Autolus

Developing Next Generation Programmed T Cell Therapies

September 2024

Autolus.com

Disclaimer

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Autolus overview – scaling towards commercialization

Building a leading CAR T company developing therapies for cancer and autoimmune diseases

Obe-cel: a potentially best-in-class CAR T

- FELIX pivotal trial in r/r adult ALL showed high ORR, encouraging EFS and favorable tolerability with low levels of high-grade CRS and ICANS
- FDA PDUFA target action date November 16, 2024
- MAAs under review with EMA and MHRA

Pipeline expansion strategy

- Expand obe-cel opportunity in B cell malignancies, autoimmune diseases & life cycle strategy
  - SLE
  - B-NHL indications
  - Bi-specific therapies (CD19 /CD22; CD19/BCMA)
- Expand to additional indications with novel CAR T therapies, alone or with partners

Scalable manufacturing and in-house facility

- Demonstrated reliable clinical trial supply (96% target dose reached in FELIX pivotal study)
- New commercial cell manufacturing facility in qualification stage; planned annual capacity 2,000+ batches
- Expected vein-to-delivery time at launch of ~16 days

Strategic collaborations

- Strategic multi-platform R&D collaboration with BioNTech
- Established technology collaborations with Moderna, BMS and Cabaletta
- Long-standing academic collaboration with University College London

Strong cash position

- Cash and cash equivalents $706M end of Q2 2024
- Fully funds obe-cel launch in adult ALL and allows for autoimmune program acceleration

Abbreviations and notes: r/r ALL – relapsed/refractory acute lymphoblastic leukemia; B-NHL – B-cell non-Hodgkin's lymphoma; SLE – systemic lupus erythematosus

LEAD CLINICAL PROGRAM

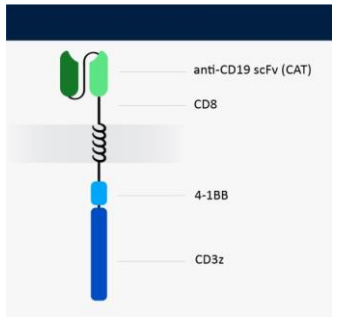
Obe-cel

A standalone, potentially best-in-class CD19 CAR T cell therapy candidate

We believe obe-cel has a unique mechanism of action

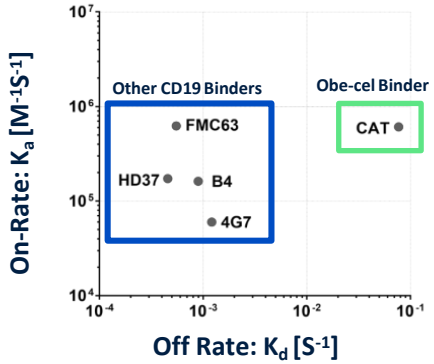
Designed for increased activity and reduced toxicity

Differentiated CD19 binder



CD19 binder
with fast off-rate

Fast off-rate



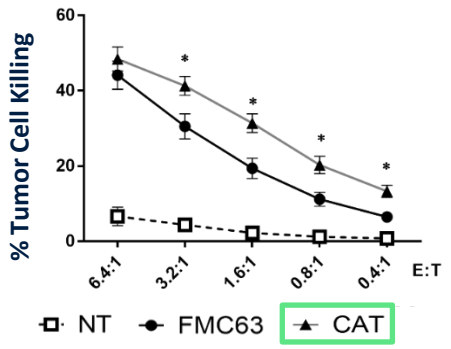
Shorter half-life of interaction compared to binders used in approved products

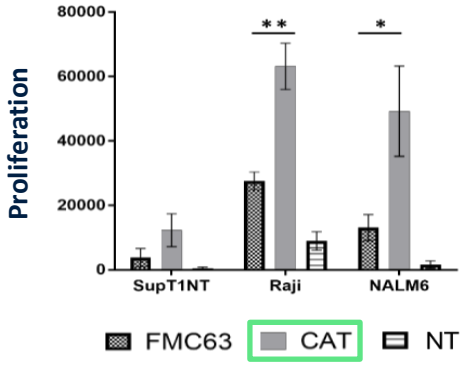
- obe-cel = 9.8 seconds
- Kymriah® = 21 minutes

Potential for improved potency, reduced toxicity

- Avoided over-activation of CAR T cells → Reduced toxicities
- Increased CAR T peak expansion → Improved persistence
- Avoided exhaustion of CAR T-cells → Improved engraftment
  Improved persistence

