult ALL		CD19				FDA, MHRA^ & EC approved <sup>†</sup>
obe-cel	Pediatric ALL	CD19					Currently enrolling
obe-cel	Lupus Nephritis	CD19					Currently enrolling
obe-cel	Progressive Multiple Sclerosis	CD19					Currently enrolling

## Early Stage / UCL Collaborations

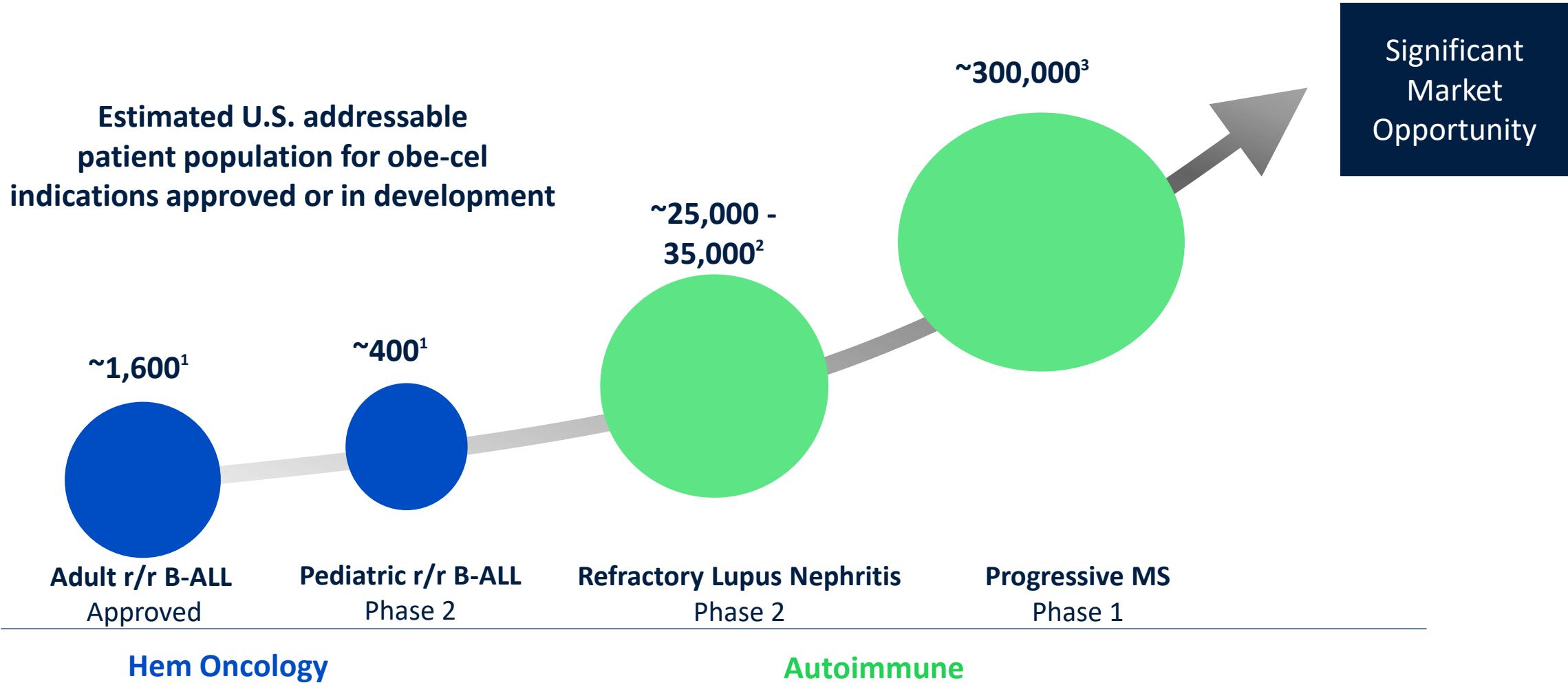
Product	Indication	Target	Preclinical	Phase 1	Status
AUTO8*	Multiple Myeloma	CD19 & BCMA			Currently enrolling
AUTO8*	Light Chain Amyloidosis	CD19 & BCMA			Currently enrolling
AUTO1/22*	Pediatric ALL	CD19 & CD22			Currently enrolling

<sup>^</sup>Conditional marketing authorization; <sup>†</sup>European Commission (EC) conditional approval; \*UCL Collaboration

