Autolus

Q1 2024 Financial Results and Business Updates

17 May 2024

Autolus.com

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Agenda

- Welcome and Introduction: Olivia Manser, Director, Investor Relations
- 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

Autolus executed to plan in Q1 2024

Clinical

- Obe-cel progressed according to plan
  - BLA accepted with a PDUFA target date of November 16
  - MAA accepted by EMA end of Q1
  - Commercial and clinical license received by MHRA for Nucleus manufacturing facility
  - Two patients enrolled in SLE Phase 1 CARLYSLE study; first trial site activated in Q1
- Oral presentations confirmed for ASCO and EHA
  - Longer f/u for FELIX study
  - Impact of stem cell transplant
  - Impact of obe-cel persistence on outcome
- Additional poster presentations at EHA
  - Impact of inotuzumab-based bridging therapy
  - Sensitive methods for CAR T persistency measurements

Operational

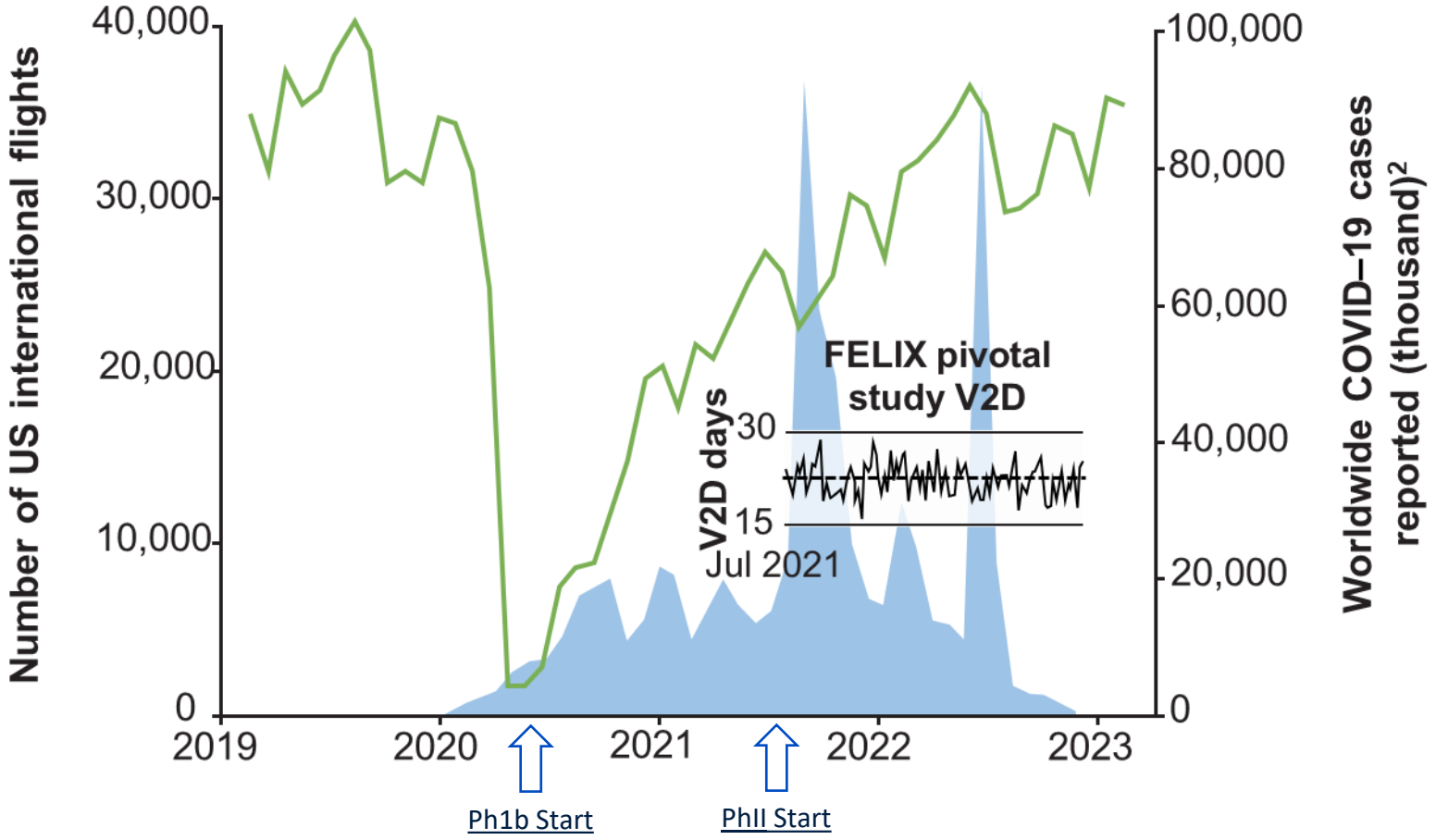
- Strategic BioNTech collaboration: $200m equity, $50m cash upfront
- Underwritten registered direct offering: $350m gross proceeds
- New board members: Mike Bonney (Chair), Ravi Rao, Bob Azelby, Lis Leiderman

