

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 13, 2024

Autolus Therapeutics plc
(Exact name of registrant as specified in its Charter)

England and Wales
(State or other jurisdiction of
incorporation or organization)

001-38547
(Commission
File Number)

Not applicable
(I.R.S. Employer
Identification No.)

The MediaWorks
191 Wood Lane
London W12 7FP
United Kingdom
(Address of principal executive offices) (Zip Code)

(44) 20 3829 6230
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, par value \$0.000042 per share	AUTL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On February 13, 2024, Autolus Therapeutics plc (the “*Company*”) posted an updated corporate presentation to its website. A copy of the presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Corporate Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AUTOLUS THERAPEUTICS PLC

Dated: February 13, 2024

By: /s/ Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

Developing Next Generation Programmed T Cell Therapies

February 2024



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 of its product candidates, including the obe-cel program; the profile and potential application of obe-cel in additional disease settings; the future clinical development, efficacy, safety and therapeutic potential of the Company's product candidates, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical and preclinical activity and milestones; expectations regarding the initiation, design and reporting of data from clinical trials and preclinical studies; the extension of the pipeline beyond obe-cel; expectations regarding the regulatory approval process for any product candidates; the benefits of the collaboration between Autolus and BioNTech, including the potential and timing to receive milestone payments and royalties under the terms of the strategic collaboration; the Company's current and future manufacturing capabilities; and the Company's anticipated cash runway. 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. These risks and uncertainties include, but are not limited to, the risks that Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early 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 20-F filed with the Securities and Exchange Commission, or the SEC, on March 7, 2023 and in Autolus' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, 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.

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

Scaling company toward commercialization



Obe-cel potentially best in class CAR T for r/r adult ALL

- FELIX pivotal trial showed high ORR, encouraging EFS and favorable tolerability with low levels of high-grade CRS and ICANS
- PDUFA date 16 Nov 2024
- EMA submission planned for 1H 2024



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 \$256.4M (Q3 2023)
- Runway into 2025*
- Enables execution on current strategy through expected approval of obe-cel

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

*Does not include proceeds from BioNTech

A 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

Commercial Infrastructure Access

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

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

Development Product Options

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

Technology Platform License

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



LEAD CLINICAL PROGRAM

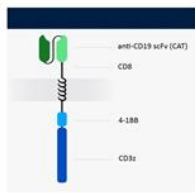
Obe-cel

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

We believe obe-cel has a unique mechanism of action

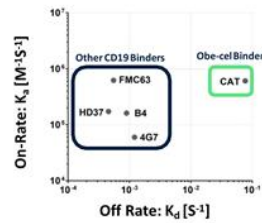
Designed for increased activity and reduced toxicity

Differentiated CD19 binder



CD19 binder with fast off-rate

Fast off-rate



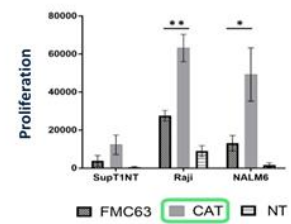
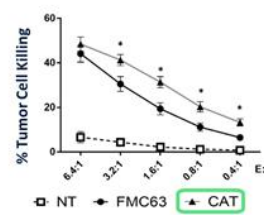
Shorter half-life of interaction compared to binders used in approved products