Enhanced cytotoxicity and proliferation

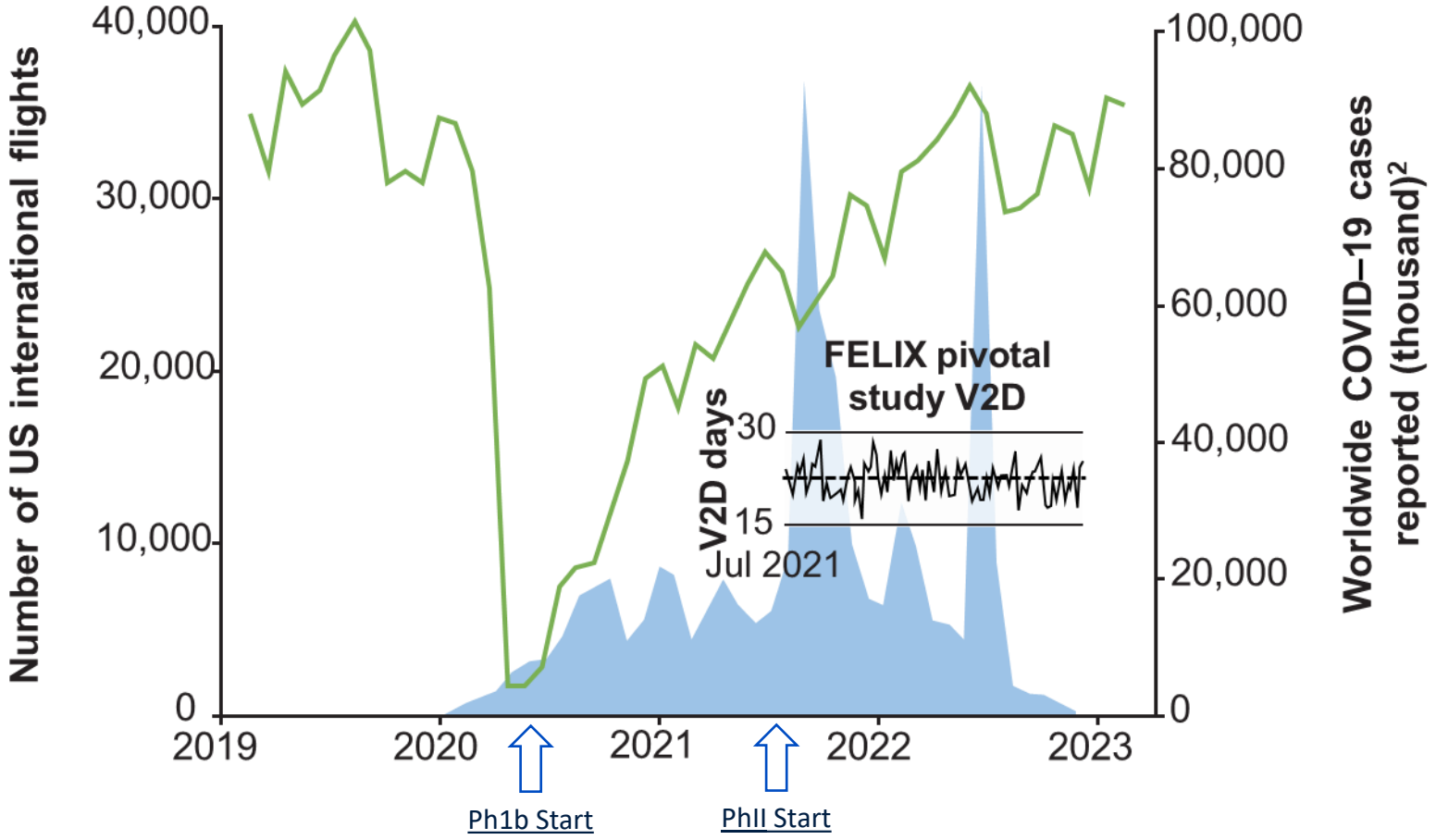




Ghorashian et al. Nature Medicine 2019

The FELIX phase 1b/2 pivotal study

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 pandemic1
- 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

Overview of FELIX 1b/2 clinical experience to date

FELIX pooled analysis of all cohorts presented ASH 2023 and ASCO/EHA 2024

Durable and robust response rates [1]

- The ORR (CR/CRi) in all patients who received obe-cel in the FELIX study was 78%
- The 12-month EFS and OS rates were 49.5% and 61.1% respectively (median follow up of 21.5 months)
- 40% of responders in ongoing remission without subsequent SCT/other therapy (median follow-up of 21.5 months)
- Survival outcomes show potential of long-term plateau

Predictable and manageable tolerability

- Low rates of Grade ≥3 CRS (2%) and low rates of Grade ≥3 ICANS (7%)[2]

Durable remission rates and toxicity inversely correlated with leukemic burden [2]

- Assessment of leukemic burden at lymphodepletion is essential for risk/benefit stratification

Timely and reliable product supply

- Obe-cel successfully manufactured for 95% of leukapheresed patients[2]
- Vein to certification time of ~21 days in pivotal study[3]; targeting ~16 days at launch

1. Roddie et al., ASCO 2024, Data cut-off date: Feb 7, 2024
2. Roddie et al., ASH 2023, Data cut-off date: Sept 13, 2023
3. Merges et al., ASH 2023, poster presentation