ASH 2023

Obe-cel pooled analysis

FELIX Phase 1b/2 trial

Reliable obe-cel supply for FELIX despite the COVID–19 pandemic

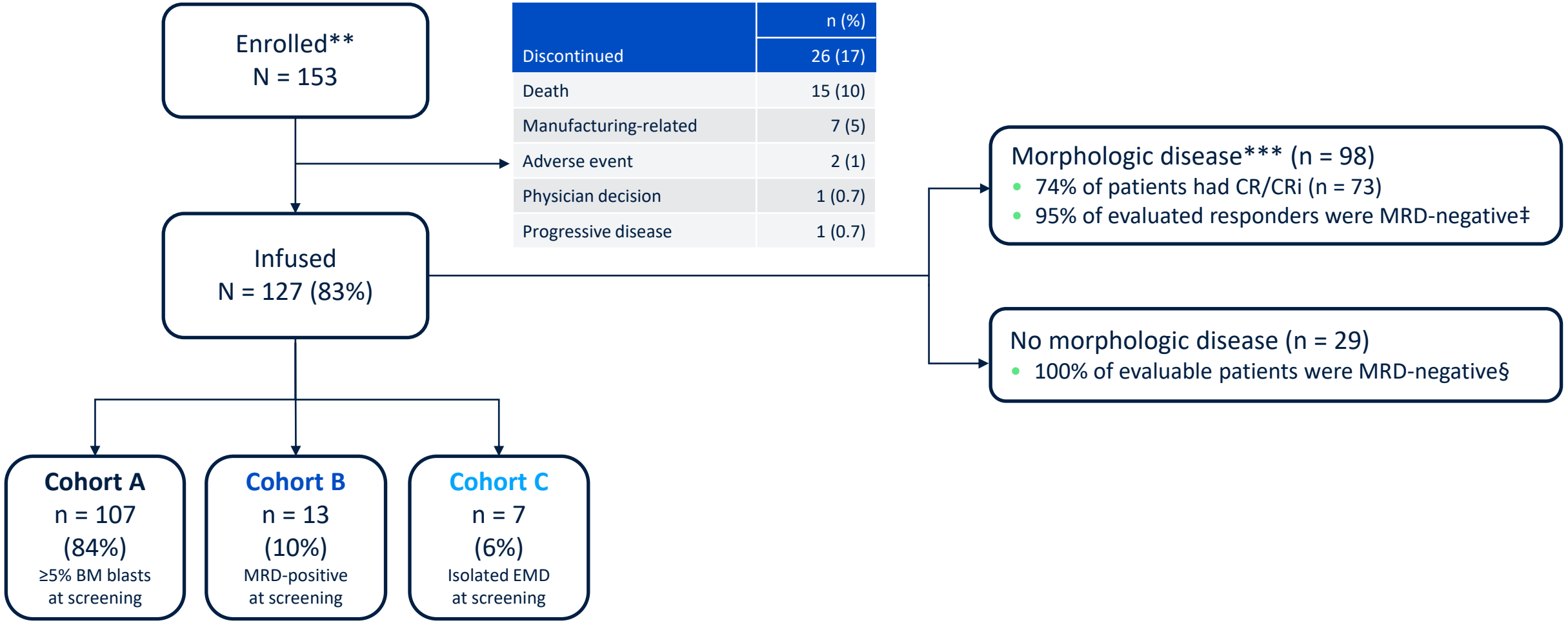


- US international airline flights decreased by 41% compared to flights from pre-COVID–19 pandemic[1]
- BUT international flights are reliable and on time
- Sample collection and drug product delivery were successfully maintained, with no batches impacted

