



# Q1 2025 Financial Results and Business Updates

May 8, 2025

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# Agenda

- Welcome and Introduction: Amanda Cray, ED, Investor Relations & External Communications
- Operational Highlights: Dr. Christian Itin, CEO
- Financial Results: Rob Dolski, CFO
- Upcoming Milestones and Conclusion: Dr. Christian Itin, CEO
- Q&A: Dr. Christian Itin and Rob Dolski

# Strong momentum in first quarter of the U.S. AUCATZYL® launch

## Q1 2025 AUCATZYL Net Product Sales

**\$9.0 million**

**Physician interest based upon product profile  
and unmet patient need is driving  
encouraging uptake**

## 39 Treatment Centers Authorized as of 05/07/25



- ~90% of total U.S. medical lives covered
- CMS published HCPCS coding determinations and OPPS payment rates, making AUCATZYL eligible for reimbursement for patients on government programs

# AUCATZYL growth opportunities in ALL

## Expansion

### Near-Term New Markets

- ✓ Conditional marketing authorization in the UK received April 25, 2025
- EMA decision expected in 2H 2025
- Country-by-country launches planned based on pricing and reimbursement decisions



### ALL Potential Indication Expansion

Strong data from the FELIX study, and experience in the market to-date, support indication expansion opportunities:

- **Adult ALL in frontline:**
  - Explore by investigator sponsored trials
- **Pediatric ALL:**
  - Ongoing P1 study with plans to report data in 2H 2025 and review regulatory path with FDA

# Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

# Obe-cel drives deep reset of the B cell compartment

Combined with a favorable tolerability profile with low levels of high-grade CRS and ICANS

## Results we have observed in clinical trials in B cell malignancies

- High MRD-negative complete remission rate in relapsed or refractory (r/r) adult and pediatric acute B cell lymphoblastic leukemia (ALL) patients (94%)<sup>1</sup>
- Long term outcomes indicate complete removal of all malignant B cells in r/r ALL<sup>1,2,3</sup>
- Experience in non-Hodgkin lymphoma indicate high metabolic complete remission rate (88% in r/r LBCL and 95% in r/r FL)<sup>4</sup>
- Long term outcomes in patients with LBCL<sup>4</sup>

## Targeted positioning of obe-cel in:

- Frontline consolidation in aggressive B cell malignancies
  - Aim for long term outcomes, while avoiding over-treatment
- B cell mediated autoimmunity with an aim to reset the B cell compartment, and remove autoreactive antibodies and B cells
  - Aim for sustained effect with a one-time therapy

1. Roddie C, et al "Obecabtagene autoleucel in B-cell acute lymphoblastic leukemia" N Engl J Med 2024; DOI: 10.1056/NEJMoa2406526

2. Ghorashian, S., Kramer, A.M., Onuoha, S. et al. Enhanced CAR T cell expansion and prolonged persistence in pediatric patients with ALL treated with a low-affinity CD19 CAR. *Nat Med* 25, 1408–1414 (2019). <https://doi.org/10.1038/s41591-019-0549-5>

3. Roddie C, et al. *J Clin Oncol* 2023;41:16\_suppl, 7000

4. Roddie et al, ASH 2023, Poster 2114

# Inflammation and structural organ damage in autoimmunity

- Autoimmune disease is driven by auto-reactive antibodies redirecting the immune system onto various organs and tissues.
- With continued inflammatory process organs and tissues become damaged, fibrotic and over time can lose function.
- An anti-inflammatory approach targeting B cells and auto-antibody producing plasmablasts or plasma cells will - if successful - remove the inflammatory auto-reactive process.
- Reversibility and full recovery of a patient will largely depend on the level of tissue and organ damage and the respective organ's ability to regenerate.

## **CD19 CAR T therapy will be focused on severe/refractory patients.**

- Key elements of patient selection:
  - Active inflammatory disease
  - Limited chronicity of disease
  - Evidence of organ involvement
  - Limited extent of organ damage
- Desired outcome:
  - Remove autoimmunity memory and antibodies
  - Stabilize impacted organ
  - Upside is improved organ function

# Initial data from CARSLYLE SLE P1 trial in patients with severe disease

Baseline SLEDAI-2K score ranges from 16 to 28

## Severe patient population

- Patients aged 19 to 50 years had 3 to 23 years of disease history and exhausted prior therapy options
- All patients had prior B-cell depleting agent exposure, 2 also BAFF inhibitors, 3/6 also calcineurin inhibitors
- Lupus nephritis: 5/6 patients had a class IV disease, 4/6 had also a class V component
- Kidney function was significantly impaired in 4 of 6 patients (<60 ml/min/SA)