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

ASCO/EHA 2024

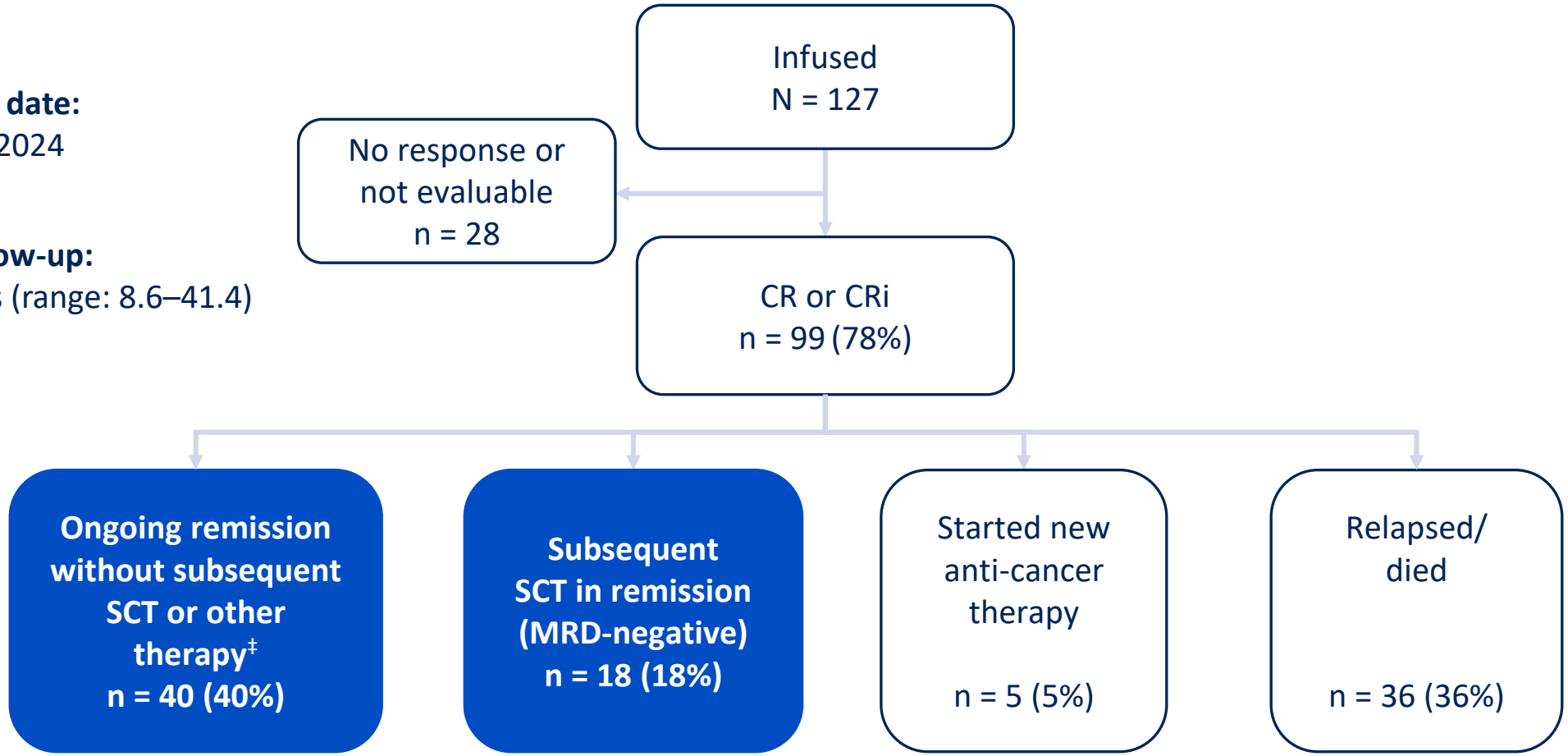
FELIX Phase 1b/2 trial

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

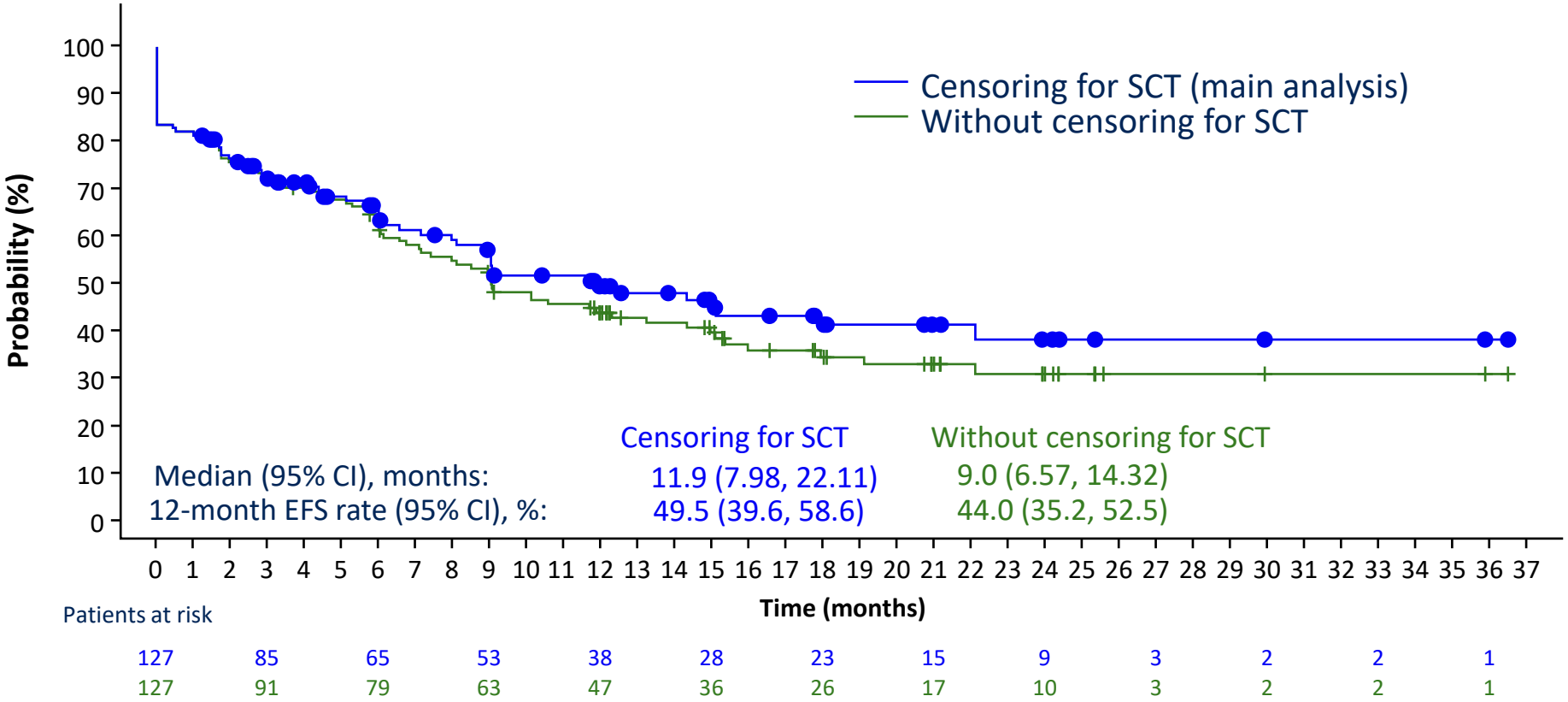
Median follow-up:
21.5 months (range: 8.6–41.4)