1United States Department of Transportation, Bureau of Transportation Statistics 2021 [online]. Available at: https://www.bts.gov/data-spotlight/commercial-aviation-2020-downturn-airline-passengers-employment-profits-and-flights Accessed October 2023;
2World Health Organization COVID–19 dashboard [online]. Available at: https://covid19.who.int/ Accessed October 2023

FELIX Phase 1b/2 pooled analysis: patient disposition

127/153 (83%) enrolled patients received obe-cel*

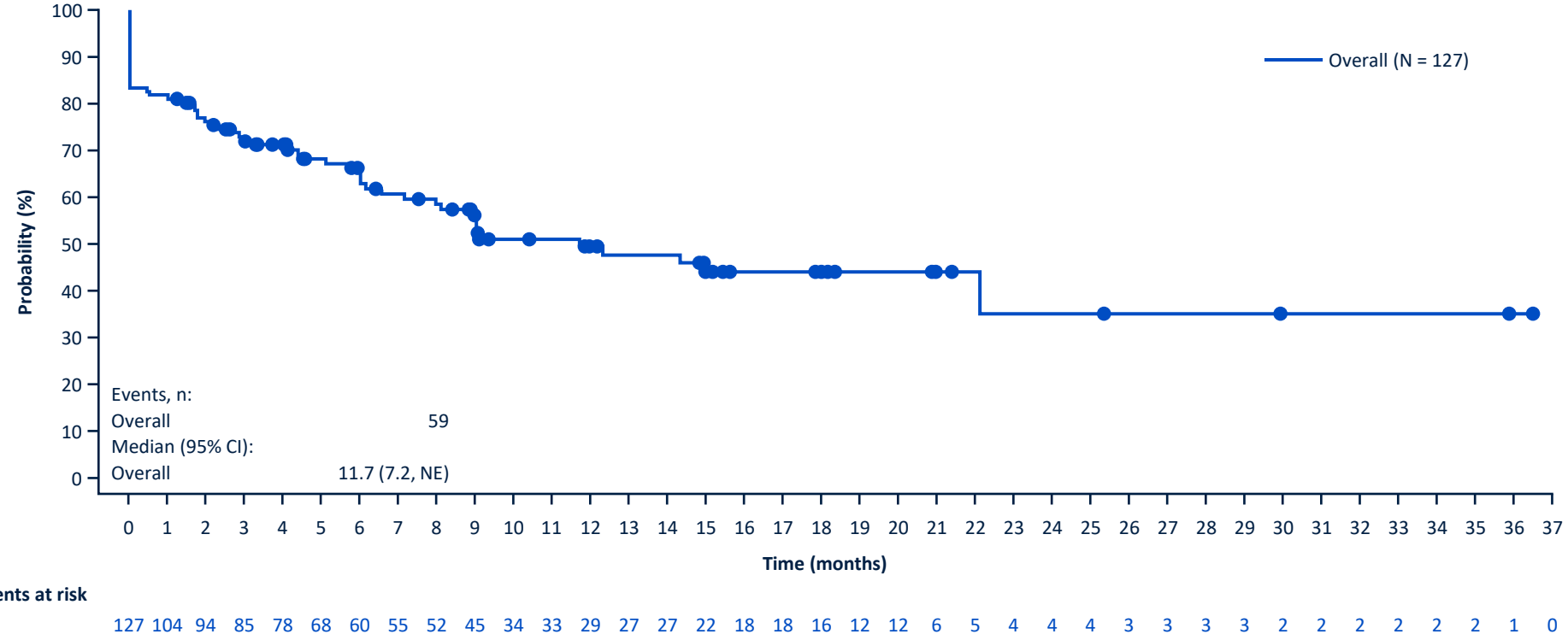


	n (%)
Discontinued	26 (17)
Death	15 (10)
Manufacturing-related	7 (5)
Adverse event	2 (1)
Physician decision	1 (0.7)
Progressive disease	1 (0.7)