# Growing the obe-cel franchise commercial opportunity

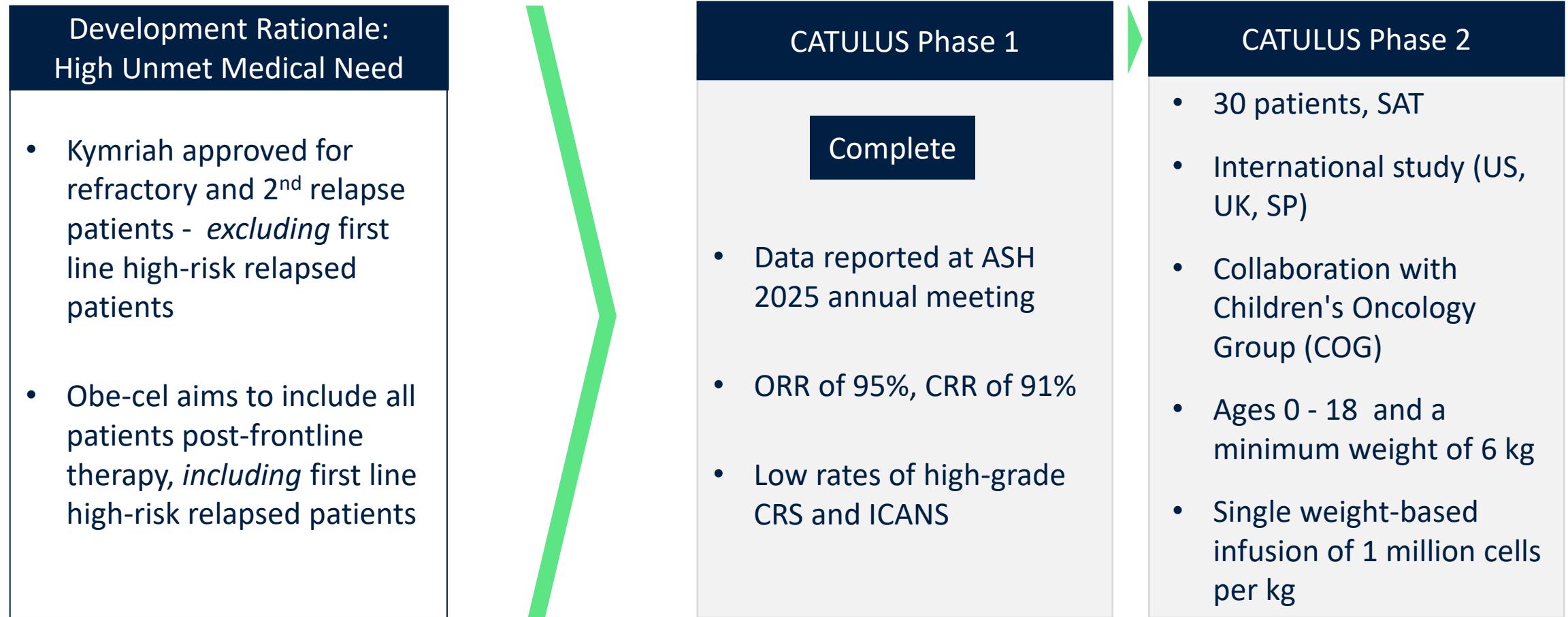
Robust clinical database and demonstrated commercial capabilities position Autolus for efficient path in new indications

*Graphic is illustrative, not to scale*



# Pediatric r/r B-ALL development strategy

Regenerative Medicine Advanced Therapy (RMAT) designation supports development pathway



**CATULUS trial is currently enrolling; enrollment expected to be complete by first half of 2027**

# CATULUS Phase 1 data support progressing into Phase 2

Safety profile of obe-cel in pediatric patients consistent with that previously reported in adults

	All infused patients, B-ALL cohort (N=23)	
	Any grade	Grade $\geq 3$
<b>Treatment-emergent adverse events, n (%)</b>	23 (100)	17 (73.9)
<b>CRS, n (%)</b>	12 (52.2)	2* (8.7)
Time to onset of CRS in days, <sup>†</sup> median (range)	7.0 (1–11)	9.5 (8–11)
<b>ICANS, n (%)</b>	4 (17.4)	2* (8.7)
Time to onset of ICANS in days, <sup>†</sup> median (range)	8.5 (8–20)	8.5 (8–9)
<b>Infections, n (%)</b>	15 (65.2)	5 (21.7)
Sepsis, n (%)	2 (8.7)	2 (8.7)
<b>Febrile neutropenia, n (%)</b>	7 (30.4)	6 (26.1)
<b>IVIG use, n (%)</b>	19 (82.6)	
<b>Treatment-related mortality, n (%)</b>	0	

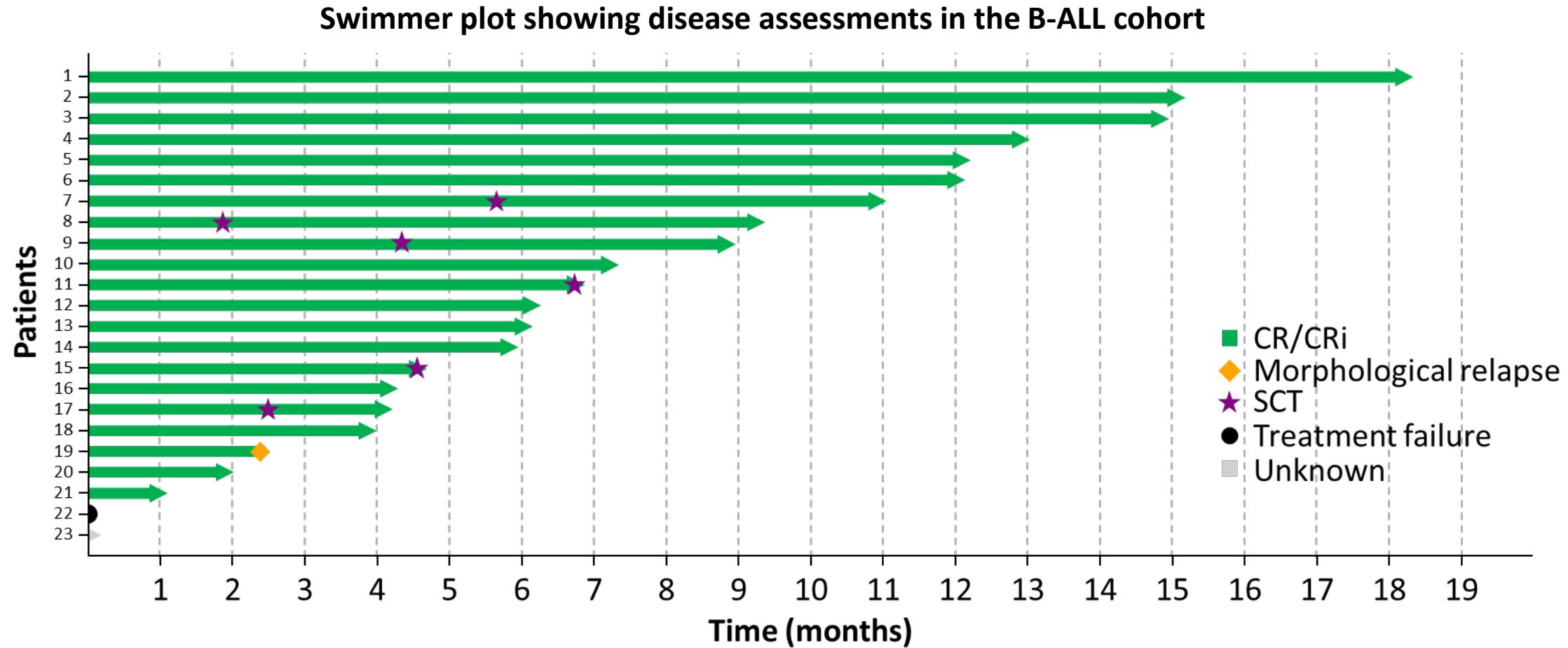
\*One patient experienced both Grade 3 CRS and Grade 3 ICANS.