Jabbour et al., ASCO 2024

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

Subset of patients benefit from standalone treatment with obe-cel

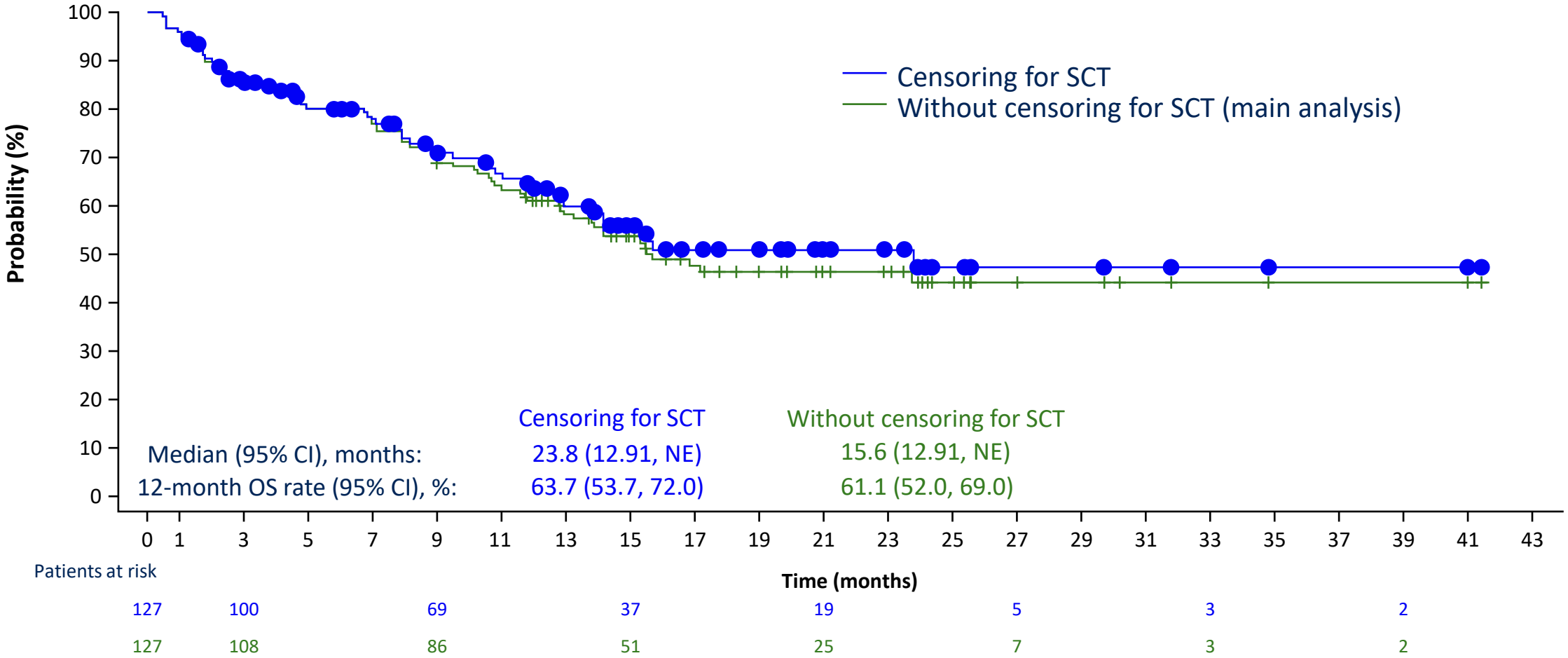


- All (18/18) patients who had SCT in remission were MRD-negative
- 10/18 patients (55.6%) had ongoing CAR T persistence prior to SCT (n = 2 ongoing without event; n = 8 relapse or death)
- Characteristics similar between patients who did and did not undergo consolidative SCT