*Seven patients received Dose 1 only; **All eligibility criteria met and the leukapheresate accepted for manufacturing; obe-cel, obecabtagene autoleucel; Roddie et al., ASH 2023, Data cut-off date: September 13, 2023; ***Morphologic disease defined as ≥5% BM blasts or presence of EMD regardless of BM blast status; ‡MRD status available for 64/73 patients, as assessed by NGS or flow cytometry; §MRD status available for 27/29 patients, as assessed by NGS or flow cytometry; BM, bone marrow; CR, complete remission; CRi, CR with incomplete hematologic recovery; EMD, extramedullary disease; MRD, measurable residual disease; NGS, next-generation sequencing; obe-cel, obecabtagene autoleucel

FELIX Phase 1b/2 pooled analysis: EFS in all treated patients*

The event-free survival estimate at 12 months was 50%



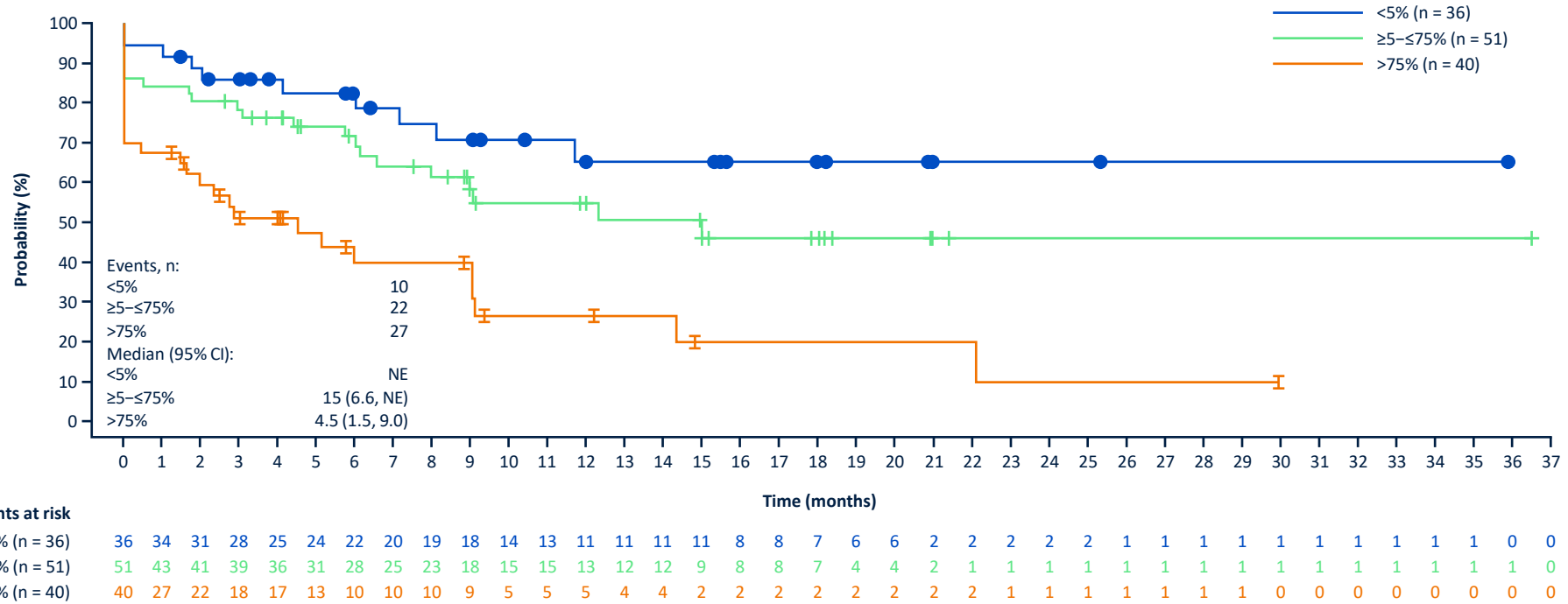
All treated patients (N = 127)	
Median EFS (95% CI), months	**11.7** (7.2, NE)
6-month EFS (95% CI), %	**65** (56, 73)
12-month EFS (95% CI), %	**50** (39, 59)