†Time to onset (days) = [(Date of start of Any grade/Grade $\geq 3$  CRS/ICANS – Date of first obe-cel infusion) +1].

B-ALL, B-cell acute lymphoblastic leukemia; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IVIG, intravenous immunoglobulin

# CATULUS data demonstrate promising initial efficacy in pediatric patients

At median follow-up of 8.8 months in pediatric r/r B-ALL patients: **ORR was 95.5%; CR was achieved in 90.9%**



# MOA and commercial capabilities are key differentiators in AID

Obe-cel is the only CD19 CAR approved in other indications that is now being tested for autoimmune disease

## Autolus Potential Advantage

- Favorable tolerability to drive acceptability in non-oncology indications
- Deep cut into the CD19+ B cells and plasma blasts
- Robust, economical and scalable manufacturing and established commercial infrastructure
- Potential for accelerated clinical program
- FDA-approved CAR-T therapy, with existing safety database, now in development for autoimmune indications



Supports differentiated approach and potential for obe-cel in autoimmune disease areas

# CARSLYLE: Obe-cel shows promise as a new approach for SLE/LN

50 million cell dose selected as recommended Phase 2 dose

## Patient population:

- Patients were significantly impaired with their kidney function and had across the board some of the highest SLEDAI-2K disease scores included in current SLE studies.

## Efficacy: Median follow up of 11.4 months in 50 million cell dose cohort

- Achievement of DORIS in 83.3% (n=5/6) of patients
- Achievement of renal complete remission in 50% (n=3/6 pts) of patients

## Safety: Obe-cel was generally well tolerated in all patients with no ICANS, no high-grade CRS

## PK/Biomarkers: All patients showed deep B-cell depletion shortly after infusion, which was subsequently followed by a predominance of naïve B-cell reconstitution, suggesting an obe-cel-driven immune reset

## Next Steps:

- Completion of adolescent (aged 12–17 years) and higher dose level patient cohorts
- Data support progression into a Phase 2 lupus nephritis trial

# CARSLYLE: Obe-cel is well tolerated with no ICANS or Grade $\geq 2$ CRS

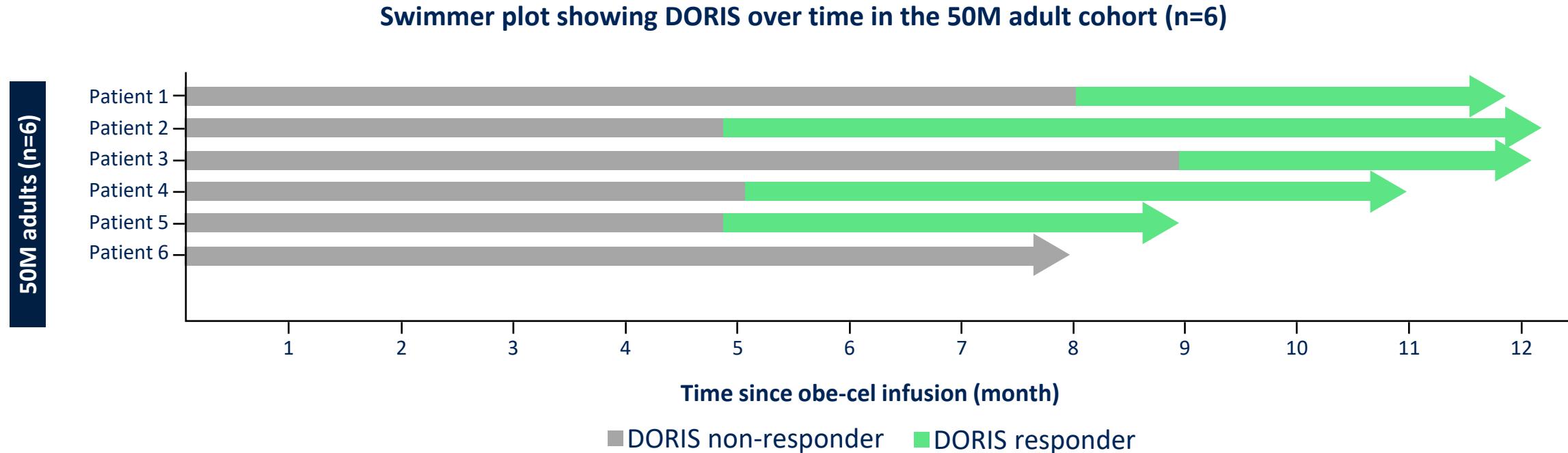
	Infused adult patients, 50M (n=6)		Infused adult patients, 100M (n=3)	
	Any grade, n (%)	Grade $\geq 3$ , n (%)	Any grade, n (%)	Grade $\geq 3$ , n (%)
<b>CRS</b>	3 (50.0)	0	3 (100)	0
<b>ICANS</b>	0	0	0	0
<b>Any treatment-emergent adverse event</b>	6 (100)	6 (100)	3 (100)	2 (66.7)
<b>Neutropenia</b>	6 (100)	6 (100)	2 (66.7)	2 (66.7)
<b>Infection</b>	6 (100)	2 (33.3)	3 (100)	0
<b>Hypertension*</b>	5 (83.3)	4 (66.7)	0	0
<b>Anemia</b>	4 (66.7)	3 (50.0)	1 (33.3)	1 (33.3)
<b>Febrile neutropenia</b>	2 (33.3)	2 (33.3)	0	0
<b>Thrombocytopenia</b>	2 (33.3)	1 (16.7)	1 (33.3)	1 (33.3)
<b>Liver injury</b>	0	0	1 (33.3)	1 (33.3)