- 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



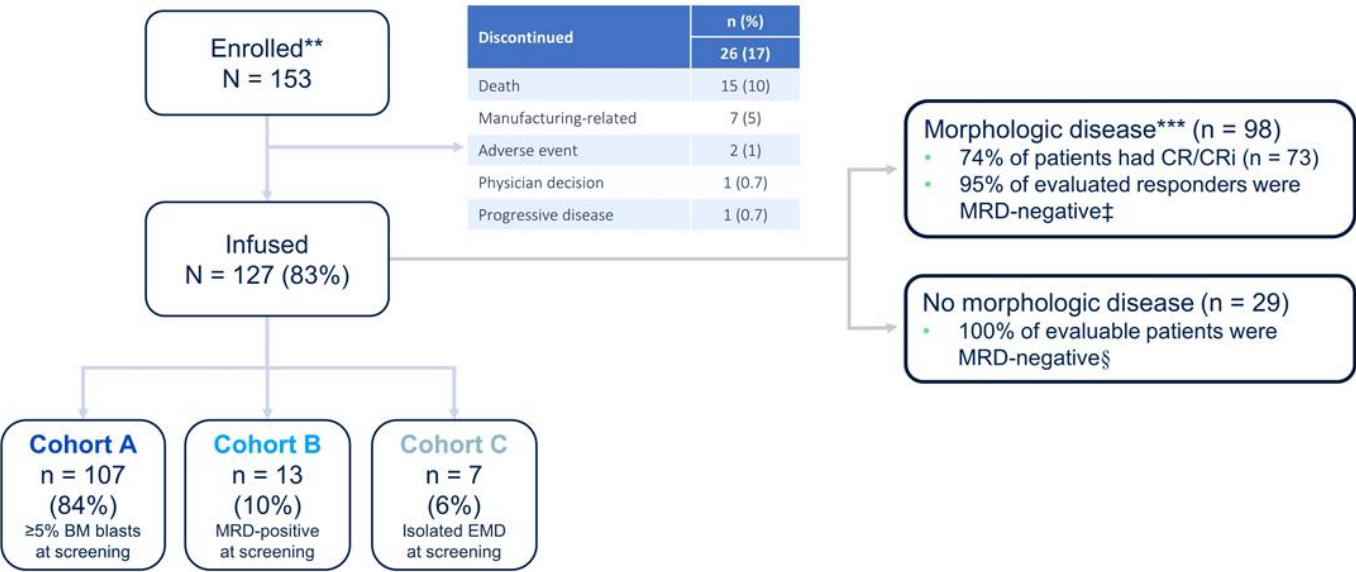
ASH 2023

Obe-cel pooled analysis

FELIX Phase 1b/2 trial

FELIX Phase 1b/2 pooled analysis: patient disposition

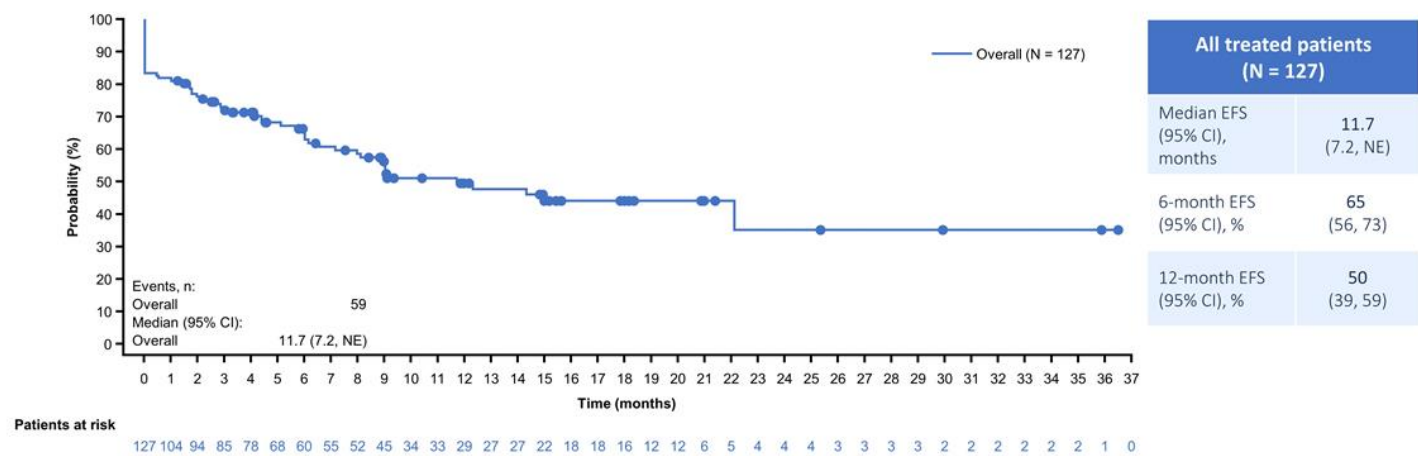
127/153 (83%) enrolled patients received obe-cel*



*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%

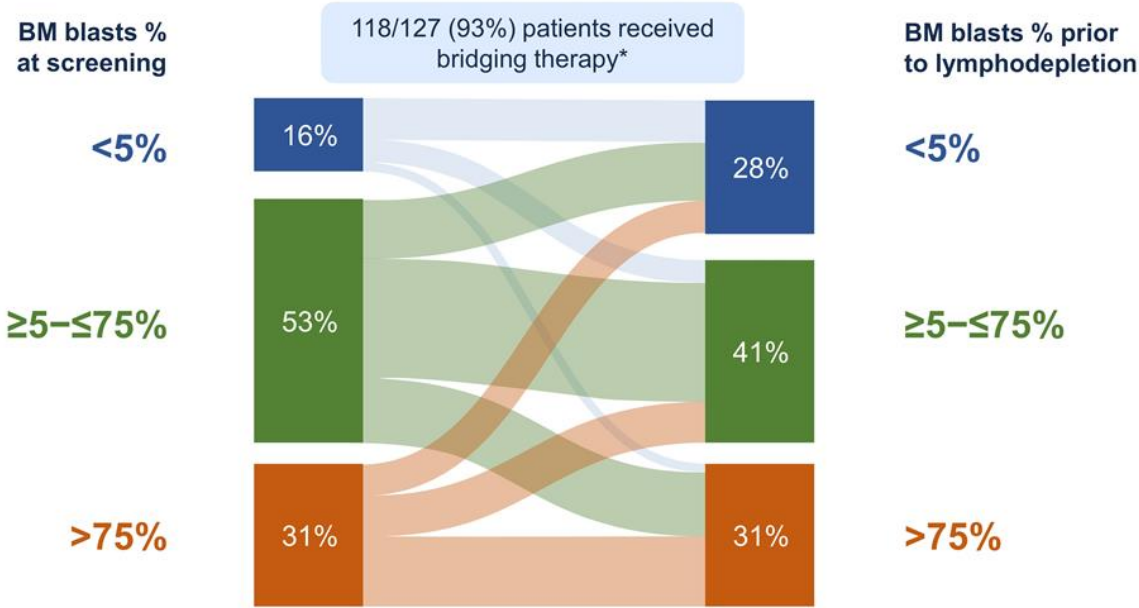


- Median follow-up time was 16.6 months (range: 3.7–36.6 months)
- 17/99 (17%) responders proceeded to SCT while in remission