- Median follow-up time was 16.6 months (range: 3.7–36.6 months)
- 17/99 (17%) responders proceeded to SCT while in remission

*Censoring new non-protocol anti-cancer therapies including SCT with disease assessment by IRRC (data cut-off date: September 13, 2023); Median EFS: ITT population – 9.8 months (95% CI: 5.9, 12.9); CI, confidence interval; EFS, event-free survival; IRRC, Independent Response Review Committee; ITT, intent-to-treat; NE, not evaluable; obe-cel, obecabtagene autoleucel; SCT, stem cell transplant; Roddie et al., ASH 2023

FELIX Ph1b/2 pooled: EFS by leukemic burden prior to lymphodepletion*

Lower leukemic burden is associated with better outcomes



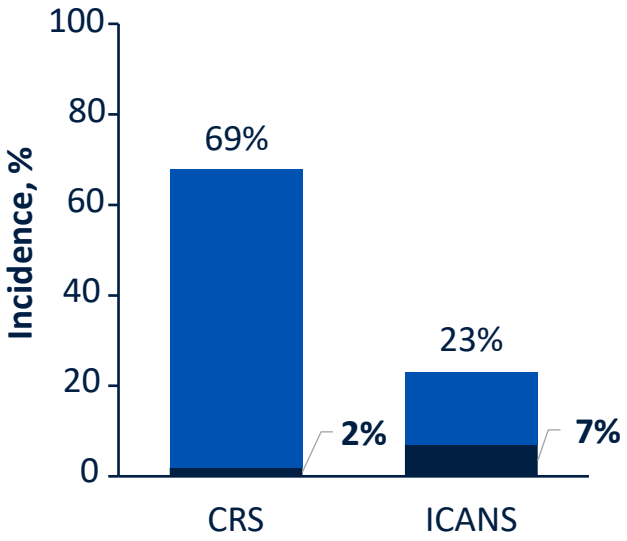
BM blasts % prior to lymphodepletion	<5% (n = 36)	≥5–≤75% (n = 51)	>75% (n = 40)
Median EFS (95% CI), months	**NE**	**15.0** (6.6, NE)	**4.5** (1.5, 9.0)
6-month EFS (95% CI), %	**83** (65, 92)	**72** (57, 82)	**40** (23, 56)
12-month EFS (95% CI), %	**65** (44, 80)	**55** (38, 69)	**27** (12, 44)

*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

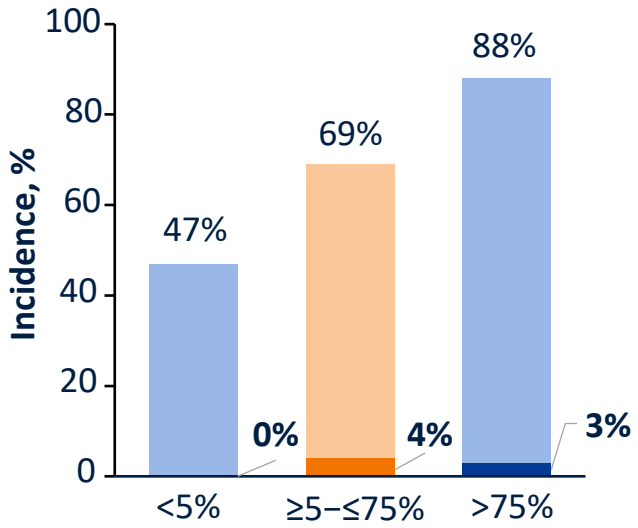
FELIX Phase 1b/2 pooled analysis: CRS and ICANS