Data cut-off: 04 November 2025. Roddie et al. 2025 ASH Annual Meeting

\*Three patients in the 50M adult cohort had a pre-existing history of hypertension.

50M,  $50 \times 10^6$  CAR T-cells; 100M,  $100 \times 10^6$  CAR T-cells; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; DLT, dose-limiting toxicity; ICANS, immune effector cell-associated neurotoxicity syndrome; obe-cel, obecabtagene autoleucel.

# 5 of 6 patients achieved DORIS with median onset of 5.1 months

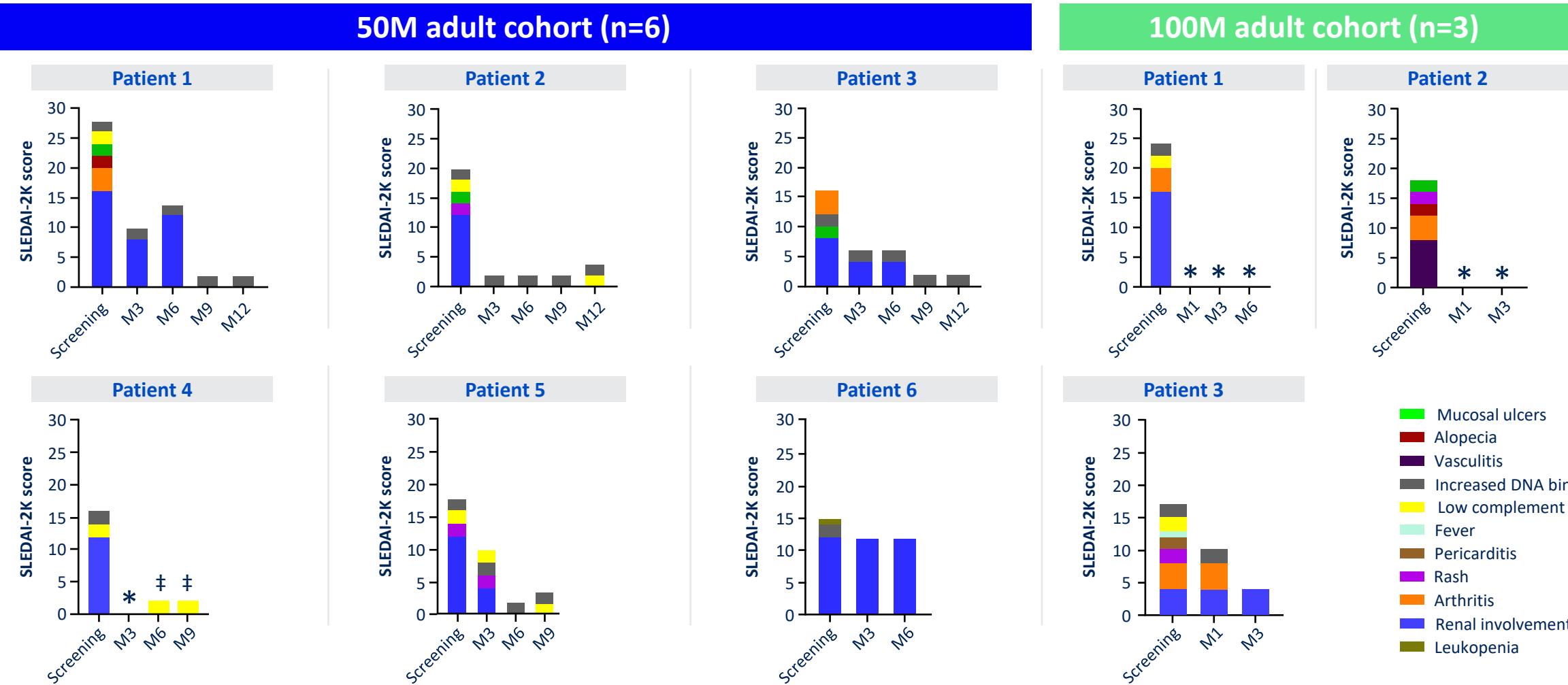


- Renal responses reported at last follow-up visit in the 50M adult cohort indicate that three patients (50.0%) achieved CRR with onset at Month 1 and one patient (16.7%) achieved PRR with onset at Month 7
- The length of follow up was insufficient to calculate DORIS response or CRR/PRR for the 100M adult cohort

Data cut-off: 04 November 2025.