*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 Phase 1b/2 pooled analysis: leukemic burden in all treated patients

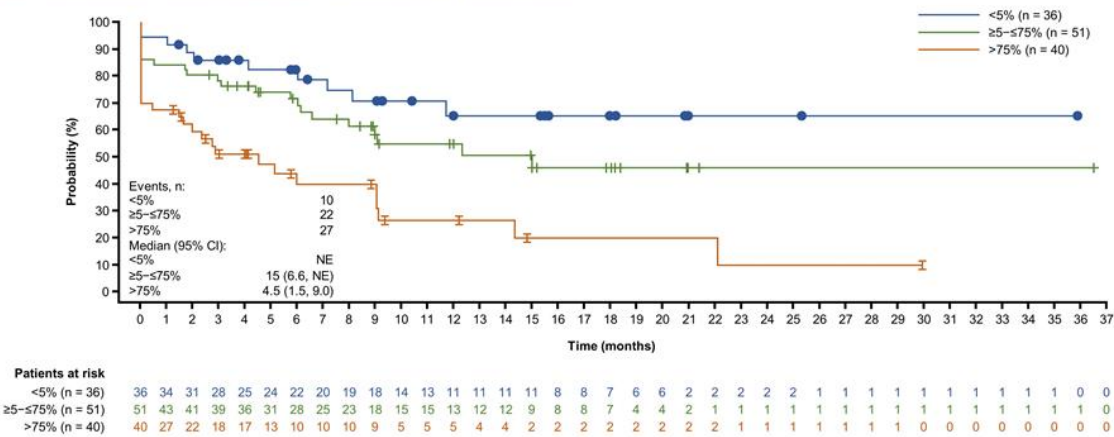
Leukemic burden at screening is not predictive of leukemic burden prior to lymphodepletion



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

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

Lower leukemic burden is associated with better outcomes

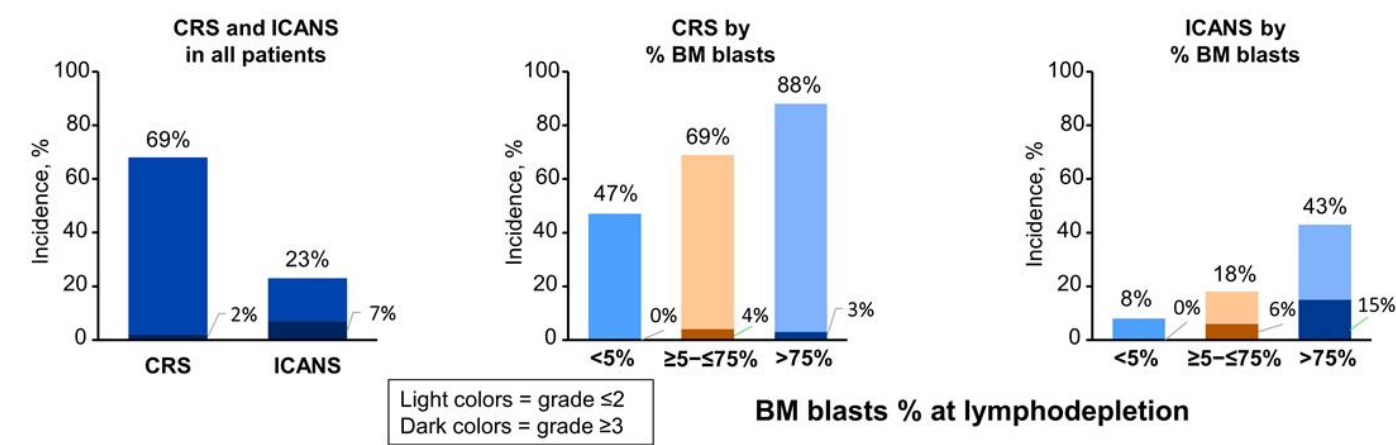


BM blasts % prior to lymphodepletion	<5% (n = 36)	≥5-≤75% (n = 51)	>75% (n = 40)
Median EFS (95% CI), months	NE	15.0 (6.6, NE)	4.5 (1.5, 9.0)
6-month EFS (95% CI), %	83 (65, 92)	72 (57, 82)	40 (23, 56)
12-month EFS (95% CI), %	65 (44, 80)	55 (38, 69)	27 (12, 44)

*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



- 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)