Jabbour et al., ASCO 2024

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

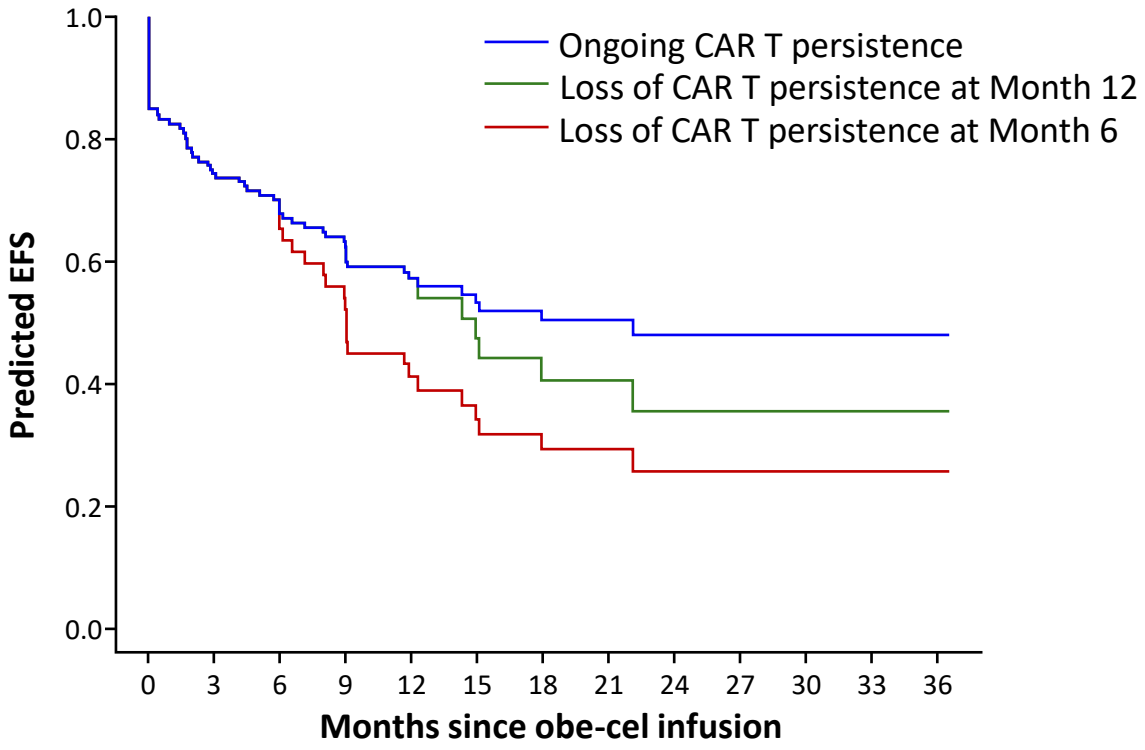
Potential long-term plateau



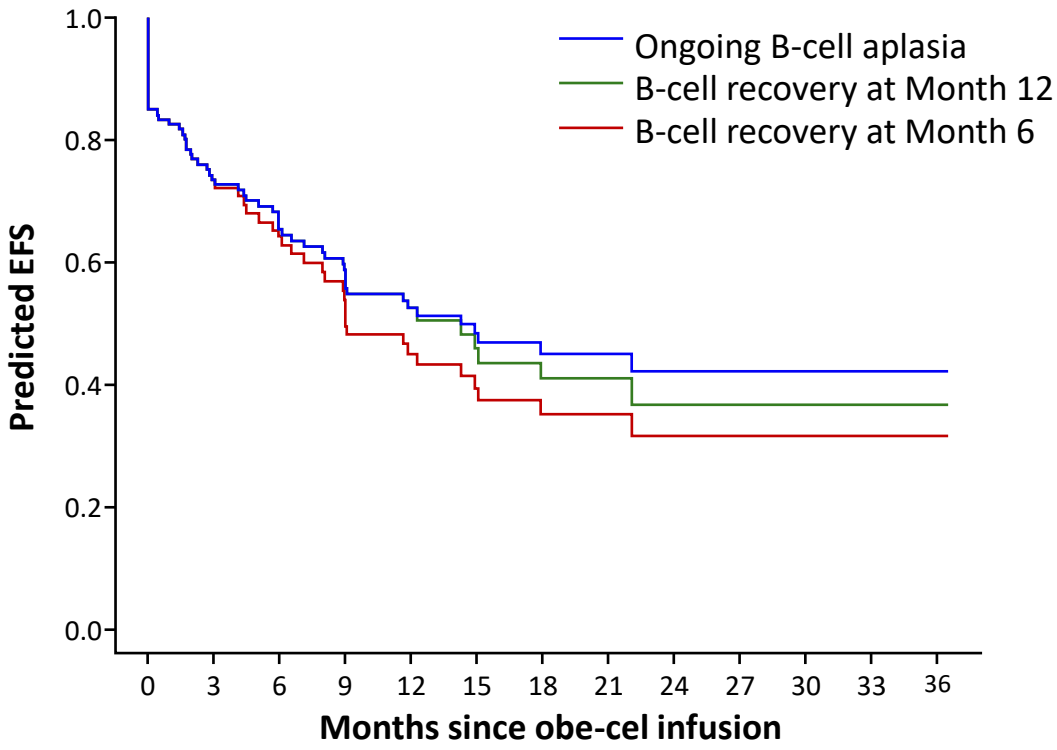
Jabbour et al., ASCO 2024

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

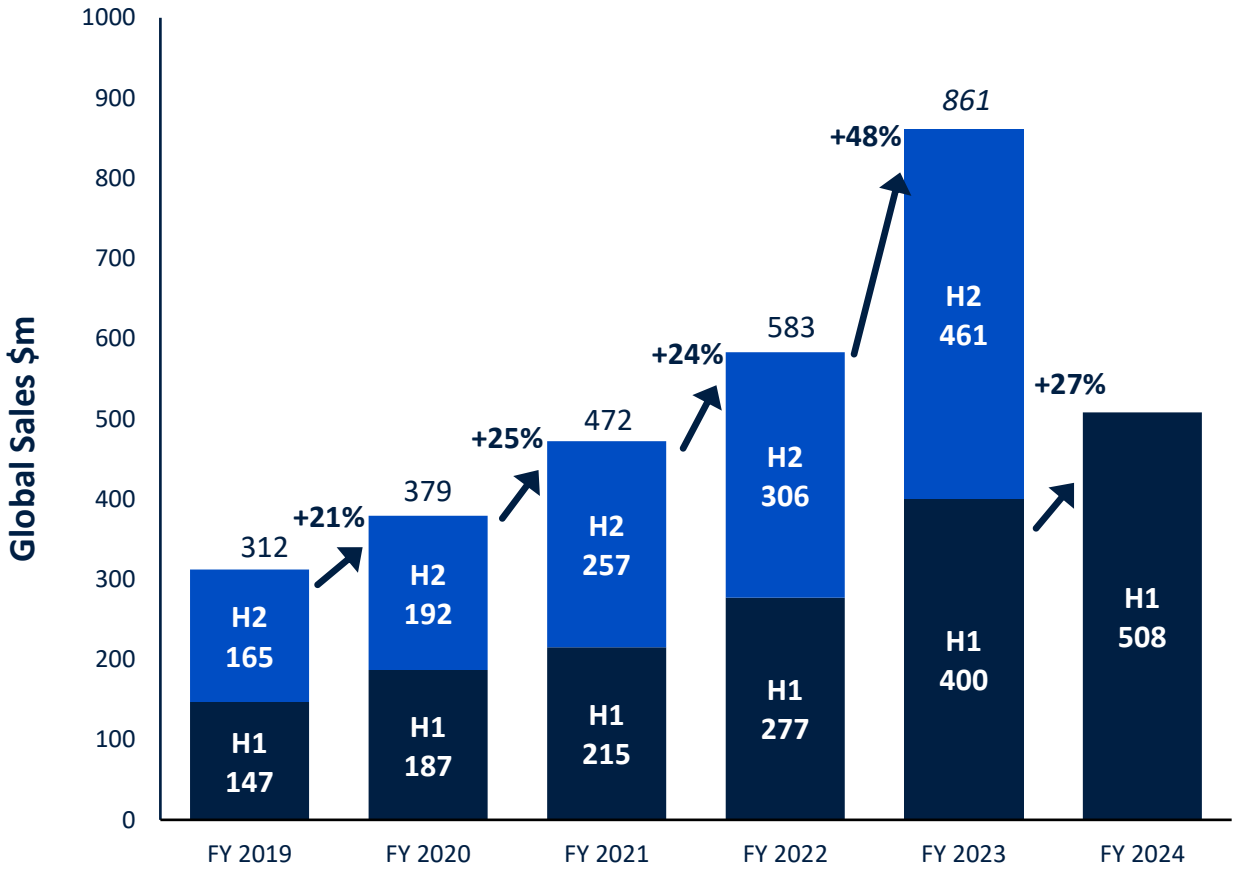
- 40% of responders in ongoing remission without subsequent SCT/other therapy, with a median follow-up of 21.5 months
- Survival outcomes show potential of long-term plateau
- SCT consolidation in remission following obe-cel did not improve EFS or OS
- Ongoing CAR T persistence was associated with improved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

ALL: unmet need and market overview

If approved, obe-cel could launch into an expanding ALL market

Blincyto®, current market leader, sales increased 48% year-over-year to $861 million for the full year 2023

Reported Blincyto® sales[1]



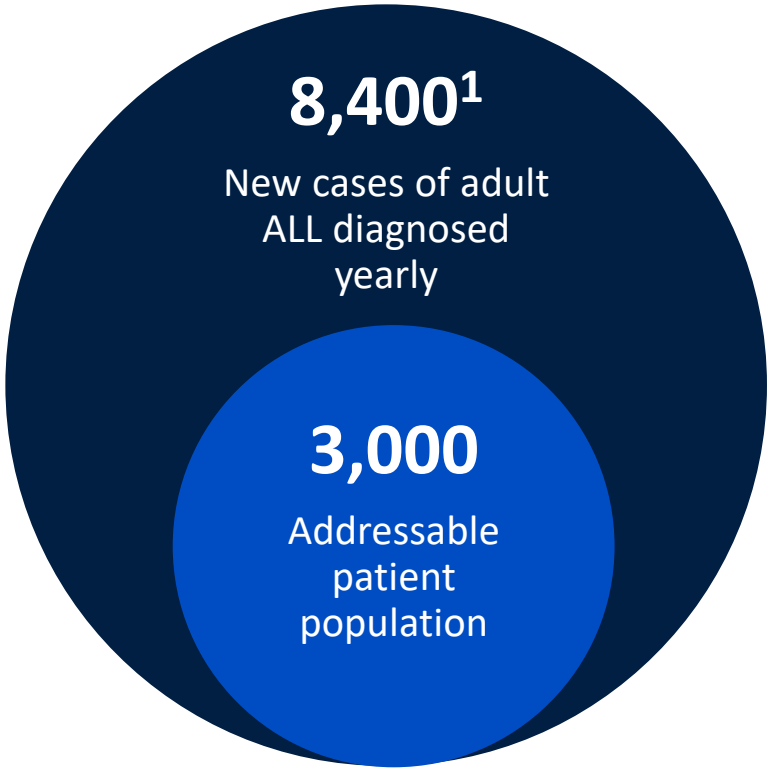
- Blincyto® sales price estimated to be $103.5k[2] (for 1 cycle) supporting approx >2,500 commercial adult ALL patients across all lines of treatment. Sales of $508M for H1 2024, a 27% increase vs. prior period
- Kymriah® is priced at $582k in pediatric ALL. Breyanzi® is priced at $487k in DLBCL[3]. Tecartus® is priced at $462k[3] for adult ALL
- Breyanzi® and other CAR T cell therapies are expanding delivery center footprint
- If approved, obe-cel has the potential to be best-in-class curative therapy and expanding use beyond academic transplant centers

