Autolus

Q2 2024 Financial Results and Business Updates

8 August 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 Q2 2024

Clinical

- Obe-cel progressing according to plan
  - FDA PDUFA target date of November 16
  - MAA submitted to MHRA in Q3; MAA accepted by EMA
  - SLE Phase 1 CARLYSLE study first patient dosed in Q2, enrolment ongoing
- Further FELIX Phase 2 data presentation at ASCO and EHA
  - Longer f/u for FELIX study – potential for long-term plateau of survival outcomes
  - Stem cell transplant consolidation does not appear to improve EFS or OS
  - Ongoing CAR T persistence appears associated with improved EFS
  - Impact of inotuzumab-based bridging therapy

Operational

- Strengthened of board of directors and promotions within senior leadership team
  - Announced Mike Bonney as new chair and Ravi Rao as a new director of the board
  - Recognizing their leadership and contributions several leaders across regulatory, commercial and product delivery areas have been promoted to SVP: Andrea Braun, Chris Gray, Markus Gruell, Claudia Mercedes Mayer and Dilip Patel

OBE-CEL IN ADULTS WITH R/R B-ALL

ASCO/EHA 2024

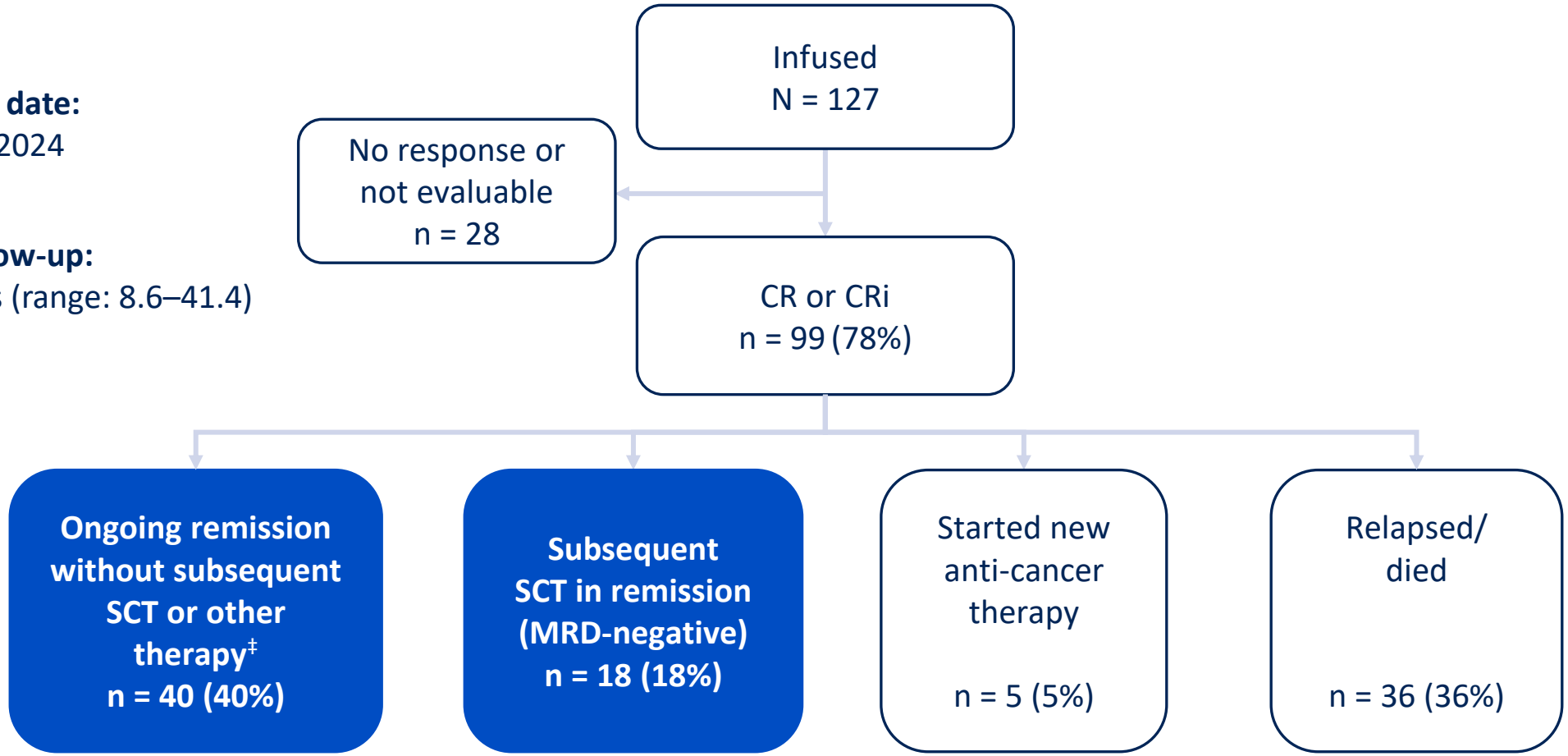
FELIX Phase 1b/2 trial

FELIX study all cohorts: Majority of responders show durable response (n=127)

40% of responders are in ongoing remission without consolidative SCT and 18% had consolidative SCT