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



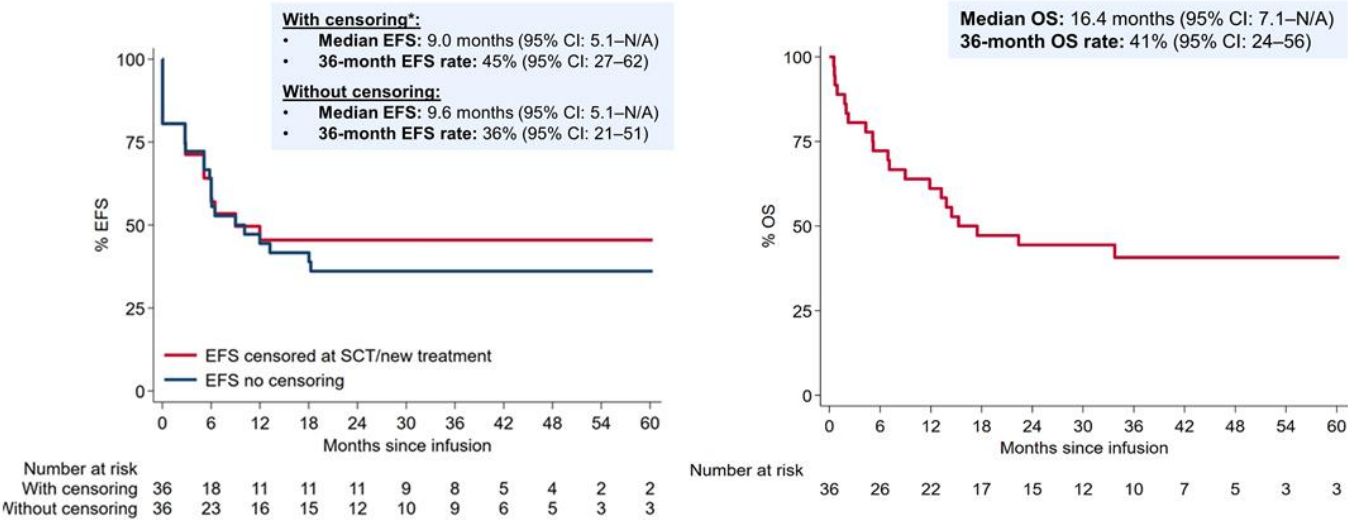
ASH 2023

Obe-cel pooled analysis

ALLCAR19 Phase 1b /FELIX Ph 1b

Long-term follow up in R/R B-ALL demonstrates favorable EFS and OS

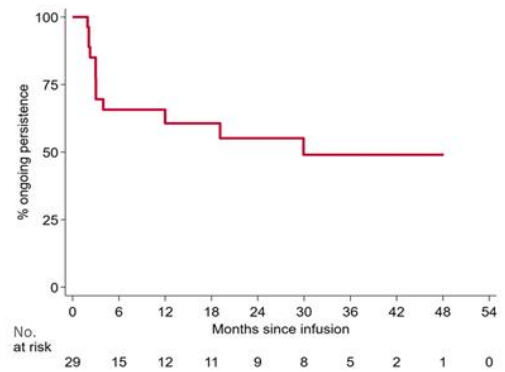
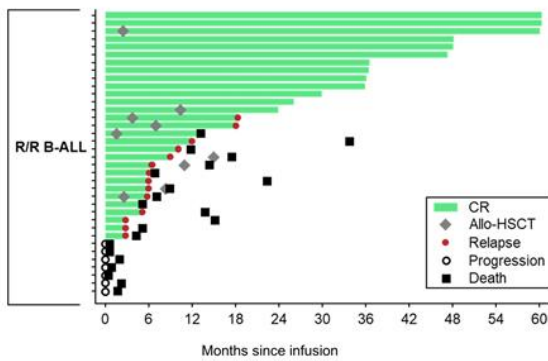
Median follow up 36.5 months; pooled analysis Phase 1b ALLCAR19/Phase 1b FELIX



*Censored for allo-HSCT and other anti-cancer treatment. Investigator-assessed disease evaluations were performed locally by CT and BM biopsy for B-ALL. Allo-HSCT, allogeneic hematopoietic stem cell transplant; B-ALL, B-cell acute lymphoblastic leukemia; BM, bone marrow; CI, confidence interval; CT, computed tomography; EFS, event-free survival; N/A, not available; obe-cel, obecabtagene autoleucel; OS, overall survival; R/R, relapsed/refractory. Roddie et al, ASH 2023, Poster 2114.

Durable remissions and prolonged persistence in patients with R/R B-ALL

Pooled analysis Phase 1b ALLCAR19 / Phase 1b FELIX



- ORR: 80.6% (95% CI: 64.0–91.8)
- All patients in ongoing remission were MRD-negative at last assessment
- Median DOR: Not reached (95% CI: 5.1–N/A)

- Ongoing CAR T persistence
 - 12 months: 60.6% (95% CI: 38.9–76.8)
 - 24 months: 55.1% (95% CI: 33.1–72.6)

Safety: No \geq grade 3 CRS reported; 4/36 \geq grade 3 ICANS; No new safety signals or deaths related to obe-cel

MRD status was determined using flow cytometry or IgH PCR/NGS (MRD-negative: $<10^{-4}$ [$<0.01\%$]). Loss of CAR T persistency was defined as the time from first obe-cel infusion to undetectable CAR T transgene (copies/ μ g DNA) in peripheral blood. Patients who proceeded to allo-HSCT with ongoing CAR T persistency were censored at the last result prior to receiving allo-HSCT. Allo-HSCT, allogeneic hematopoietic stem cell transplant; B-ALL, B-cell acute lymphoblastic leukemia; BM, bone marrow; CI, confidence interval; CR, complete remission; CT, computed tomography; DOR, duration of response; MRD, measurable residual disease; N/A, not available; NGS, next-generation sequencing; ORR, overall response rate; PCR, polymerase chain reaction; R/R, relapsed/refractory. Roddie et al, ASH 2023, Poster 2114.