Low rates of Grade ≥3 CRS and/or ICANS were observed

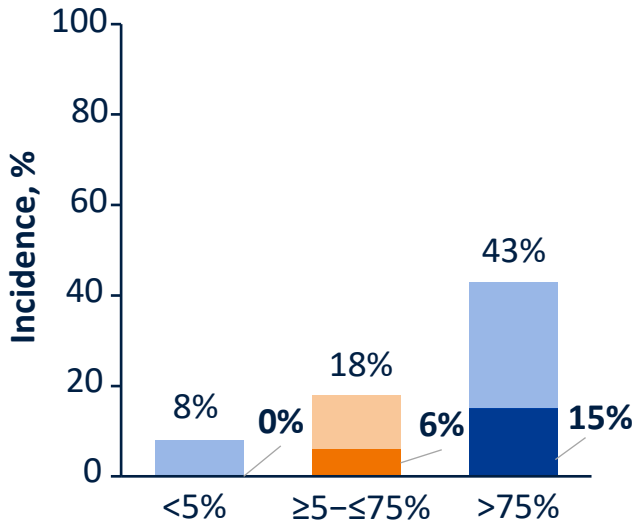
CRS and ICANS in all patients



CRS by % BM blasts



ICANS by % BM blasts



BM blasts % at lymphodepletion

- No grade ≥3 CRS and/or ICANS were observed in patients with <5% BM blasts at lymphodepletion
- Vasopressors were used to treat CRS in 2.4% of patients
- The treatment was generally well tolerated
- Two deaths were considered treatment-related per investigator assessment: neutropenic sepsis (n = 1); acute respiratory distress syndrome and ICANS (n = 1)

Light colors = grade ≤2
Dark colors = grade ≥3

BM, bone marrow; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; ICU, intensive care unit; Roddie et al., ASH 2023

Commercial Launch Readiness

Obe-cel steps to commercialization

Roadmap to a commercial launch in r/r adult ALL

Q1	Q2	Q3	Q4

Obe-cel BLA accepted by FDA

Nucleus MHRA inspection & approval
Obe-cel EMA MAA

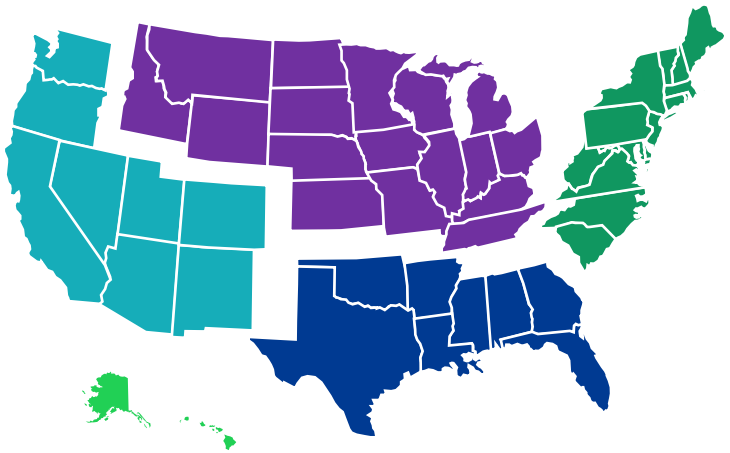
Obtained MHRA MIA together with accompanying GMP certificate

Obe-cel MHRA authorization application

Filing of MHRA marketing authorization application (MAA) planned for H2 2024

FDA PDUFA

Target FDA Action Date November 16



Commercial Readiness

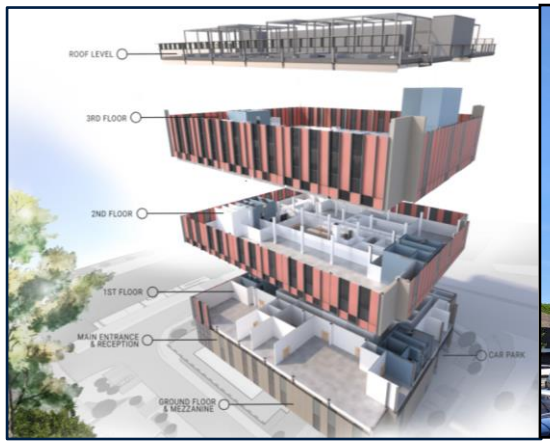
- Medical affairs engagement
- Value and HEOR evidence generation
- US Center onboarding
- US supply chain, logistics and systems testing

The Nucleus – Our Commercial Manufacturing Facility

State of the art design and operations established – groundbreaking to complete validation in 2 years