**DORIS is defined as: SLEDAI = 0 (irrespective of serology), PGA <0.5, and ≤5 mg/day corticosteroid use.** Use of stable antimalarials and immunosuppressives, including biologics, is allowed.  
50M,  $50 \times 10^6$  CAR T-cells; 100M,  $100 \times 10^6$  CAR T-cells; CAR, chimeric antigen receptor; CRR, complete renal response; **DORIS, Definition of Remission in systemic lupus erythematosus;**  
**PGA, Physician Global Assessment; PRR, partial renal response; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.**

# Clinically meaningful reduction in SLEDAI-2K score observed

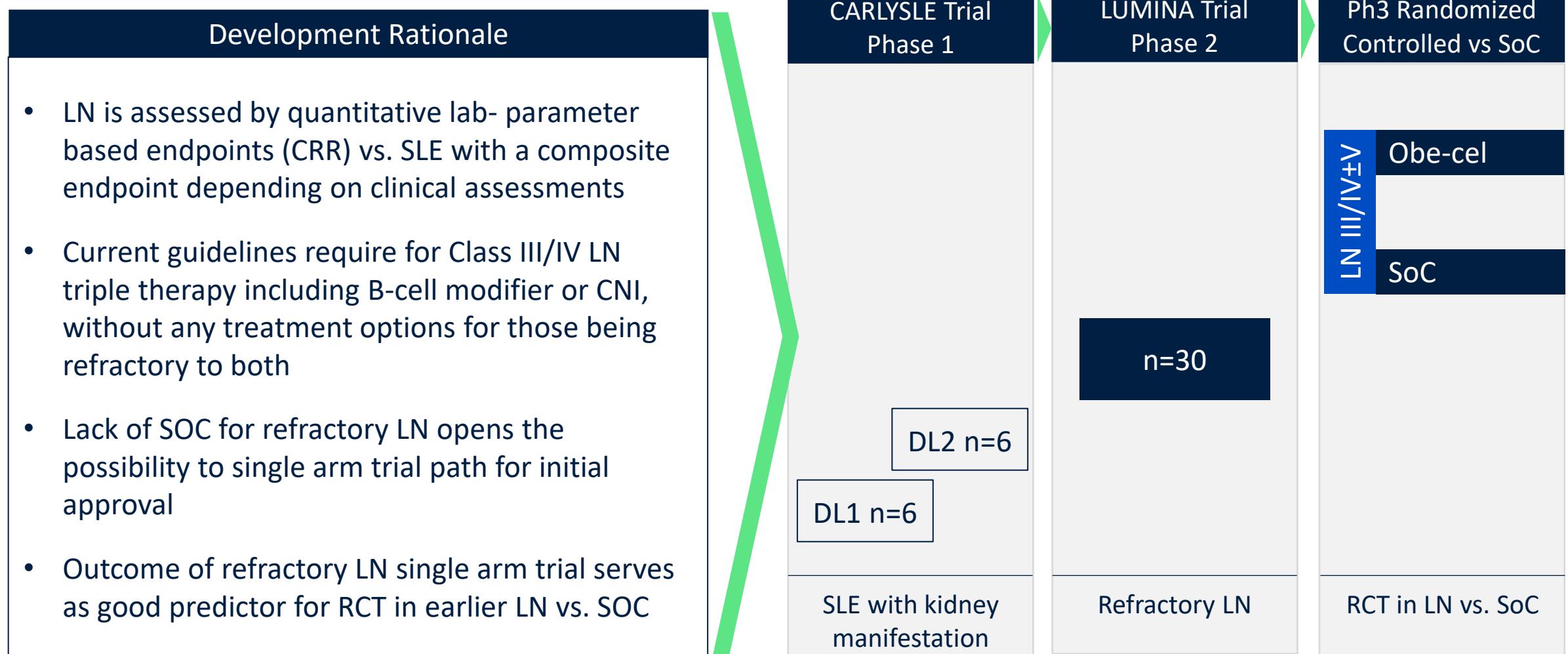


Data cut-off: 04 November 2025. SLEDAI-2K is an instrument designed to evaluate current SLE activity (not chronic damage) across 9 different organ systems. \*SLEDAI-2K score of zero. <sup>†</sup>C3=0.84 g/L considered presence of low complement at M6 and M9 using a local lab lower limit of normal of 0.9 g/L.

50M,  $50 \times 10^6$  CAR T-cells; 100M,  $100 \times 10^6$  CAR T-cells; C3, complement 3; CAR, chimeric antigen receptor; DNA, deoxyribonucleic acid; M, month; SLE, systemic lupus erythematosus; SLEDAI-2K, SLE Disease Activity Index 2000.