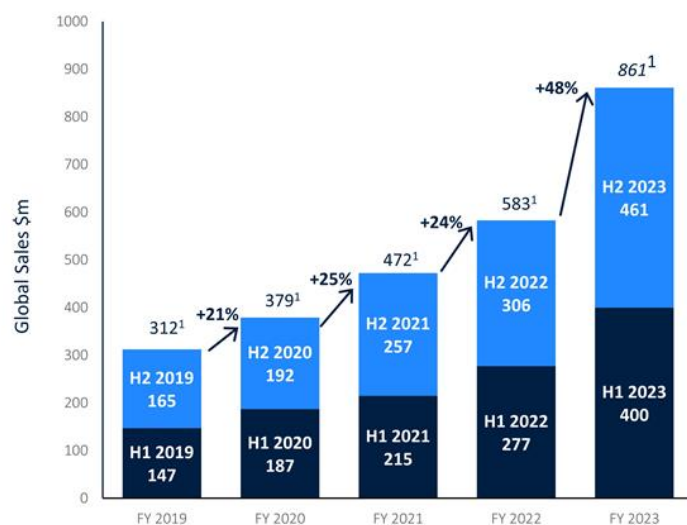


ALL: unmet need and market
overview

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

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

Reported Blincyto® sales¹



- Blincyto® sales price estimated to be \$103,5k² (for 1 cycle) supporting approx >2,500 commercial adult ALL patients across all lines of ALL treatment. Sales increased 48% year-over-year to \$861 million for the full year 2023
- Kymriah® is priced at \$508k in pediatric ALL. Breyanzi® is priced at \$447k in DLBCL³. Tecartus® is priced at \$424k³ for adult ALL
- Breyanzi® and other CAR T cell therapies are expanding delivery center footprint
- Tecartus® is expected to establish CAR T use in adult ALL
- If approved, obe-cel has the potential to be best-in-class curative therapy and expanding use beyond academic transplant centers

NOTES

1. As per Amgen quarterly SEC filings

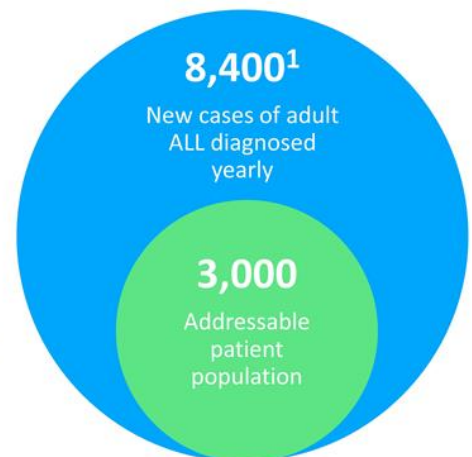
2. <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files>

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



NOTES

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

Critical drivers for potential market adoption if approved

CLINICAL DATA¹

Durable and robust response



- Morphological disease: CR/CRi rate of 74%, with 95% of evaluated responders were MRD negative¹
- No morphological disease: 100% of evaluable patients were MRD negative
- The event-free survival estimate at 12 months was 50% (median 16.6 months' follow-up)

Predictable and manageable tolerability

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

TREATMENT EXPERIENCE GOALS

Timely & reliable product supply

- Quality product with low out-of-spec rates
- Timely delivery
 - Sufficient capacity and manufacturing slot access
 - Short vein-to-release times

