

Autolus

AUCATZYL[®]
(*obecabtagene autoleucel*)

FDA Approval Conference Call

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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, the expected clinical benefits of AUCATZYL; Autolus’ manufacturing, sales and marketing plans for AUCATZYL, including expectations regarding the timing of 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 AUCATZYL, 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 21, 2024, 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.

AUCATZYL® now FDA approved



Please see full prescribing information [Prescribing information](#)

- ✓ **AUCATZYL indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (B-ALL)**
- ✓ **First chimeric antigen receptor T-cell (CAR T) therapy approved by the FDA with no requirement for a REMS program (Risk Evaluation Mitigation Strategy)**
- ✓ **Novel and differentiated mechanism of action: first and currently only approved CD19 CAR T with a fast off-rate**
- ✓ **First and currently only approved CAR T therapy with customized, tumor-burden guided dosing**

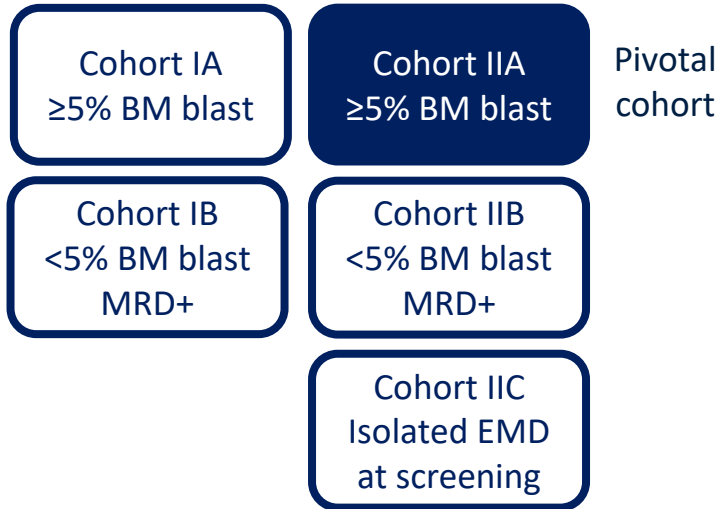
Important Safety Information

- The safety of AUCATZYL includes a boxed warning for CRS, neurologic toxicities, and secondary hematological malignancies. ICANS, including fatal or life-threatening reactions, occurred in patients receiving AUCATZYL. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies.
- In the FELIX trial, severe, including life-threatening and fatal infections occurred in patients after AUCATZYL infusion. The non-COVID-19 infections of all grades occurred in 67% (67/100) of patients. Grade 3 or higher non-COVID-19 infections occurred in 41% (41/100) of patients.
- Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.

AUCATZYL was approved based on results from the FELIX trial



FELIX Phase 1b/2



	Ph1b/2 pooled ¹	Ph2 pivotal IIA cohort ²
Patients (N)		
Enrolled	153	112
Infused	127	94

Background

- Open-label, multicenter, multinational, single-arm Phase 1b/2 trial in adult patients with R/R B-ALL¹⁻²
- 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