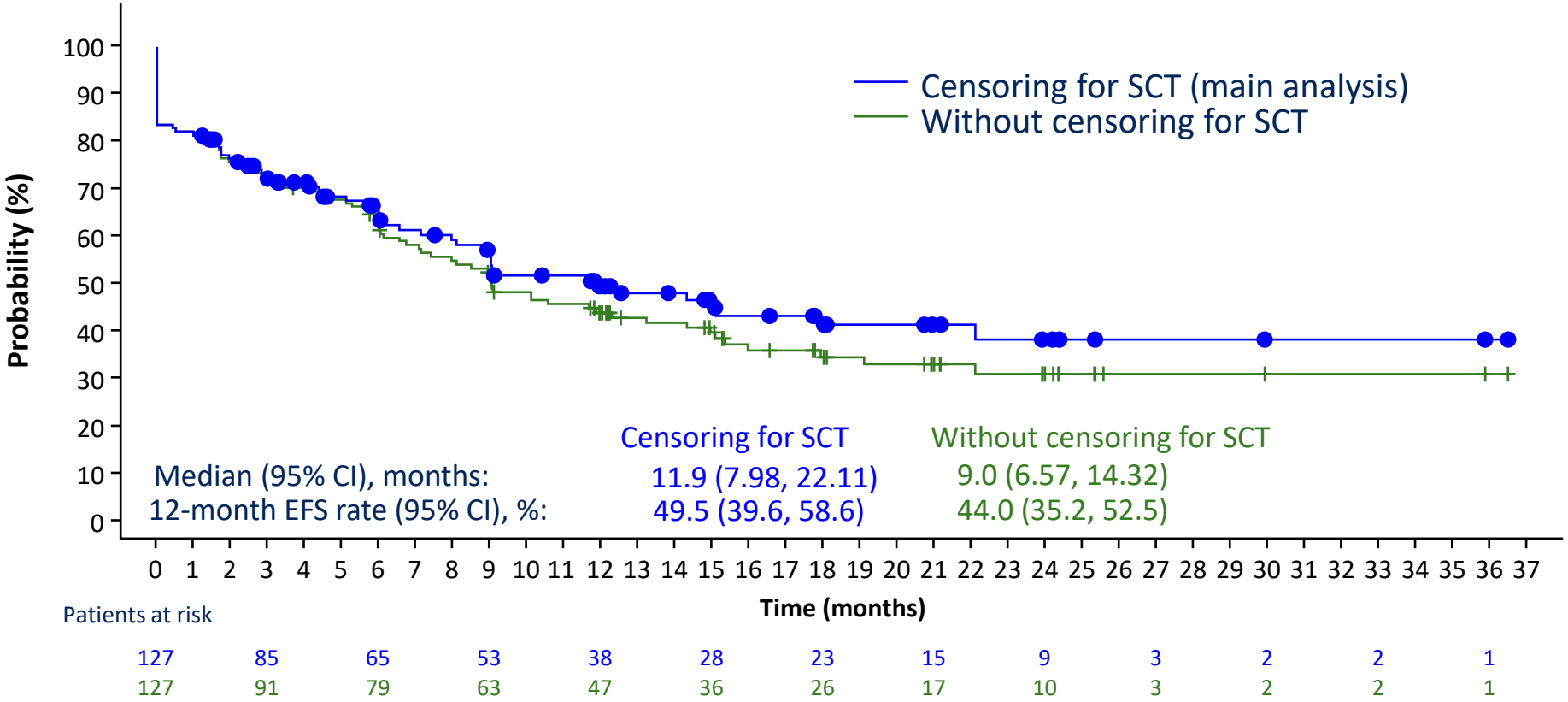
Data cut-off date:
February 7, 2024

Median follow-up:
21.5 months (range: 8.6–41.4)



FELIX study all cohorts: Event-free survival (n=127)

Subset of patients benefit from standalone treatment with obe-cel

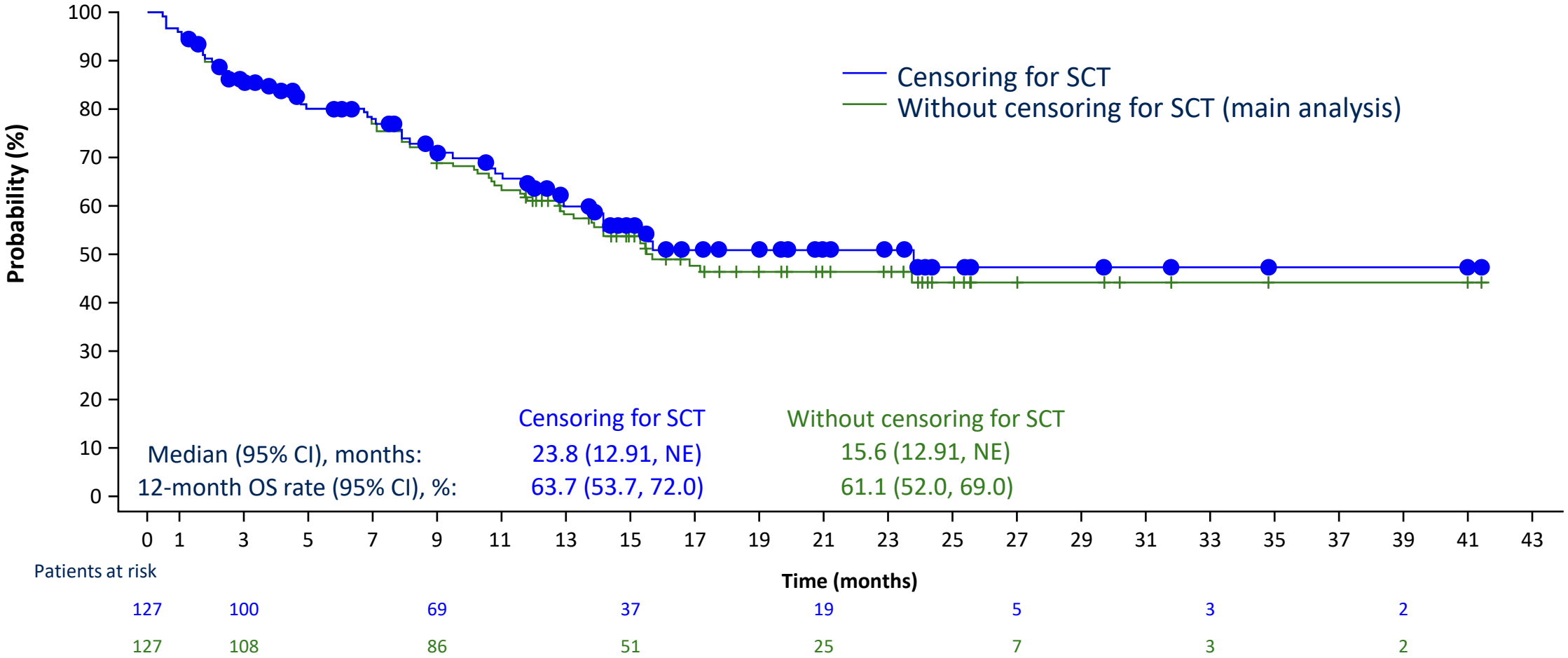


- All (18/18) patients who had SCT in remission were MRD-negative
- 10/18 patients (55.6%) had ongoing CAR T persistence prior to SCT (n = 2 ongoing without event; n = 8 relapse or death)
- Characteristics similar between patients who did and did not undergo consolidative SCT