## No high-grade CRS, No ICANS observed No DLTs observed

Transient hypertension, including G3, due to abnormal kidney function prior to start of therapy according to PI's judgement nor pre-existing hypertension (3/6)

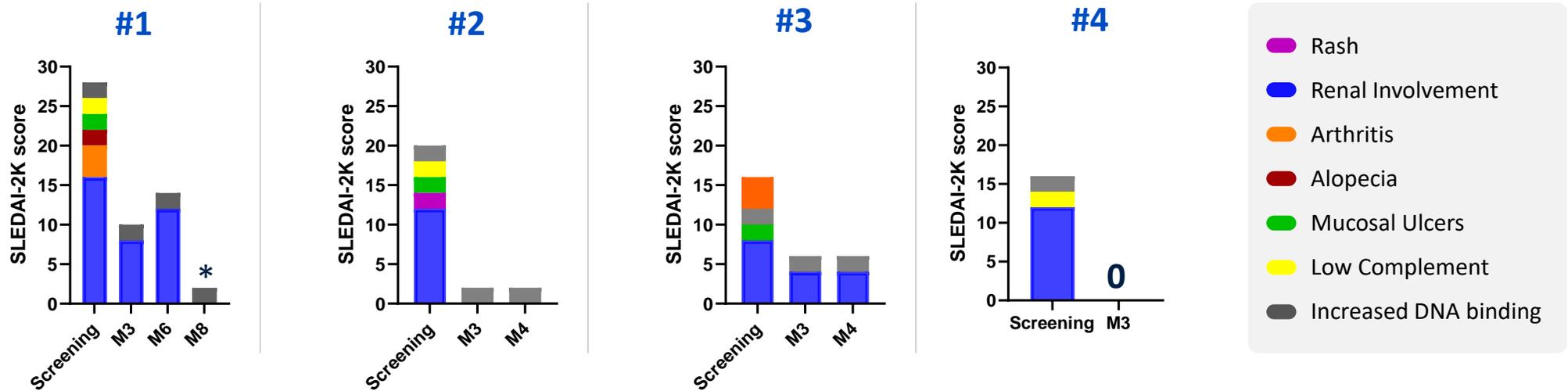
### Highest grade of treatment-emergent adverse event observed by patient:

TEAE, Grade	#1	#2	#3	#4	#5	#6	Patients, n (%)
CRS	-	-	1	-	1	1	3 (50%)
ICANS	-	-	-	-	-	-	0 (0%)

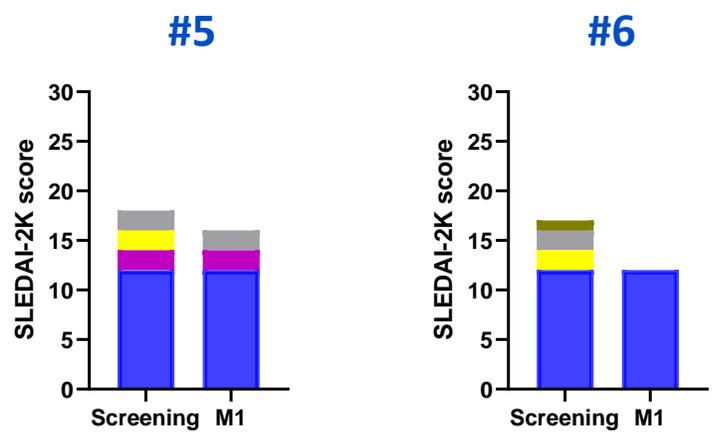
# Preliminary CARLYSLE results; additional follow up planned for H2 2025