# Lupus nephritis development strategy

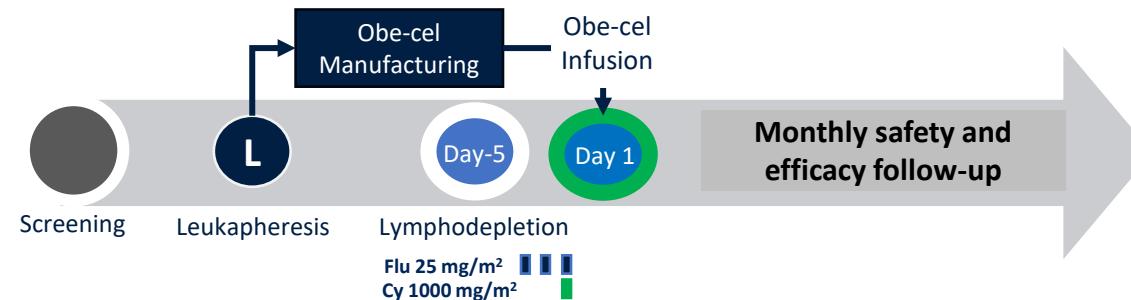
Leveraging a fast to market strategy



LUMINA trial is currently enrolling

# Phase 2 LUMINA trial supports efficient path to market

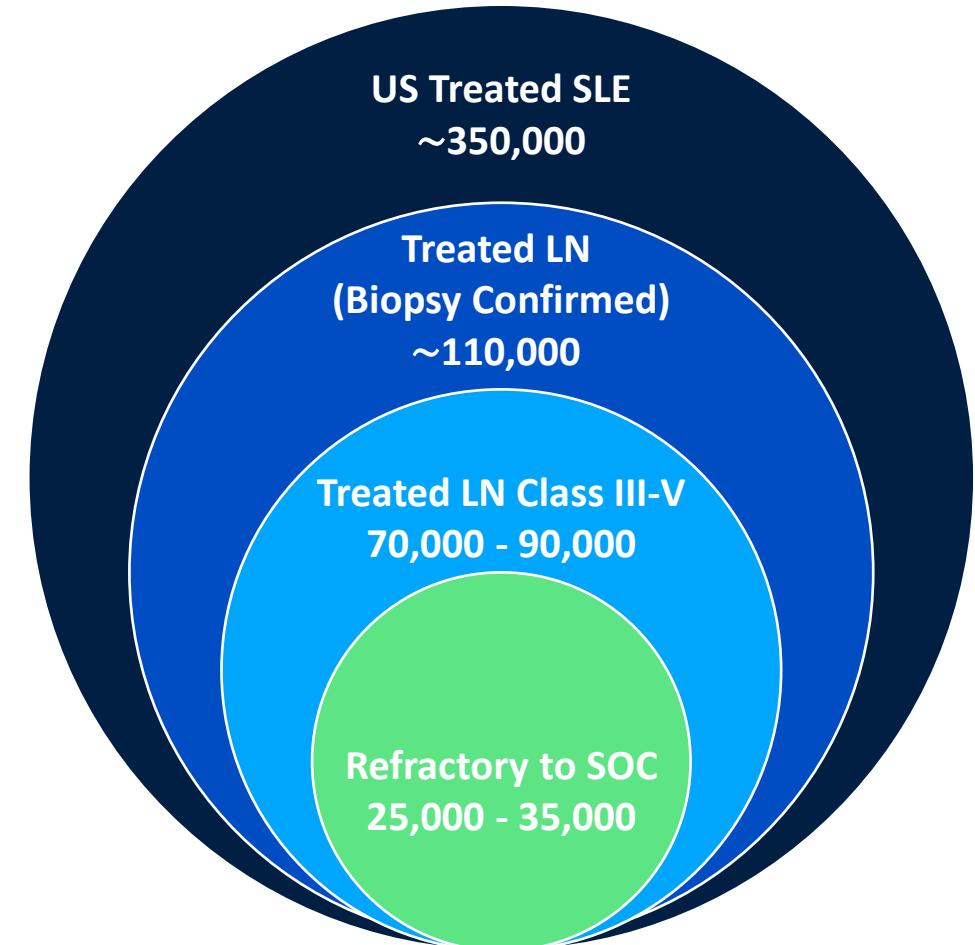
Evaluating severe, refractory lupus nephritis (LN)



Trial design	Single arm, open-label, multi-centre, phase 2
Sample size	30 patients
Patient population	<ul style="list-style-type: none"> <li>12-65 years of age, body weight <math>\geq 40\text{kg}</math></li> <li>Diagnosis of SLE based on (EULAR)/ (ACR) 2019 classification</li> <li>Positive (ANA) (<math>\geq 1:80</math>), or anti-dsDNA (<math>\geq 30 \text{ IU/mL}</math>) or anti-Smith (<math>&gt; \text{ULN}</math>), anti-histone or anti-chromatin (<math>&gt; \text{ULN}</math>)</li> <li>Severe, refractory LN (ongoing active class III, IV or V (only in combination with III or IV)</li> <li>Prior immunosuppressive and biologic therapies with inadequate response or intolerance</li> </ul>
Treatment	$50 \times 10^6$ CAR positive T-cells following Flu/Cy lymphodepletion
Endpoints	<p>Primary: Complete Renal Response at 6 months</p> <p>Key Secondary: DORIS at 6 months</p>
Timing	<ul style="list-style-type: none"> <li><b>LUMINA trial is currently enrolling</b></li> </ul>

# Refractory lupus nephritis is a high unmet medical need

- Kidneys are one of the most common organs involved in SLE - 30% – 40% are lupus nephritis patients
- High disease activity is associated with inflammatory processes
- Uncontrolled inflammation leads to high chronicity due to accumulated kidney damage
- Despite treatment advances including regulatory approvals of belimumab and voclosporin the goal to sufficiently improve short and long-term outcomes in patients with LN remains unmet
- There are no treatment options for refractory patients