1. As per Amgen quarterly SEC filings
2. https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files
3. Red Book pricing database https://www.ibm.com/products/micromedex-red-book/pricing

Over 8,000 new cases of adult ALL annually worldwide

Successful therapy requires high level of activity and sustained persistence paired with good tolerability

- Median overall survival is < 1 year in r/r adult ALL
- Combination chemotherapy enables 90% of adult ALL patients to experience Complete Response (CR)
  - Only 30% to 40% achieve long-term remission
- Current T cell therapies for adult patients are Blincyto® and Tecartus®
  - Both therapies are highly active, but frequently followed by subsequent treatments (e.g. alloSCT)
  - Blincyto®: favorable safety profile, few patients experiencing severe CRS and ICANS, but limitations on convenience – continuous i.v. infusion during 4-week treatment cycles
  - Tecartus® more challenging to manage – induces elevated levels of severe CRS, a high levels of severe ICANS, and requires vasopressors for many patients
- Opportunity to expand the addressable patient population in earlier lines of therapy



1. SEER and EUCAN estimates (respectively) for US and EU

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

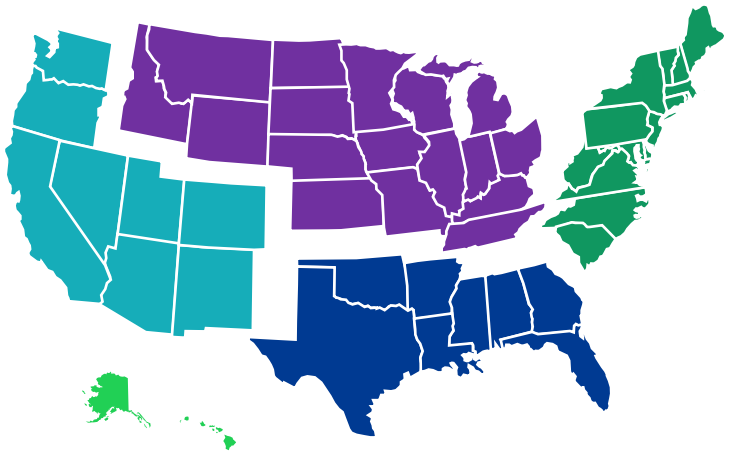
Nucleus MHRA inspection & approval Obe-cel EMA MAA

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

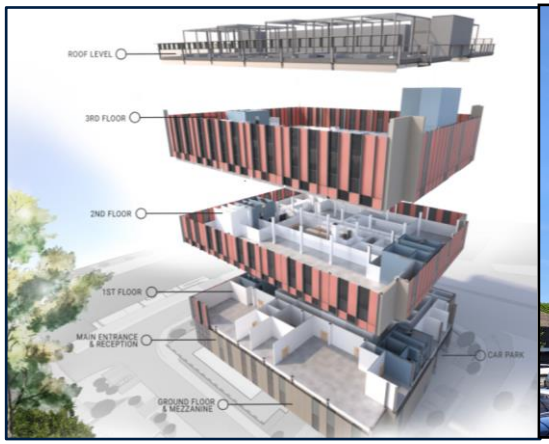
*FDA=US Food and Drug Administration; PDUFA=Prescription Drug User Fee Act

The Nucleus – Our Commercial Manufacturing Facility

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

- Facility ~70,000 sq ft
- Modular build (70% built off-site)
- Timeline to validation reduced by ~60%
- Excellent BREEAM sustainability rating
- Designed for 2,000+ batches per year
- Target vein to delivery 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