10+ point drop in SLEDAI-2K scores and 3 of 6 patients with renal CRs by month 3

M3+ follow up



M1 follow up

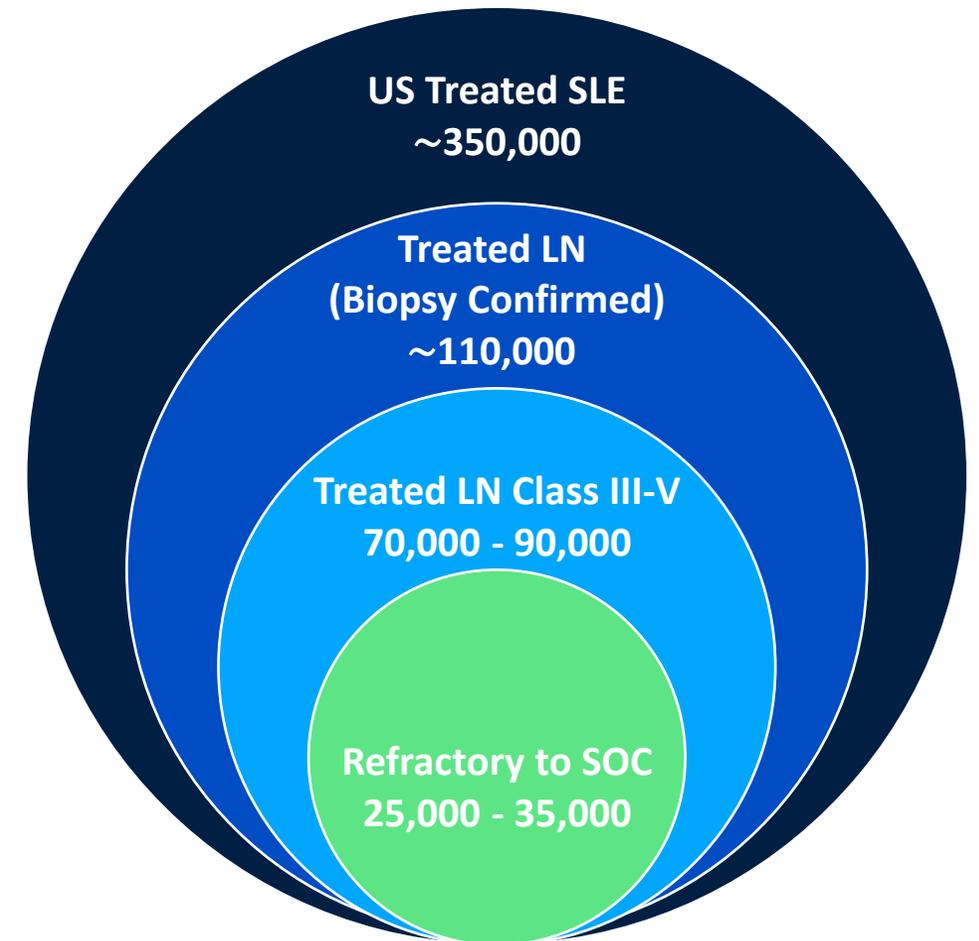


- All patients benefited significantly from obe-cel
- Skin: rash, alopecia and mucosal ulcers resolved by M3
- Musculoskeletal: Arthritis resolved by M1
- Complement normalized in all patients by M1
- 3 of 6 patients with complete renal response by M3
- Two patients had only one month follow up

\*Kidney biopsy on month 7 showed no disease activity

# Refractory lupus nephritis is a high unmet medical need

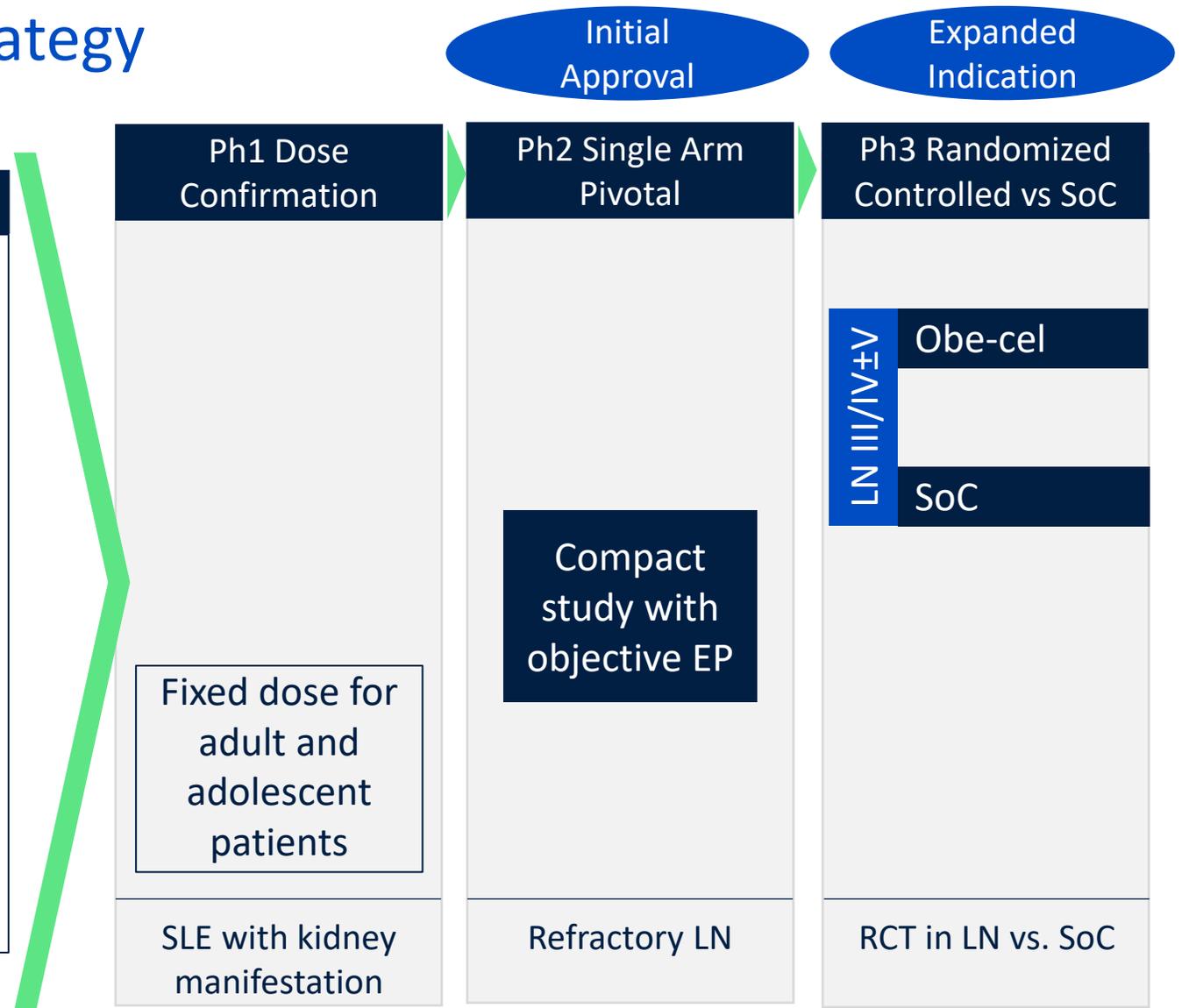
- Kidneys are one of the most common organs involved in SLE - 30% – 40% are lupus nephritis patients
- High disease activity is associated with inflammatory processes
- Uncontrolled inflammation leads to high chronicity due to accumulated kidney damage
- Despite treatment advances including regulatory 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