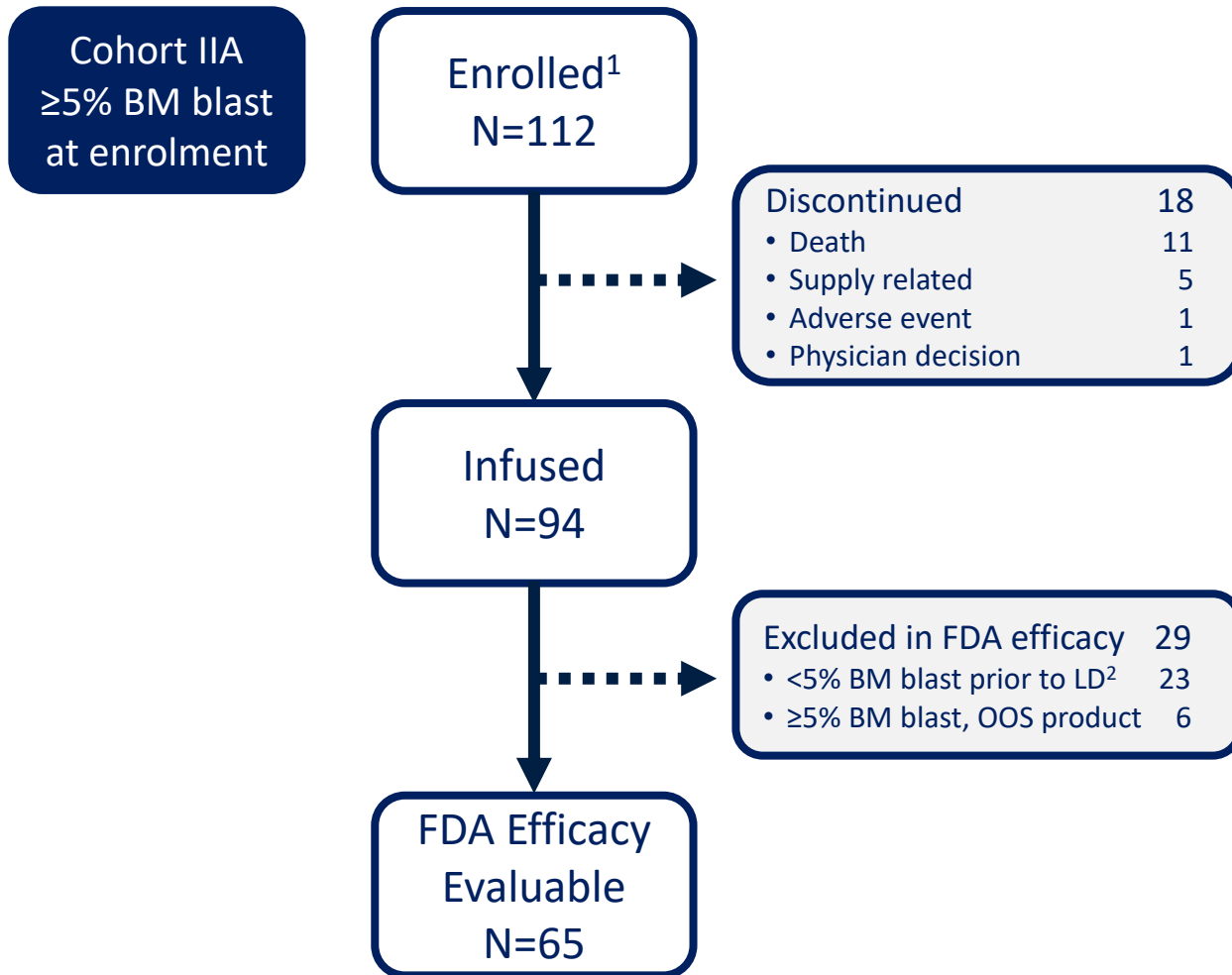
- High ORR, encouraging EFS/OS and favorable tolerability with low levels of high-grade cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS)
- Timely and reliable clinical product supply and logistics
- Across all Phase 1b/2 cohorts, 40% of responders in ongoing remission without subsequent stem cell transplant/other therapy¹
- Survival outcomes suggesting potential of long-term plateau¹

¹ FELIX Ph1b/2 pooled data presented at ASH 2023 (data cut off Sept. 13, 2023; median follow up 16.6 months) and ASCO & EHA 2024 (data cut off Feb. 7, 2024; median follow up 21.5 months)

² FELIX Ph2 pivotal data (morphological cohort IIA) presented at ASCO 2023 (data cut off Mar. 16, 2023; median follow up 9.5 months)

FELIX trial was conducted during pandemic, in real-world setting

FDA efficacy excludes 23 patients with <5% bone marrow blasts prior to lymphodepletion as a result of bridging therapy



Bridging therapy prior to lymphodepletion (LD)