# Multiple sclerosis development strategy

## Establish Phase 1 Clinical Proof of Concept in MS

- 3 x 6 dose escalation design - a higher dose may be required for CNS effect
- Biomarker readouts to provide nearer term evidence of biological effect at 6 months +
- Definitive clinical outcomes based on clinical disability progression at 12 months +

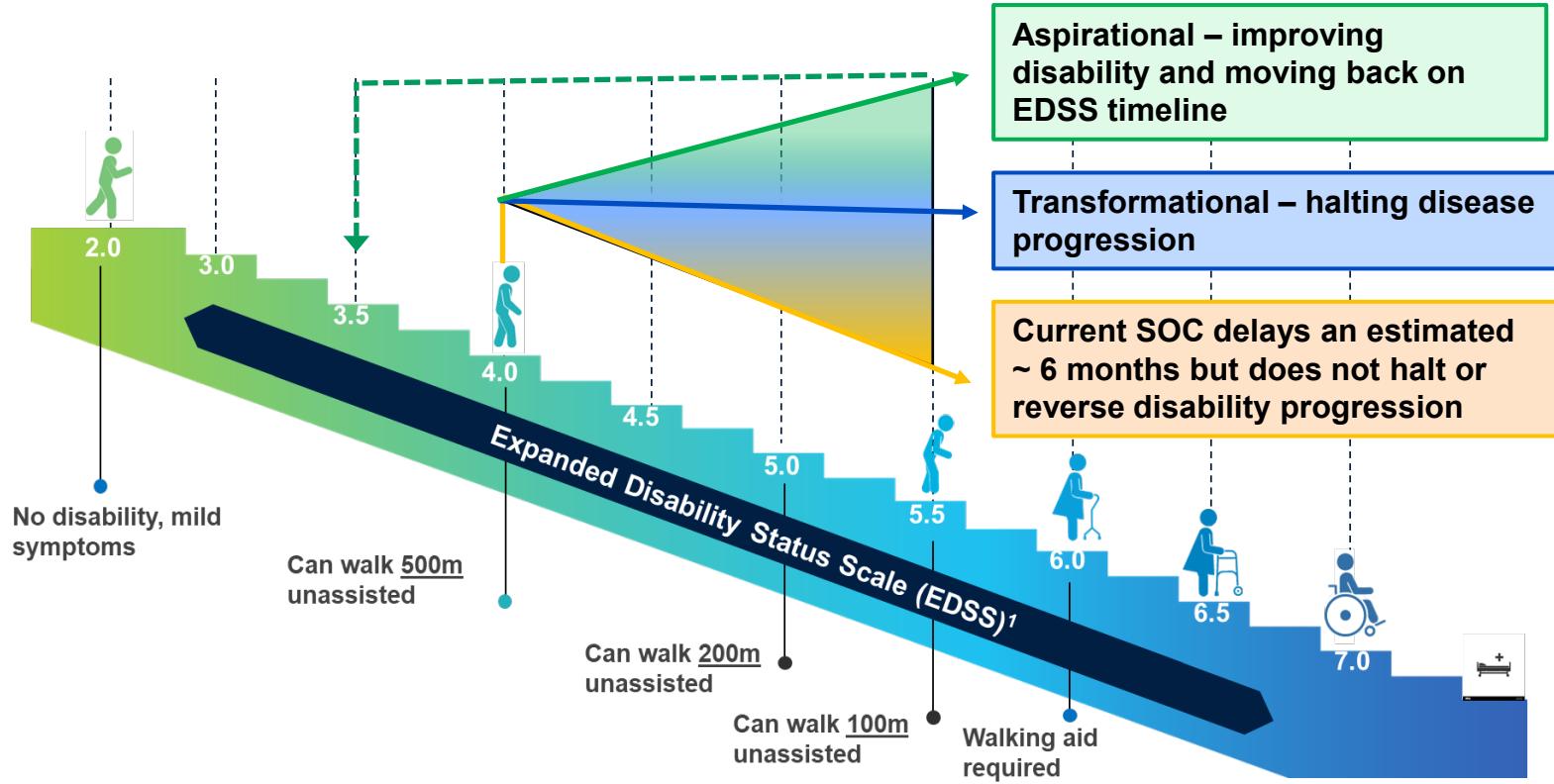
## Initiate Phase 2/3 study in progressive MS patients exhibiting PIRA

- Anticipate a randomised phase 2/3 study design as path to approval
- Phase 1 clinical PoC is derisking for initiation of development in other neurology indications

First patient dosed in October 2025

# BOBCAT study population represents the highest unmet need in MS

1. Progressive forms of MS including all forms of progressive MS with EDSS scores of 3.5 to 6.5 included
2. Will include both active and non-active patients
3. Have failed high efficacy therapy for at least six months (e.g. CD20 mAb, S1P inhibitor)



# BOBCAT Phase 1 study design

**Sample size:** 12-18 patients infused with obe-cel

**Dosing:** Standard Flu/Cy based preconditioning and a single infusion of 100 or 200 million CART cells and flexibility to adjust dose up or down

**Primary endpoint:**

- Safety

**Secondary endpoints:**

- 12-week confirmed disability progression (CDP) at one-year, composite measure of disability at one year, confirmed disability improvement
- Other functional measures: cognition, fatigue, QoL
- Imaging: MRI lesion counts (T1 Gd+, T2), MRI – MTR, MRI – regional brain volumes, MRI – cervical spinal cord volume, SEL, PRL)
- Biomarkers (blood and CSF): OCBs, IgG index, NfL, GFAP, Kappa chains, PK