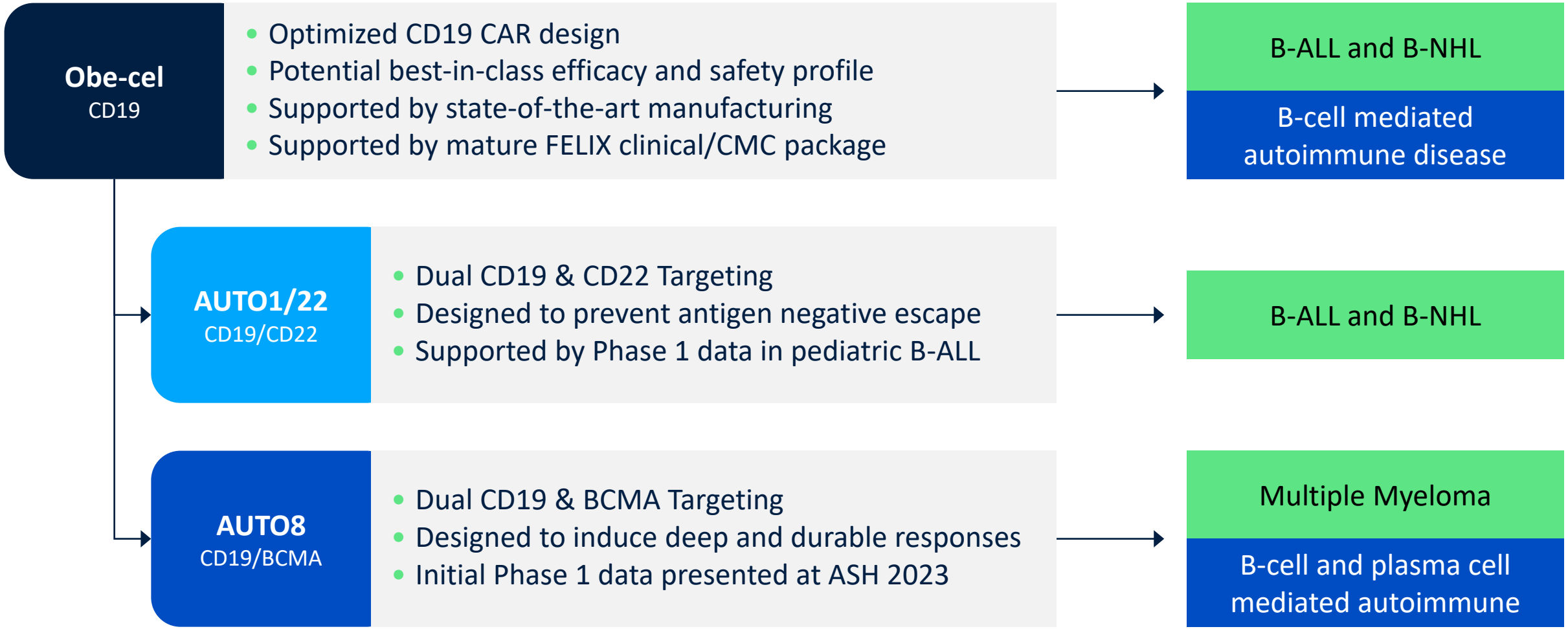
2024

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



Uniquely positioned to develop CAR T therapy candidate in autoimmune disease

Obe-cel's potential characteristics	Supporting evidence
Favorable tolerability to drive physician and patient acceptability in rheumatology settings	• Potential best-in-class risk/benefit profile in pivotal FELIX trial in adult ALL • Low rates of high-grade CRS and ICANS across all patients observed to date in the cancer setting
Deep cut into the CD19+ B and plasma cell compartment to remove all autoreactive clones	• Evaluation in B-ALL with very high rate of MRD negative complete remissions (95% of evaluated responders) in FELIX study
Development of robust, economical and scalable manufacturing and commercial infrastructure	• Potential approved, commercial manufacturing facility in adult ALL with attractive cost of goods at launch for SLE • Commercial systems and CAR T center services established with potential adult ALL launch
Potential for smaller clinical program and accelerated regulatory path to launch if a high degree of treatment effect is observed	• Treatment effect reported in Erlangen* proof-of concept using a different CAR T product candidate • Clinical safety data from ALLCAR19 and FELIX as well as potential commercial patient data to supplement SLE pivotal study

* New England Journal of Medicine: DOI: 10.1056/NEJMc2107725 – August 2021

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 design summary

- Number of patients: 6 (option to add 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

Status and updates

- Initial cohort (n=6) revised enrollment projection; expect completion of patient dosing in Q1 2025
- Initial patient data in Q1 2025
- Presentation of full data with follow-up targeted for 2H 2025 at a medical conference

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

Initial clinical experience in r/r NHL, r/r pALL and in r/r MM

Obe-cel ALLCAR19 study, AUTO1/22 CARPALL study and AUTO8 McCARTY study

Obe-cel in NHL*

- 22 r/r NHL patients treated (DLBCL, MCL, FL)
- 21 of 22 patients achieved a metabolic CR
- No ≥ grade 3 CRS and no ICANS of any grade reported
- Durable outcomes and CART cell persistence
- Majority of patients in ongoing remission with a median f/u of 21 months

AUTO1/22 in pALL*

- Kymriah ineligible r/r pALL patients (4 Kymriah failures, 3 CD19neg disease, 3 non-CNS extramedullary disease)
- Favorable adverse event profile with no severe CRS
- Excellent CAR T expansion and very encouraging activity:
- 83% MRD negative CR/Cri
- 1-year EFS 60%
- At median FU 8.7 months, no cases of leukemic relapse or emergence of MRD related to antigen escape

AUTO8 in r/r MM*

- 11 r/r MM patients treated
- No ≥ grade 3 CRS and no ICANS of any grade reported
- ORR 100%; 3 PR*, 1 VGPR*, 7 CR*/sCR* (all evaluable MRD-)
- Two patients remained in sCR at >12 months; overall PFS was not reached
- Additional dose levels to be explored

*Roddie et al., ASH 2023 Poster 2114
*Ghorashian et al., EBMT Annual Meeting 2023
*Lee et al., ASH 2023

Partnerships, 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 Q1 2025
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

Leveraging our industry leading technology platform via partnerships

Technology partnerships

Leveraging our modular programming technology to generate safer and more effective therapies

Tumor targeting, pharmacological control and activity enhancement for cellular therapies

Validating collaborations with leading pharma and biotech companies

Potential for value creation through near term option exercise fees, milestone payments and royalties from net sales

BIONTECH

Leveraging technology platform for BioNTech's programs

Bristol Myers Squibb

Access to the RQR8 safety switch for selected cell therapy programs for the treatment of cancer

moderna

Access to proprietary binders for the development of mRNA-based therapeutics for the treatment of cancer

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	Q1 2025

Summary

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Thank you

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Appendix

FELIX Phase 1b/2 pooled analysis: patient disposition

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

Enrolled**
N = 153

	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)

Infused
N = 127 (83%)

Morphologic disease*** (n = 98)
- 74% of patients had CR/CRi (n = 73)
- 95% of evaluated responders were MRD-negative‡

No morphologic disease (n = 29)
- 100% of evaluable patients were MRD-negative§

Cohort A
n = 107
(84%)
≥5% BM blasts
at screening

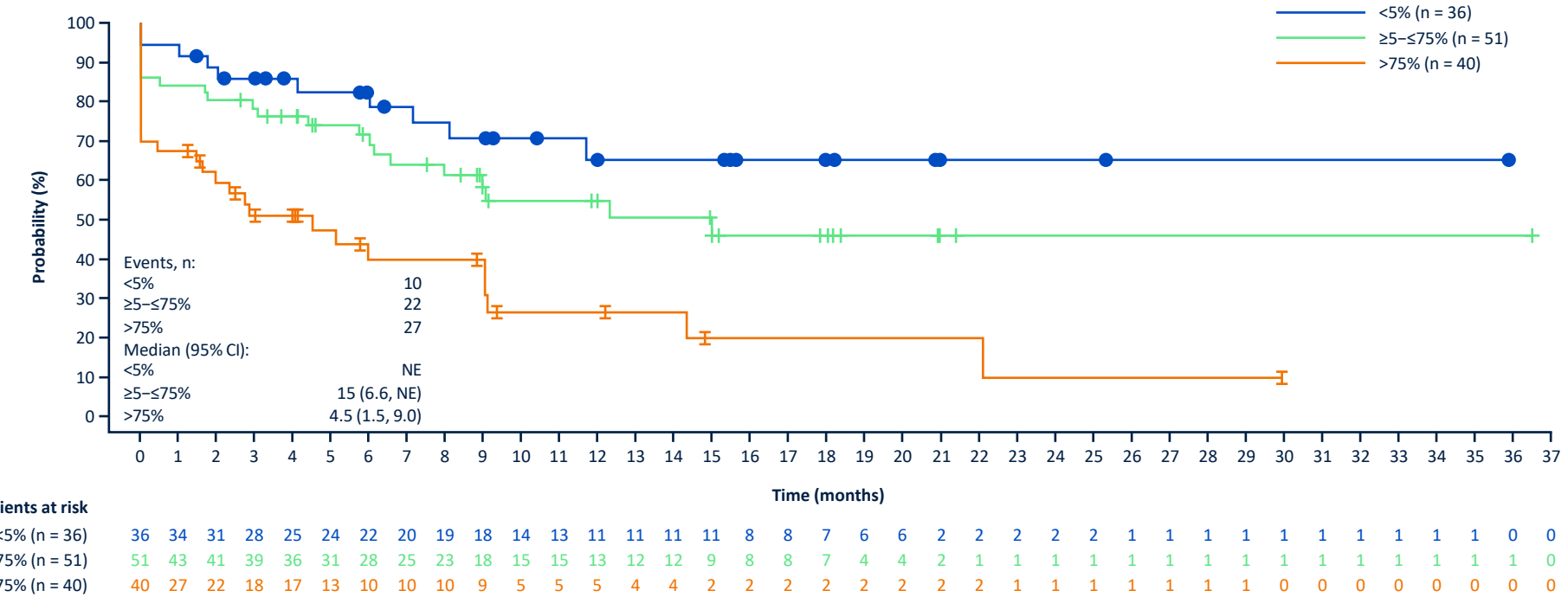
Cohort B
n = 13
(10%)
MRD-positive
at screening