- FELIX permitted standard of care bridging therapy, including high dose chemotherapy, inotuzumab and TKIs; blinatumomab not used for bridging
- Intense bridging therapy can reduce bone marrow blast prior to LD and dosing below 5% and prolong bone marrow recovery time
- Patients had highly advanced disease:
 - Disease progression resulting in death drove >60% of dropout before CAR T dosing
 - Median age 51 years
- 84% of enrolled patients were infused

FDA efficacy evaluation

- 69% of infused patients had more than 5% BM blast at LD and were evaluated for efficacy
- 24% of infused patients were below 5% BM blast at LD and were not evaluated for efficacy
- Remaining patients were out-of-specification (OOS) and not evaluated

¹ FELIX Ph2 pivotal data (morphological cohort IIA) presented at ASCO 2023

² 1 of the 23 patients also had OOS/non-conforming product

FDA evaluable patients/analysis

FDA efficacy-evaluable patients	n = 65
OCR (CR+CRi) [#]	63%
CR within 3 months	42%
CR "At Anytime"	51%
CRi "At Anytime"	12%
DoR [#] of OCR (mos)	14.1
FDA safety-evaluable patients	n = 100
CRS ≥ 3	3%
ICANS ≥ 3	7%
Neurotox* ≥ 3	12%

* Not reported at time of event/analysis

From 94 patients infused, 65 were analyzed for efficacy:

- 23¹ patients were removed for less than 5% bone marrow blasts prior to lymphodepletion (LD)
- 6 patients with more than 5% bone marrow blasts were removed with out-of-specification (OSS) products

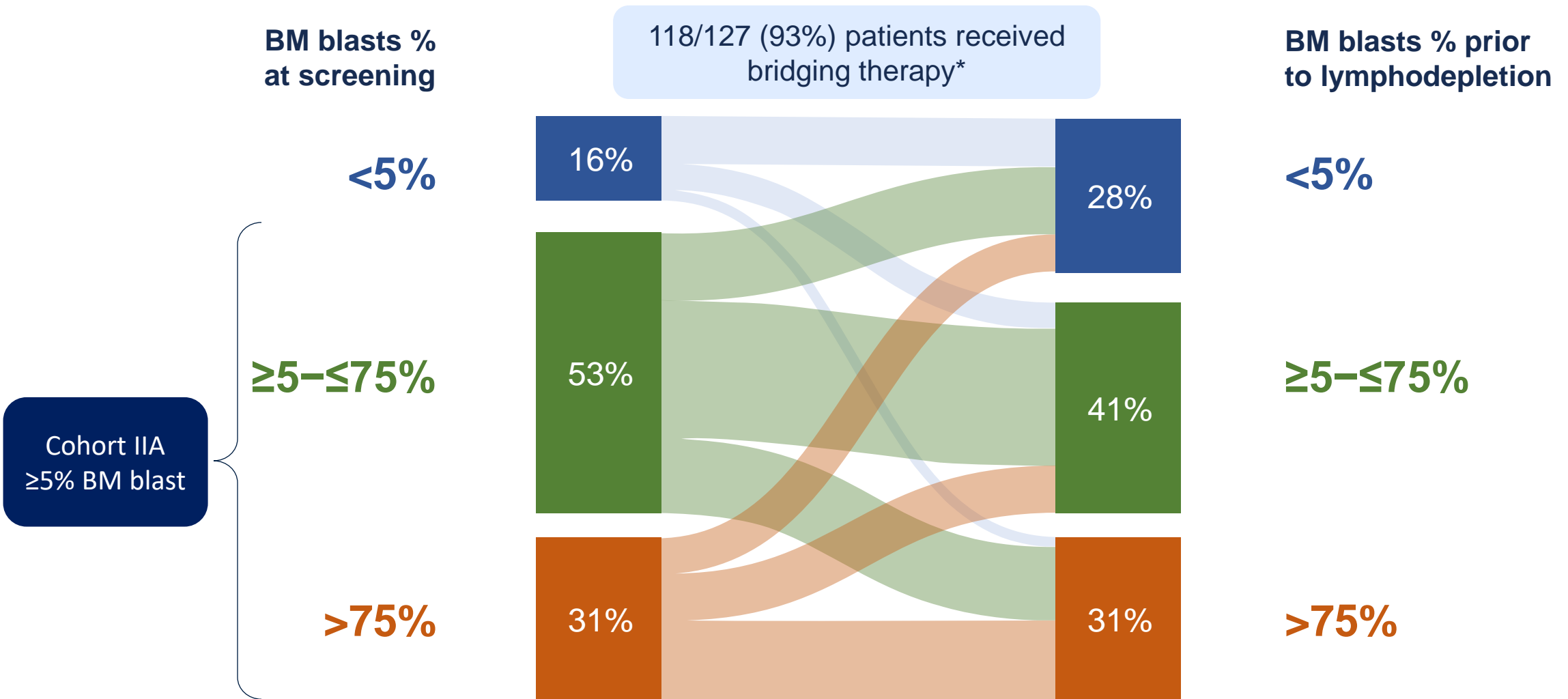
[#]OCR (CR+CRi) = overall complete remission includes complete remission (CR) and complete remission with incomplete hematologic recovery (CRi)