Jabbour et al., ASCO 2024

FELIX study all cohorts: Overall survival (n=127)

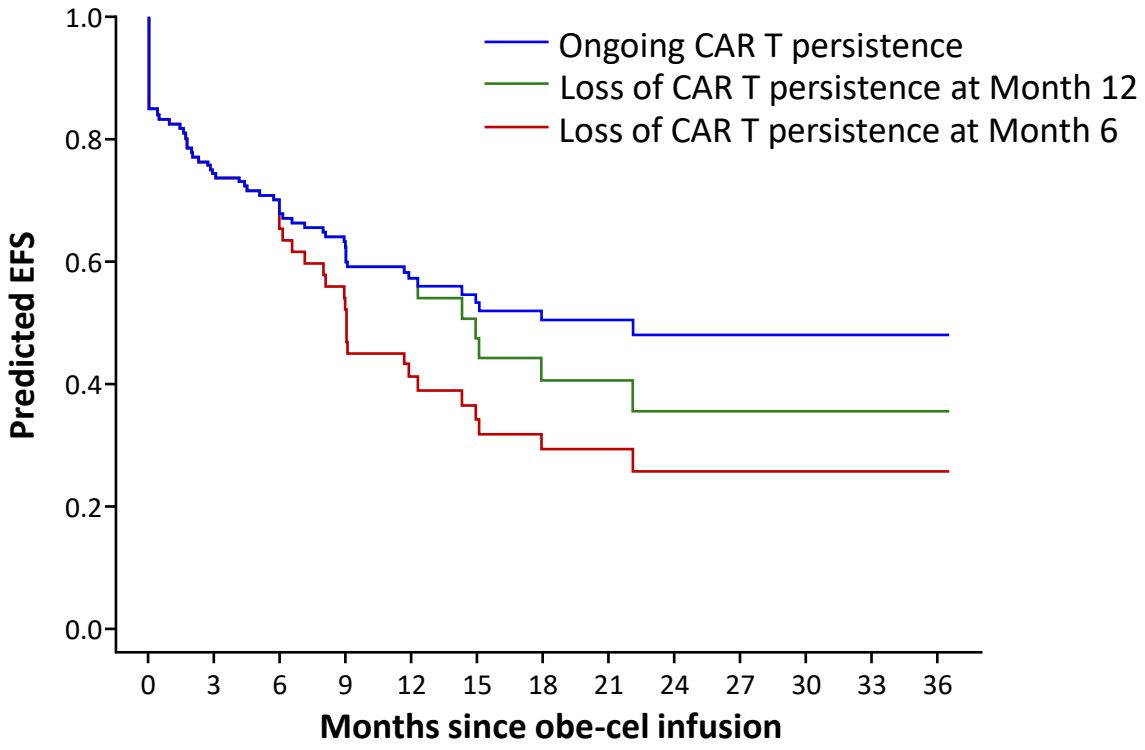
Potential long-term plateau



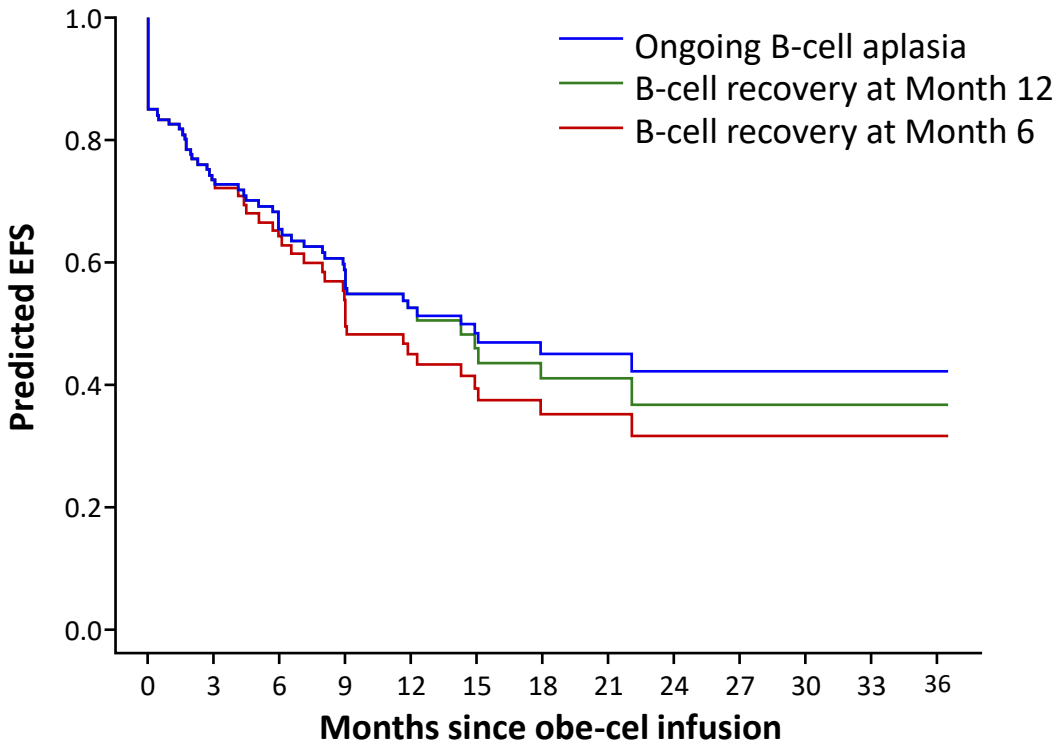
Jabbour et al., ASCO 2024

FELIX study all cohorts: CAR T persistence and predicted relapse

Ongoing CAR T persistence correlates with long-term EFS



HR 2.7 (95% CI: 1.4, 5.3)



HR 1.7 (95% CI: 0.7, 3.8)

Jabbour et al., ASCO 2024

ASCO 2024 takeaway messages

FELIX study - pooled analysis of all cohorts