- ~70,000 sq ft facility
- Modular build using PAMs
- 70% built off-site
- 60% reduced build time
- BREEAM Excellent rating for sustainability
- Designed for 2,000+ batches per year
- Target vein to delivery time 16 days at launch

Design



Build

Operations

2021

Nov 8, 2021
Groundbreaking

2022

Nov 25, 2022
First clean room operational

Dec 14, 2022
First Prodigy operational

2023

May 2023
Capacity challenge

2H 2023
Facility validation complete

2024

Q1 2024
MHRA GMP certificate

Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

The obe-cel product family and franchise opportunity

Obe-cel
CD19

- Optimized CD19 CAR design
- Potential best-in-class efficacy and safety profile
- Supported by state-of-the-art manufacturing
- Supported by mature FELIX clinical/CMC package

→ B-ALL and B-NHL
→ B-cell mediated autoimmune disease

AUTO1/22
CD19/CD22

- Dual CD19 & CD22 Targeting
- Designed to prevent antigen negative escape
- Supported by Phase 1 data in pediatric B-ALL

→ B-ALL and B-NHL

AUTO8
CD19/BCMA

- Dual CD19 & BCMA Targeting
- Designed to induce deep and durable responses
- Initial Phase 1 data presented at ASH 2023

→ Multiple Myeloma
→ B-cell and plasma cell mediated autoimmune

Dynamic environment in cell therapy for autoimmune patients

Thoughts on clinical data from compassionate use and limited clinical trial experience

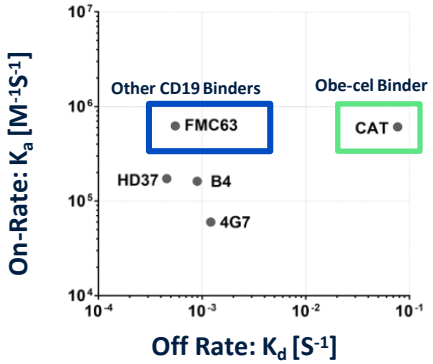
- Available clinical data is largely based on compassionate use experience, not clinical trials
- A Kymriah-like autologous CAR T program showed transformational clinical outcomes in refractory autoimmune patients
  - To date a single myositis patient relapsed after 18 months (compassionate use cohort)
- With T cell engagers (TCE), initial experience with blinatumomab with experimental c.i.v. administration resulted in clinical improvement, without eliminating the B cell compartment fully
  - "T cell engagers did not appear to drive deep/durable remissions beyond treatment and as such would require chronic therapy", Georg Schett*
- Redosing in autoimmune patients may be challenging due to the risk of immunogenicity of CAR T and s.c. administered T cell engager products

*Cantor Fitzgerald research note April 29, 2024

Obe-cel is similar to Erlangen CD19 CART

- Erlangen CD19 CART was developed for treating paediatric ALL
  - CD19 CAR is identical to Kymriah
  - Manufacturing modified from Kymriah
  - Initial data shown in paediatric ALL patients at ASH 2021 in line with data from Kymriah
- Obe-cel has a modified design to reduce immunological toxicity compared to Kymriah
- Obe-cel experience in pediatric and adult ALL confirm differentiated profile
  - High level of molecular complete remissions
  - Lasting responses
  - Similar persistence of CART cells
  - Reduced immunological toxicity (CRS, ICANS)

Differentiated CD19 engagement (fast off-rate)



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

- obe-cel = 9.8 seconds (CAT)
- Kymriah® = 21 minutes (FMC63)

	obe-cel			Kymriah
	CARPALL[1]	FELIX[2]	FELIX[2] low disease burden	ELIANA[3]
Indication	Pediatric	Adult	Adult	Pediatric
n	14	127	29	75
ORR	86%	78%	100%	83%
12mth EFS	54%	50%	65%	50%
CRS any Grade	93%	69%	47%	77%
CRS ≥ Grade 3	**0%**	2%	**0%**	**48%**
ICANS any Grade	50%	23%	8%	71%
ICANS ≥ Grade 3	**7%**	7%	**0%**	**22%**

