## Autolus

## Q1 2025 Financial Results and Business Updates

May 8, 2025

For Investor communication only. Not for use in product promotion. Not for further distribution.



## Disclaimer

These slides contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to: statements regarding Autolus' development and commercialization of its product candidates; Autolus' manufacturing, sales and marketing plans for AUCATZYL, including expectations regarding the commercial launch in the United States and the ability to reach patients in a timely manner; the amount and timing of milestone payments under Autolus' collaboration and license agreements; and future development plans of obe-cel, including the timing or likelihood of expansion into additional markets or geographies and related regulatory approvals. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: Autolus' ability to maintain regulatory approval of AUCATZYL; its ability to execute its commercialization strategy for AUCATZYL; its ability to develop, manufacture and commercialize its other product candidates and the timing or likelihood of expansion of AUCATZYL into additional markets or geographies; Autolus' ability to establish and expand a commercial infrastructure and to successfully launch, market and sell AUCATZYL; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or future regulatory approval; the labelling for AUCATZYL/obe-cel in any future indication or patient population, if approved; the potential for payors to delay, limit or deny coverage for AUCATZYL; Autolus' ability to obtain, maintain and enforce intellectual property protection for AUCATZYL or any product candidates it is developing; the results of clinical trials are not always being predictive of future results; the cost, timing and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; and possible safety and efficacy concerns. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus' actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 20, 2025, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and Exchange Commission. All information in this presentation is as of the date of the presentation, and Autolus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this presentation.

## 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<sup>®</sup> 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	<ul> <li>Conditional marketing authorization in the UK received April 25, 2025</li> <li>EMA decision expected in 2H 2025</li> <li>Country-by-country launches planned based on pricing and reimbursement decisions</li> </ul>		
	strong data from the FELIX study, and experience in the market to-date, support indication expansion opportunities:		
ALL Potential Indication Expansion	<ul> <li>Adult ALL in frontline:</li> <li>Explore by investigator sponsored trials</li> </ul>	<ul> <li>Pediatric ALL:</li> <li>Ongoing P1 study with plans to report data in 2H 2025 and review regulatory path with FDA</li> </ul>	

# 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

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

<sup>2.</sup> 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

<sup>3.</sup> Roddie C, et al. J Clin Oncol 2023;41:16\_suppl, 7000

<sup>4.</sup> 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 autoreactive 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)</li>

#### 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)

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

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

## 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





- 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

#### 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**

- LN is assessed by quantitative lab- parameter based endpoints (CRR) vs. SLE with a composite endpoint depending on clinical assessments
- 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
- Lack of SOC for refractory LN opens the possibility to single arm trial path for initial approval
- Outcome of refractory LN single arm trial serves as good predictor for RCT in earlier LN vs. SOC



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

#### Progressive multiple sclerosis is a high unmet medical need



1: GlobalData MS Market Forecast 2020-2030 April 2023

#### 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 +



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\*

00) Q1 202	Q1 2024	Variance
evenue, net	8,982	- 8,982
evenue, net	- 10,091	(10,091)
operating expenses:		
iles (	',951) ·	- (17,951)
and development expenses, net (	5,734) (30,671)	) 3,937
eneral and administrative expenses (	9,534) (18,177)	) (11,357)
operations (	(38,757)	(26,483)
prehensive loss (	(52,632)	) (6,461)
operating expenses:iles(1)and development expenses, net(1)eneral and administrative expenses(1)operations(1)operations(1)operations(1)	',951)	- (: ) ) (: ) (:

\*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

\*Cash, cash equivalents and marketable securities

## 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

#### obe-cel Oncology obe-cel Autoimmune/B cell mediated disease

## 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\*



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



# Thank you

Autolus.com