- 40% of responders in ongoing remission without subsequent SCT/other therapy, with a median follow-up of 21.5 months
- Survival outcomes show potential of long-term plateau
- SCT consolidation in remission following obe-cel did not improve EFS or OS
- Ongoing CAR T persistence was associated with improved EFS

Commercial Launch Readiness

Obe-cel steps to commercialization

Roadmap to a commercial launch in r/r adult ALL

2024	Q1	Q2	Q3	Q4

Obe-cel BLA accepted by FDA

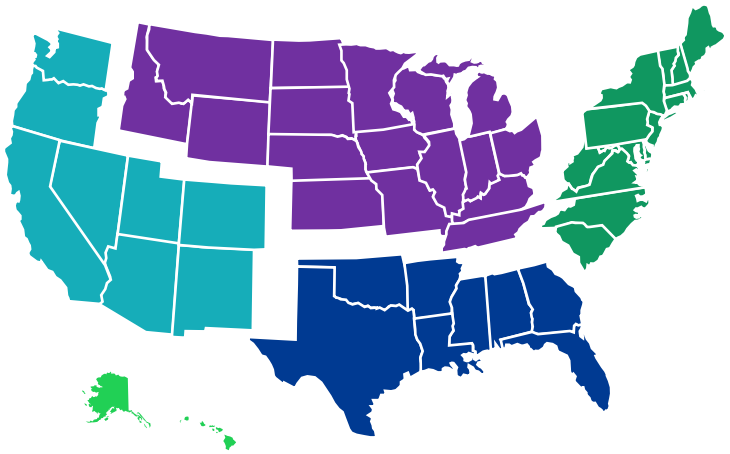
Nucleus MHRA inspection & approval Obe-cel EMA MAA