1. Ghorashian et al., *Nature Medicine* 2019
2. Roddie et al, ASH 2023
3. USPI 2023, Maude et al., *NEJM* 2018

Low disease burden defined as <5% bone marrow blast at lymphodepletion

Phase 1 study in r/r SLE – open for enrollment

Primary goal of the Phase 1 study will be confirming the fixed dose in adult SLE patients

CARLYSLE Study

- A Single-Arm, Open-Label, Phase I Study to Determine the Safety, Tolerability and Preliminary Efficacy of Obecabtagene Autoleucel in Patients with Severe, Refractory Systemic Lupus Erythematosus (SLE)*

Study details

- **Number of patients:** 6 (option to add further cohort of 6 patients)
- **Primary endpoint:** to establish the tolerability and safety of obe-cel in patients with severe, refractory SLE
- **Secondary endpoints:** to evaluate the preliminary efficacy of obe-cel using measures of SLE disease activity
- **Dosing:** 50 x 10^6 CD19 CAR-positive T cells
- **Follow up:** up to 12 months

- First two patients enrolled; initial clinical data expected in late 2024

* A Study of CD19 Targeted CAR T Cell Therapy in Patients With Severe, Refractory Systemic Lupus Erythematosus (SLE) – Full Text View – ClinicalTrials.gov

Other pipeline programs and technologies

A broad portfolio of potential next generation modular T cell therapies

Autolus pipeline

Obe-cel product family

Product	Indication	Target	Study Name	Partner	Phase	Status/Expected Milestones
Obe-cel	Adult B-ALL	CD19	FELIX		Pivotal	Submitted to EMA and FDA (PDUFA November 16, 2024)
Obe-cel	Systemic Lupus Erythematosus	CD19	CARLYSLE		Phase 1	Initial data late 2024
Obe-cel	B-NHL and CLL	CD19	ALLCAR19	UCL	Phase 1	Data in peer reviewed journal
Obe-cel	PCNSL	CD19	CAROUSEL	UCL	Phase 1	Data in peer reviewed journal
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL	UCL BIONTECH*	Phase 1	Data in BLOOD August 2023
AUTO8	Multiple Myeloma	CD19 & BCMA	MCARTY	UCL	Phase 1	Updated clinical data in H2 2024

Additional pipeline programs

Product	Indication	Target	Study Name	Partner	Phase	Status/Expected Milestones
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1		Phase 1	Data in peer reviewed journal
AUTO5	TRBC2+ Peripheral TCL	TRBC2	–		Preclinical	Data in peer reviewed journal
AUTO6NG	Neuroblastoma	GD2	MAGNETO	UCL | BIONTECH*	Phase 1	Study open for enrollment
AUTO9	Acute Myeloid Leukemia	CD33, CD123 & CLL1	TBD	UCL	Preclinical	Estimated Phase 1 start 2025

* BioNTech holds an option to co-fund and co-commercialize

Oncology Autoimmune

Financial Results

Financial summary (unaudited)

USD	Q1 2024 ($ '000)	Q1 2023 ($ '000)	Variance ($ '000)
License revenues	10,091	1,292	8,799
R&D	(30,671)	(27,388)	(3,283)
G&A	(18,177)	(9,284)	(8,893)
Loss on disposal of property and equipment	-	(3,768)	3,768
Total operating expense, net	(38,757)	(39,148)	391
Other (expense) income, net	(1,605)	782	(2,387)
Interest Income	6,933	3,446	3,487
Interest expense	(19,269)	(4,905)	(14,364)
Income tax benefit	8	14	(6)
Net loss after tax	(52,690)	(39,811)	(12,879)

	Q1 2024 ($ '000)	Q4 2023 ($ '000)	Variance ($ '000)
Cash and cash equivalents	758,529	239,566	518,963

Upcoming news flow

Autolus planned news flow

Anticipated Milestone or Data Catalysts	Anticipated Timing
Obe-cel FELIX data update at ASCO, EHA & ASH 2024	June & December 2024
Obe-cel Marketing Authorization Application to MHRA	Second half 2024
Obe-cel U.S. FDA PDUFA target action date	November 16, 2024
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study	Late 2024

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Thank you