Best-in-class commercial systems and services integration

- Optimize relationship with accredited treatment centers

Commercial Launch
Readiness Plan

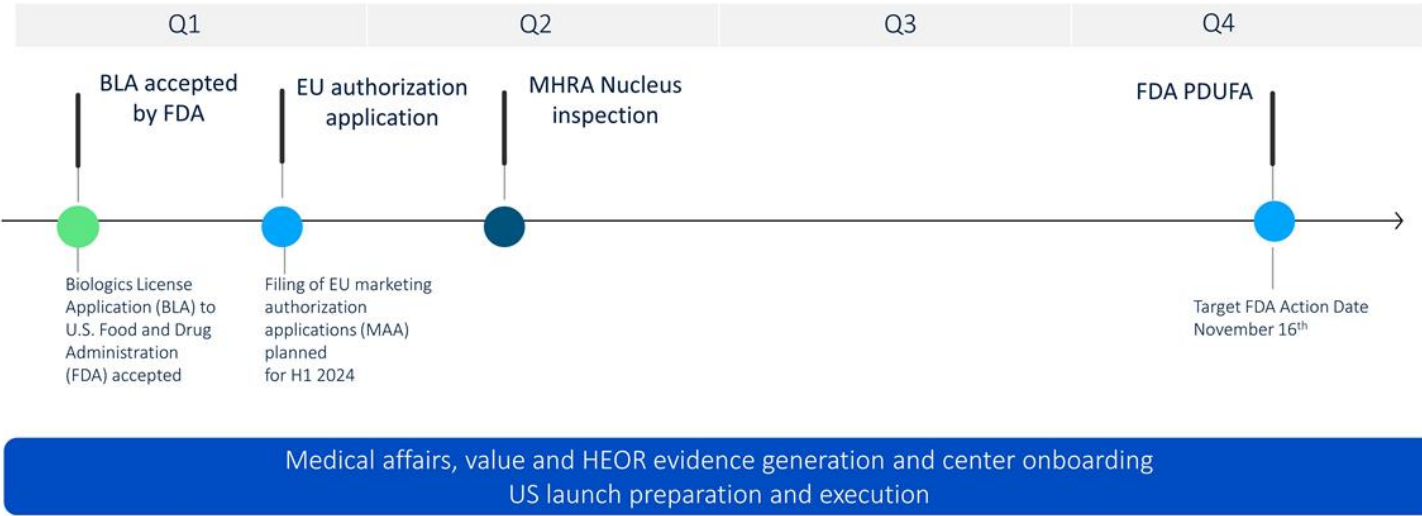
1. Roddie et al., ASH 2023, Data cut-off date: September 13, 2023



Commercial Launch Readiness

Obe-cel steps to commercialization in r/r adult B-ALL

Roadmap to a 2024 commercial launch



The Nucleus

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

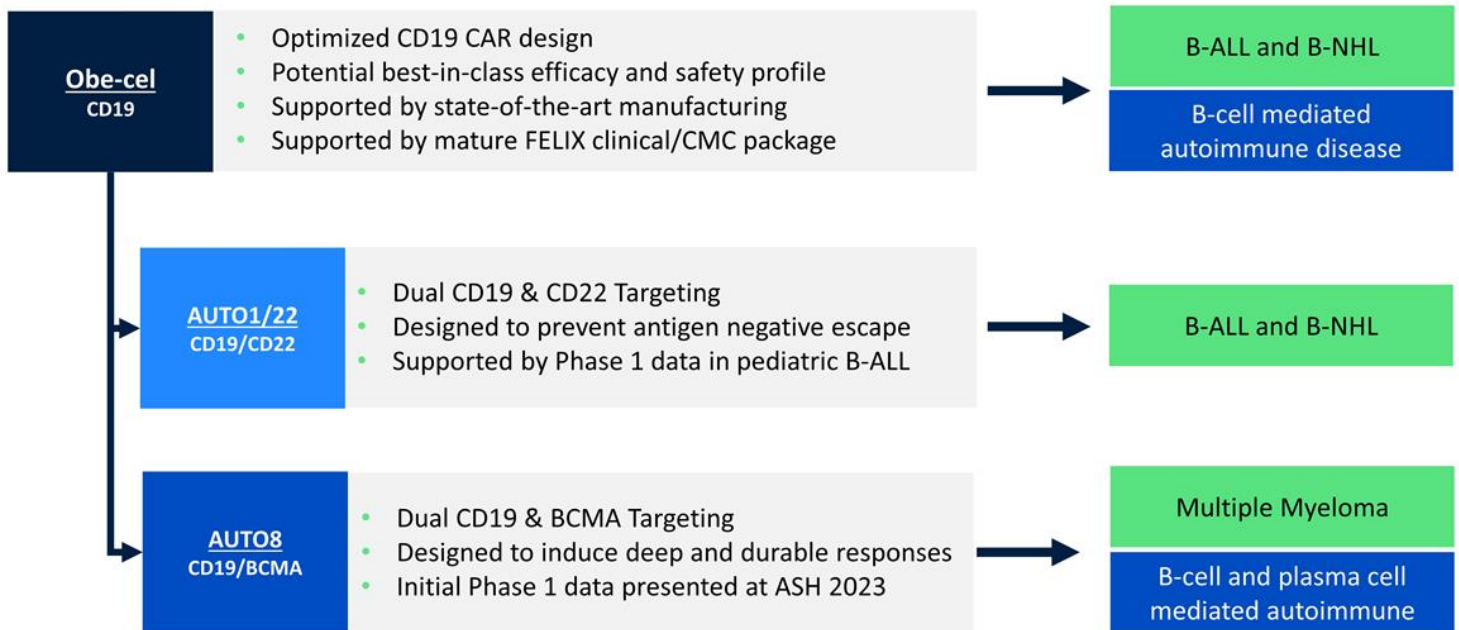




Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

The obe-cel product family and franchise opportunity



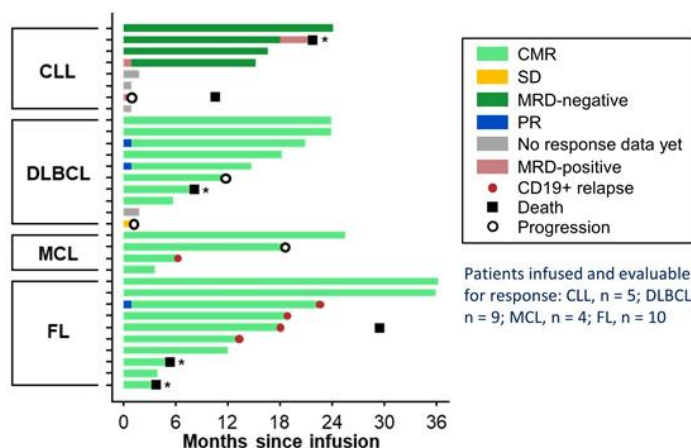
Obe-cel in B-NHL/B-CLL: High response rates with durable remissions