# Lupus nephritis development strategy

Leveraging a fast to market strategy

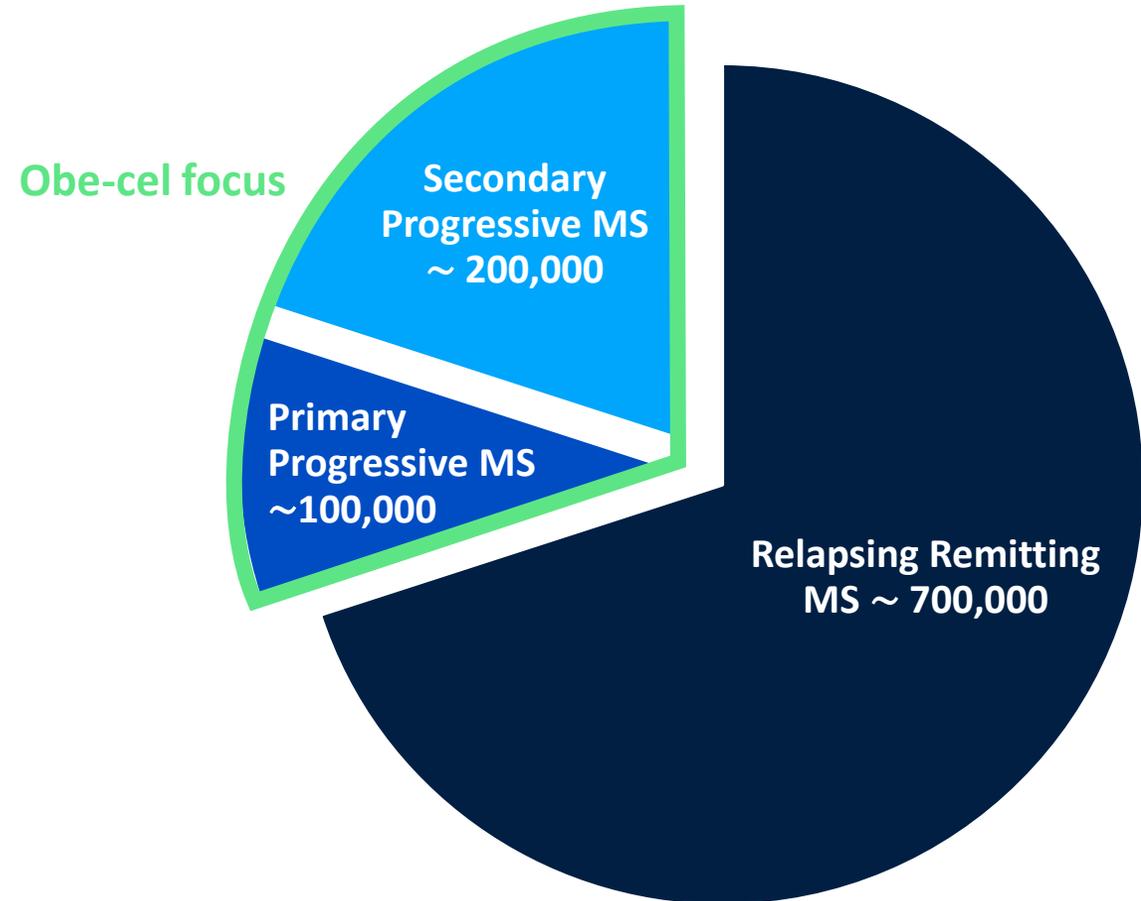
Development Rationale
<ul style="list-style-type: none"> <li>LN is assessed by quantitative lab- parameter based endpoints (CRR) vs. SLE with a composite endpoint depending on clinical assessments</li> <li>Current guidelines require for Class III/IV LN triple therapy including B-cell modifier or CNI, without any treatment options for those being refractory to both</li> <li>Lack of SOC for refractory LN opens the possibility to single arm trial path for initial approval</li> <li>Outcome of refractory LN single arm trial serves as good predictor for RCT in earlier LN vs. SOC</li> </ul>