[#]DoR = duration of response

¹ 1 of the 23 patients also had OOS/non-conforming product

Illustrative purposes - ASH 2023 FELIX Phase 1b/2 pooled data

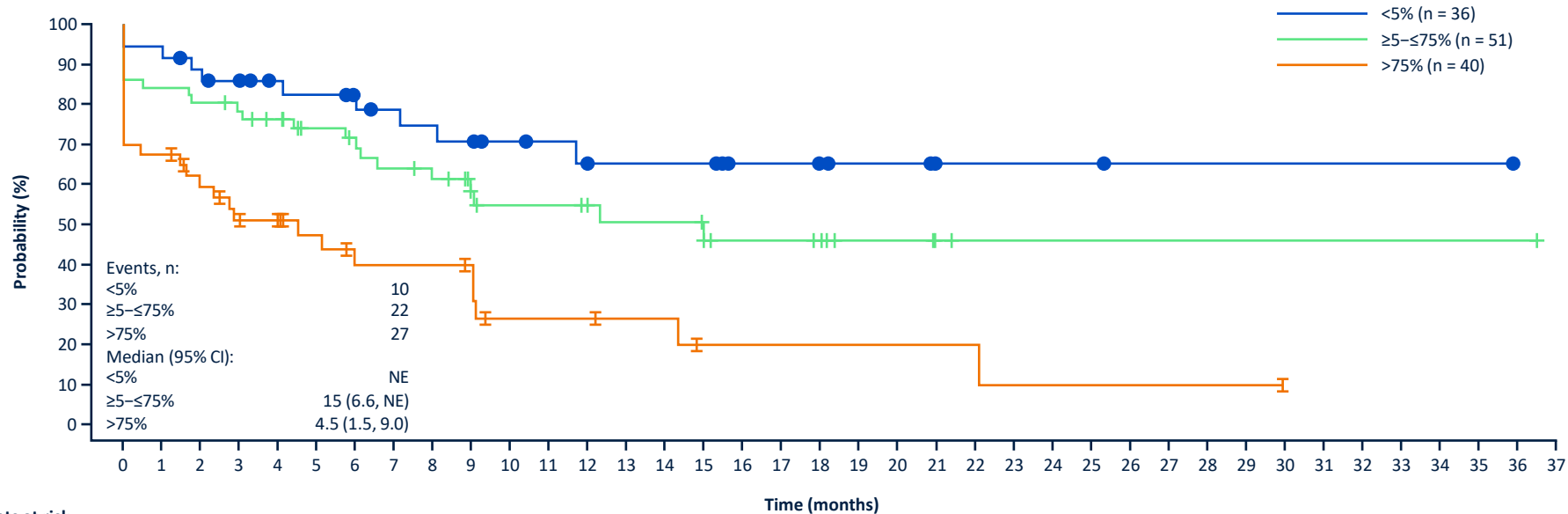
Leukemic burden at screening is not predictive of leukemic burden prior to lymphodepletion