Data from ALLCAR19 extension: Long term persistence driving durable outcomes

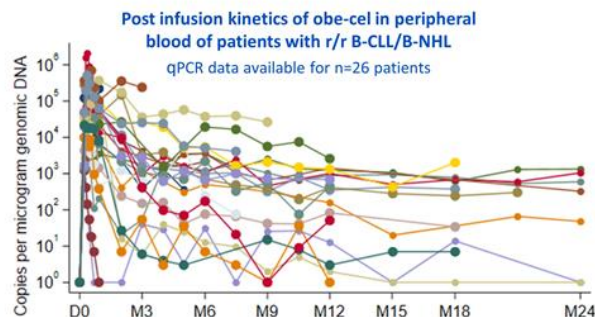
Responses by subtype

Subtype	ORR, n/N (%)
R/R CLL	4/5 (80)
R/R DLBCL	8/9 (89)
R/R MCL	4/4 (100)
R/R FL	10/10 (100)

Median follow-up 20.9 months (range 0.9 – 36.2)



• No ≥ grade 3 CRS and ICANS reported



Collaboration with

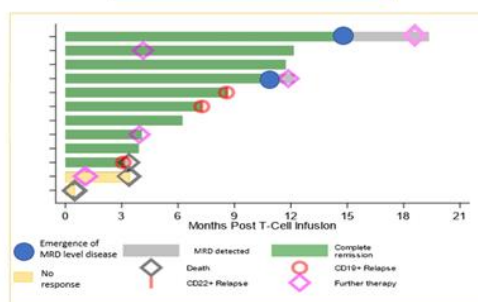
Analysis of ALLCAR19 extension phase in R/R B-CLL and B-NHL, data cut-off date September 13, 2023. *Patient death unrelated to obe-cel and without relapse or disease progression (COVID-19 [DLBCL and FL, n = 1 each]; grade 5 appendicitis on a background of myelodysplastic syndrome [FL, n = 1]; unrelated esophageal cancer [CLL, n = 1]). Roddie et al., ASH 2023 Poster 2114.

AUTO1/22 in pediatric ALL

No antigen negative relapse seen in responding patients

CARPALL Disease Response (n=12)	
Molecular MRD neg CR/Cri by d30	10 (83%)
Disease progression	2
Relapse	
Antigen negative relapse	0
CD19+/CD22+ relapse	5

Median follow-up 8.7 months



- Favorable adverse event profile with no severe CRS
- Excellent CAR T expansion and very encouraging activity:
 - 83% MRD negative CR/Cri
 - Despite high-risk pts (4 Kymriah failures, 3 CD19neg disease, 3 non-CNS extramedullary disease)
- 2 of 3 patients who had CD19neg disease achieved CR/Cri demonstrating a response to the CD22 CAR
- 1-year EFS 60% despite the high-risk patient cohort
- At median FU 8.7 months, no cases of leukemic relapse or emergence of MRD related to antigen escape

Collaboration with **UCL**

Ghorashian et al., EBMT Annual Meeting 2023

AUTO8: combining a sensitive BCMA CAR with the CD19 CAR from obe-cel

Designed to induce deep and durable responses

AUTO8

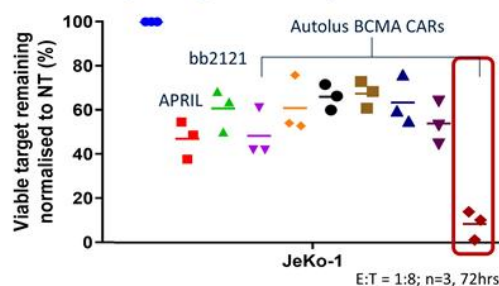
BCMA CAR

Novel format CAR designed to be highly sensitive to low BCMA density found on malignant plasma cells

CD19 CAR

Coupled to obe-cel to drive persistence and long-term durability of response, and to deplete CD19+ myeloma stem cell