Obtained MHRA MIA together with accompanying GMP certificate

Obe-cel MHRA authorization application

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

US treatment center timelines for authorization and first patient readiness

Centers have their own internal processes / requirements to fulfil prior to administering CAR T; therefore,
not every center will be ready to prescribe upon receiving Autolus authorization

Autolus Authorization

1. Conduct final trainings based on FDA approved label
2. Administer Risk Evaluation & Mitigation Strategy training

Example Center-defined Activities *(varies by center)*

- ✓ Center Electronic Health Records order sets for obe-cel
- ✓ Pharmacy & Therapeutics Committee review
- ✓ Value assessment
- ✓ Financial clearance finalized
- ✓ External center authorization document
- ✓ Addition to Authorized Treatment Center locator

*FDA=US Food and Drug Administration; PDUFA=Prescription Drug User Fee Act

Key steps from approval to patients dosed

Final steps of center activation are driven by the actual label

Key steps	Anticipated Timing
Complete site accreditation (e.g. final label, training plans, REMS and Out of Specification (OOS) protocol)	2 – 12 weeks
Patient screening and leukapheresis scheduled/completed	1 – 2 weeks
Anticipated vein to delivery time	16 days

Based on a potential November approval and considering year-end holidays, expectation would be for a first patient dosed early 2025

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

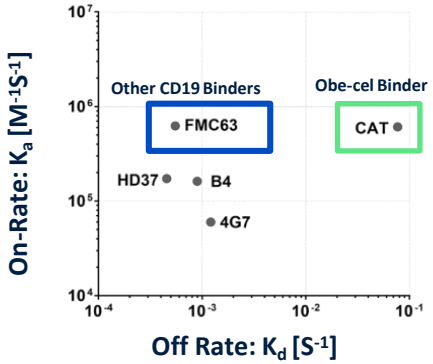
EULAR updates continue to support overall proof of concept/biology in autoimmune disease

- Available clinical data is largely based on compassionate use experience with more clinical trial data emerging
- 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)
  - Response rate expectations for the field were set high ~100%
- Some variability in clinical outcomes is beginning to emerge
  - All CD19 CAR Ts may not be alike; different design and manufacturing process may contribute
  - Patient populations vary across data sets
  - All autoimmune indications may not be alike – inflammatory process versus structural damage
- Obe-cel has shown profound removal of the B cell compartment, indicated by the long-term outcomes in ALL without subsequent therapy while showing a favorable safety profile in this challenging patient population.
- Obe-cel shows a comparable profile to Erlangen CAR-T program in dose, molecular remission rates, persistence based on pediatric ALL experience while differentiating with lower immunological toxicity (CRS, ICANS)

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 – enrollment ongoing

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
- 3 centers enrolling in UK and Spain

- 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, MHRA 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	Update in 2025

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	Open and actively recruiting
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 ($' 000)	Q2 2024	Q4 2023	Variance
Cash and cash equivalents	705,939	239,566	466,373

	Q2 2024	Q2 2023	Variance
Operating expenses:			
R&D	(36,612)	(33,232)	(3,380)
G&A	(21,903)	(11,122)	(10,781)
Loss on disposal of property and equipment	-	(23)	23
Impairment of operating lease right-of-use assets and related property and equipment	(414)	-	(414)
Total operating expense, net	**(58,929)**	**(44,377)**	**(14,552)**
Other income, net	1,226	482	744
Interest Income	9,656	3,403	6,253
Interest expense	(10,174)	(5,020)	(5,154)
Income tax expense	(51)	(40)	(11)
Net loss	**(58,272)**	**(45,552)**	**(12,720)**

Upcoming news flow

Autolus planned news flow

Anticipated Milestone or Data Catalysts	Anticipated Timing
Obe-cel U.S. FDA PDUFA target action date	November 16, 2024
Obe-cel FELIX data update at ASH 2024	December 2024
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study	Late 2024

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Thank you