**Anticipate dosing first patient in Phase 2 pivotal trial by year end 2025**

# 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



1: GlobalData MS Market Forecast 2020-2030 April 2023

2: Watson, C., Thirumalai, D., Barlev, A. et al. Treatment Patterns and Unmet Need for Patients with Progressive Multiple Sclerosis in the United States: Survey Results from 2016 to 2021. *Neurol Ther* 12, 1961–1979 (2023). <https://doi.org/10.1007/s40120-023-00532-2>

# 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

Anticipate dosing first patient in Phase 1 trial by year end 2025

# Financial Results

## Financial summary – key metrics\*

USD (\$' 000)	Q1 2025	Q1 2024	Variance
<b>Product revenue, net</b>	8,982	-	8,982
License revenue, net	-	10,091	(10,091)
<b>Cost and operating expenses:</b>			
Cost of sales	(17,951)	-	(17,951)
Research and development expenses, net	(26,734)	(30,671)	3,937
Selling, general and administrative expenses	(29,534)	(18,177)	(11,357)
<b>Loss from operations</b>	<b>(65,240)</b>	<b>(38,757)</b>	<b>(26,483)</b>
<b>Total comprehensive loss</b>	<b>(59,093)</b>	<b>(52,632)</b>	<b>(6,461)</b>

\*Select metrics only; for full financials please refer to the Company's 10-Q filing

**\$516.6M\***  
as of  
Q1 2025

The Company is well capitalized to drive the launch and commercialization of obe-cel in r/r B-ALL and to obtain data in the LN pivotal trial and MS Phase 1 trial



Upcoming news flow

## Upcoming milestones

Anticipated Milestone or Catalyst	Anticipated Timing
Longer-term follow up from FELIX clinical trial	Mid-Year
Notification from EU regarding MAA decision in adult r/r ALL	H2 2025
Initial data from PY01 trial in pediatric ALL	H2 2025
SLE Phase 1 trial presentation at medical conference	Q4 2025
First patient dosed in Phase 2 trial in lupus nephritis	YE 2025
First patient dosed in progressive MS Phase 1 trial	YE 2025
First patient dosed in AL amyloidosis Phase 1 trial (UCL collaboration)	YE 2025

# Autolus is positioned for value creation

Building on a strong foundation with obe-cel

- AUCATZYL US launch: strong first quarter, building to 60 centers in H2 2025
  - Established infrastructure for manufacturing and commercialisation to support execution
  - UK MHRA authorisation received; launch in preparation
  - EMA approval decision expected H2 2025
- Obe-cel is a highly active, fast off-rate CD19 CAR T therapy with a well managed tolerability profile
  - First US FDA-approved CAR T therapy without a REMS obligation
  - H1 2025: Long term follow-up from FELIX trial
  - H2 2025: Results from pediatric ALL PY1 trial
  - H2 2025: Results from SLE P1 trial
- Q1 2025 cash position of \$516.6M\*

\*Cash, cash equivalents and marketable securities



A CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia  
See full Prescribing Information, including **BOXED WARNING** at <http://www.autolus.com/AUCATZYL-USPI/>



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukemia

Autolus

Thank you