*Bridging therapy per physician's choice, including inotuzumab ozogamicin; BM, bone marrow; Roddie et al., ASH 2023

Illustrative purposes - ASH 2023 FELIX Phase 1b/2 pooled data

Lower leukemic burden prior to lymphodepletion* is associated with better outcomes



Patients with <5% BM blast prior to LD had most favorable EFS outcomes

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37		
<5% (n = 36)	36	34	31	28	25	24	22	20	19	18	14	13	11	11	11	11	8	8	7	6	6	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0	0	
≥5-≤75% (n = 51)	51	43	41	39	36	31	28	25	23	18	15	15	13	12	12	9	8	8	7	4	4	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
>75% (n = 40)	40	27	22	18	17	13	10	10	10	9	5	5	5	4	4	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	

BM blasts % prior to lymphodepletion	<5% (n = 36)	≥5-≤75% (n = 51)	>75% (n = 40)
Median EFS (95% CI), months	NE	15.0 (6.6, NE)	4.5 (1.5, 9.0)
6-month EFS (95% CI), %	83 (65, 92)	72 (57, 82)	40 (23, 56)
12-month EFS (95% CI), %	65 (44, 80)	55 (38, 69)	27 (12, 44)

*Censoring new non-protocol anti-cancer therapies including SCT with disease assessment by IRRC (data cut-off date: September 13, 2023); BM, bone marrow; CI, confidence interval; EFS, event-free survival; IRRC, Independent Response Review Committee; NE, not evaluable; SCT, stem cell transplant; Roddie et al., ASH 2023

Pillars to drive launch success

Prioritizing activation of centers Post-approval

30 key centers primed for activation
covering ~ 60% of r/r B-ALL target population
with **~30** additional centers to follow by end 2025

Team dedicated to successful commercial efforts

Experienced team with multiple CAR T launches
Strong **scientific communication** and **physician
engagement** within medical affairs
Dedicated single point-of-contact for every center

Robust and reliable supply

The Nucleus: Autolus' state-of-the-art, dedicated
purpose-built facility

Target vein-to-release time
of **~16 days**



Pricing strategy focused on delivering value to customers and achieving broad coverage

\$525,000
WAC¹

Pricing reflects clinical evidence, differentiated safety
profile, economic value

¹Wholesale acquisition cost, or WAC, before any discounts, rebates or other price concessions

Dedicated-point of contact and comprehensive set of services for treatment centers, patients and caregivers



AutolusAssist™ Services

Treatment Centers,
Patients &
Caregivers

- ✓ Dedicated AutolusAssist case manager
- ✓ Scheduling and cell journey logistics
- ✓ Medical information
- ✓ Product reporting

Personalized
patient support
services

- ✓ Disease education
- ✓ Transportation, lodging & meal support*
- ✓ Copay & Insurance support*
- ✓ Patient Assistance program*

Origins of obe-cel/AUCATZYL®

Close collaboration with University College London (UCL) and Great Ormond Street Hospital (GOSH) in London, UK



Sara Ghorashian
GOSH

Claire Roddie
UCL



Martin Pule
Autolus/UCL



Leila Mekkaoui
Anne Kramer
Gordon Cheung
Autolus/UCL



GREAT ORMOND STREET
HOSPITAL CHARITY



University College
London Hospitals
NHS Foundation Trust



Persis Amrolia
GOSH



Karl Peggs
UCL





THANK
YOU

We are truly grateful for all those who have helped us bring AUCATZYL to patients and supported our mission of developing life changing therapies for cancer and autoimmune disease



Q&A

Dr. Christian Itin, Chief Executive Officer

Chris Vann, Chief Operating Officer

Rob Dolski, Chief Financial Officer