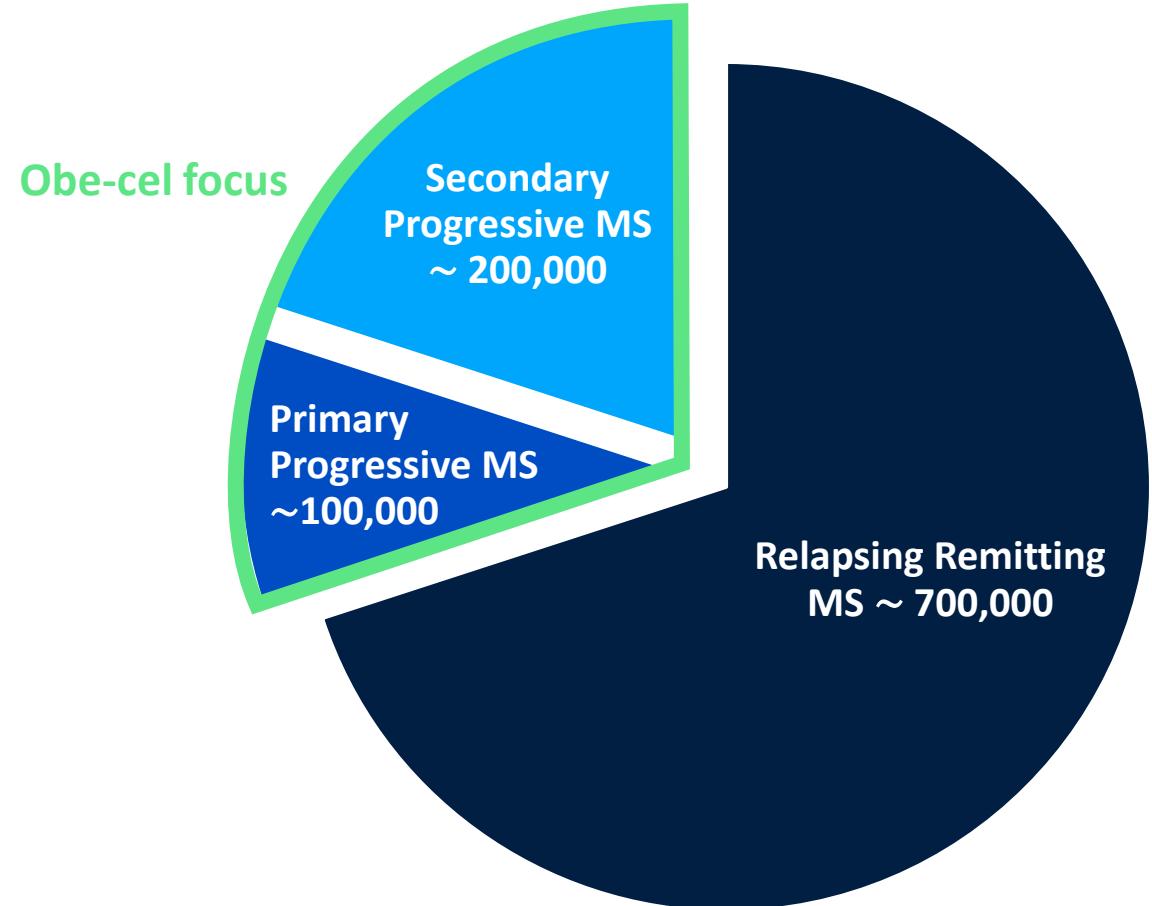
**Interim analysis at 6 months:**

- Biomarkers including OCBs, IgG index, NfL, MRI lesions, MTR, Kappa chains, PK

SEL: slowly expanding lesions, PRL: paramagnetic rim lesions, NfL: Neurofilament light chain, GFAP: glial fibrillary acidic protein

# Progressive multiple sclerosis is a high unmet medical need

- MS impacts approximately 1,000,000 individuals in the US<sup>1</sup> and there is currently no known cure
- Around 30% of patients have progressive disease and more than half of Progressive MS patients experience disability progression despite receiving disease modifying agents<sup>2</sup>
- Highest unmet need for patients who continue to progress despite being treated with highly effective agents for at least 6 months



## Upcoming milestones

Anticipated Milestone or Catalyst	Anticipated Timing
Updated real world experience data from ROCCA consortium	H1 2026
Longer-term follow up data from CARLYSLE trial	ACR Annual Meeting 2026
Initial clinical data from BOBCAT Phase 1 trial in progressive MS	By YE 2026
Initial clinical data from ALARIC Phase 1 trial in AL amyloidosis (UCL collaboration)	By YE 2026
CATULUS trial in pediatric r/r B-ALL fully enrolled	H1 2027

# Building value with obe-cel



## Strong execution in r/r B-ALL:

- ✓ Market leadership
- ✓ Broad market access / coverage
- ✓ Reliable product delivery
- ✓ Significant opportunity to grow CAR T market in adult B-ALL
- ✓ Physician interest in ISTs in 1L ALL

## Leveraging investments:

- Optimize manufacturing operating model and technology
- Business process efficiencies targeting margin improvement

## Potential “pipeline in a product” new indications:

- Pediatric ALL – Potential pivotal study
- Lupus nephritis – Potential pivotal study
- Multiple sclerosis – Phase 1 study

2026 Focus: Drive market share in ALL – Improve margins – Expand beyond ALL



# Thank you

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