Cohort C
n = 7
(6%)
Isolated EMD
at screening

*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

ASH2023: EFS by leukemic burden prior to lymphodepletion*

Lower leukemic burden is associated with better outcomes



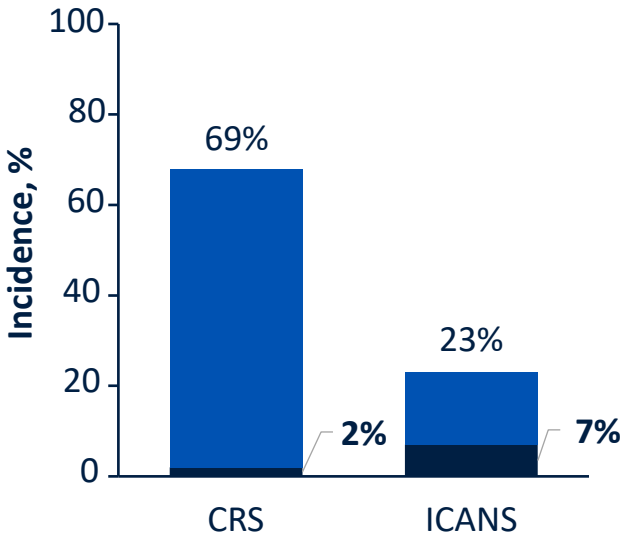
BM blasts % prior to lymphodepletion	<5% (n = 36)	≥5–≤75% (n = 51)	>75% (n = 40)
Median EFS (95% CI), months	**NE**	**15.0** (6.6, NE)	**4.5** (1.5, 9.0)
6-month EFS (95% CI), %	**83** (65, 92)	**72** (57, 82)	**40** (23, 56)
12-month EFS (95% CI), %	**65** (44, 80)	**55** (38, 69)	**27** (12, 44)

*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

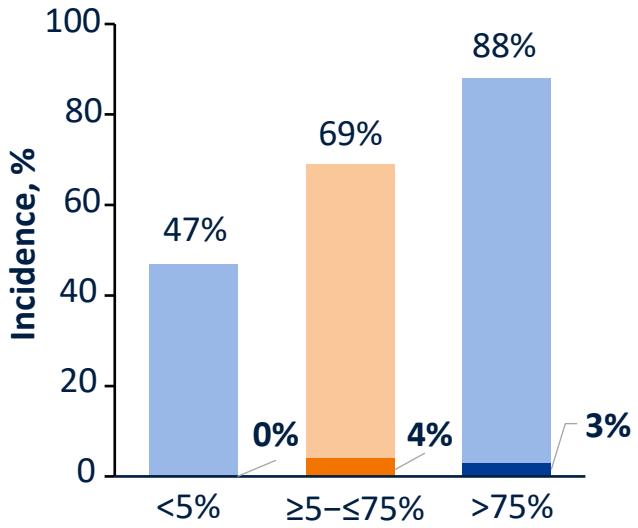
ASH2023 FELIX Phase 1b/2 pooled analysis: CRS and ICANS

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

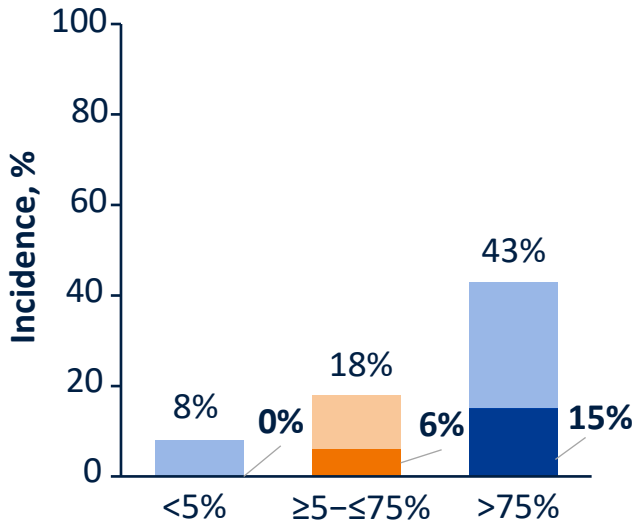
CRS and ICANS in all patients



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

ASH 2023 takeaway messages

- Obe-cel successfully manufactured in 95% of leukapheresed patients
- High remission rates independent of leukemic burden at lymphodepletion
- 50% EFS estimate at 12 months, with only 17% of responders proceeding to SCT while in remission
- Favorable safety profile: 2% grade ≥3 CRS and 7% grade ≥3 ICANS
- Severe toxicity mostly limited to patients with high leukemic burden at lymphodepletion
- Durable remission rates and toxicity inversely correlated with leukemic burden at lymphodepletion
- Assessment of leukemic burden at lymphodepletion is essential for risk/benefit stratification

Strategic multi-platform R&D collaboration with BioNTech

CAR T Cell Therapies

BioNTech to financially support obe-cel planned/potential commercial launch in adult ALL (Acute Lymphoblastic Leukemia) and expansion of development program

Development Product Options

BioNTech to receive co-development and co-commercialization options for AUTO1/22 (CD19/22) and AUTO6NG (GD2) programs

Commercial Infrastructure Access

BioNTech to receive option to access Autolus' GMP product supply and commercial infrastructure for their CAR T program, BNT211

Technology Platform License

BioNTech to receive license and options to access proprietary binders, safety switches and technologies for certain BioNTech programs

Deal Financials

Upfront Payments

- $200 million upfront for equity
- $50 million upfront cash

Downstream Economics

- Up to $580 million in further option exercise and milestones payments
- BioNTech to receive up to mid-single digit royalty on obe-cel project financing
- Autolus eligible for an additional equity investment of $20m, an option exercise payment and profit share based on products manufactured for BioNTech's BNT211 program
- BioNTech has option to co-fund and co-commercialize AUTO1/22 and AUTO6NG, if approved, in return for profit share
- Technology license and options provided in exchange for milestones and royalties