Screening for high sensitivity BCMA binders



Phase 1 Design

Cohort 1: BCMA CAR

50MM — 150MM

Cohort 2: BCMA CAR
+ CD19CAR

50MM — 150MM

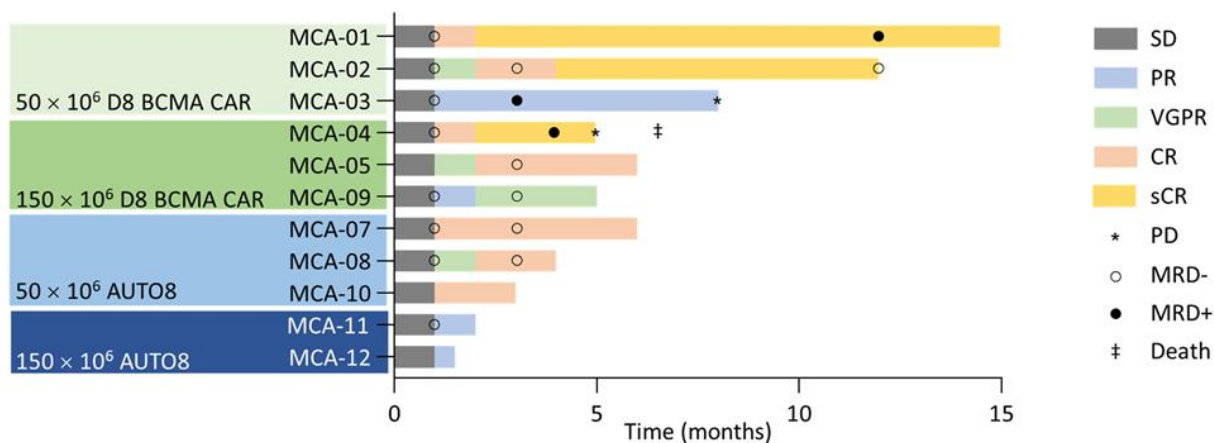
Initial data at ASH 2023; study ongoing

Collaboration with **UCL**

Initial data from MCARTY Phase 1 showed clinical responses in all patients

Both D8 BCMA CAR and AUTO8 associated with high response rate

- 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



Collaboration with **UCL**

AUTO8, D8 BCMA + obe-cel CARs; Median follow up 6 months (range 1–15); Lee et al., ASH 2023, Publication number 350. Data cut off 13 Nov 2023

* PR – partial response; VGPR – very good partial response, CR – complete response; sCR – stringent complete response

Initial safety data Phase 1 MCARTY study

D8 BCMA CAR and AUTO8 did not result in severe ICANS/CRS and were well tolerated with no DLTs

Adverse events, n (%)	D8 BCMA CAR 50 x 10 ⁶ (N = 3)		D8 BCMA CAR 150 x 10 ⁶ (N = 3)		AUTO8 50 x 10 ⁶ (N = 3)		AUTO8 150 x 10 ⁶ (N = 2)	
	Grade 1–2	Grade ≥3	Grade 1–2	Grade ≥3	Grade 1–2	Grade ≥3	Grade 1–2	Grade ≥3
Hematological								
Anemia	0	1 (33)	1(33)	2(67)	0	2 (67)	1(50)	1(50)
Neutropenia	0	3 (100)	0	3 (100)	0	3 (100)	0	2 (100)
Thrombocytopenia	1 (33)	1 (33)	1 (33)	2 (67)	0	2 (67)	0	1 (50)
CRS	3 (100)	0	3 (100)	0	2 (67)	0	2 (100)	0
ICANS	0	0	0	0	0	0	0	0

- CRS in 10 patients (91%) and all low grade; no patients reported ICANS
- Tocilizumab given to 7 patients (64%) and steroids to 2 patients (18%)

Collaboration with 

AUTO8, D8 BCMA + obe-cel CARs; Lee et al., ASH 2023, Publication number 350 – Data cut off 13 Nov 2023

Plan to start SLE Phase 1 study in early 2024 in sites in the UK and Spain

Uniquely positioned to develop CAR T therapy candidate in autoimmune disease

Obe-cel's potential characteristics

Favorable tolerability to drive physician and patient acceptability in rheumatology settings

Deep cut into the CD19+ B and plasma cell compartment to remove all autoreactive clones

Development of robust, economical and scalable manufacturing and commercial infrastructure

Potential for smaller clinical program and accelerated regulatory path to launch if a high degree of treatment effect is observed

Supporting evidence

- ✓ 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
- ✓ Evaluation in B-ALL with very high rate of MRD negative complete remissions (95% of evaluated responders) in FELIX study
- ✓ 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
- ✓ 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



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	H1 2024: MAA Application to EMA November 16, 2024: PDUFA date
Obe-cel	Systemic Lupus Erythematosus	CD19	CARLYSLE		Preclinical	Early 2024: Phase 1 initiation in UK
Obe-cel	B-NHL and CLL	CD19	ALLCAR19		Phase 1	Data in peer reviewed journal
Obe-cel	PCNSL	CD19	CAROUSEL		Phase 1	Data in peer reviewed journal
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL	  *	Phase1	Data in BLOOD August 2023
AUTO8	Multiple Myeloma	CD19 & BCMA	MCARTY		Phase 1	Updated clinical data in 2024

Additional pipeline programs						
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1		Phase 1	Data in peer reviewed journal
AUTO5	TRBC2+ Peripheral TCL	TRBC2	-		Preclinical	Preclinical data in peer reviewed journal
AUTO6NG	Neuroblastoma	GD2	MAGNETO	  *	Phase 1	Study open for enrollment
AUTO9	Acute Myeloid Leukemia	CD33, CD123 & CLL1	TBD		Preclinical	Estimated Phase 1 start 2025

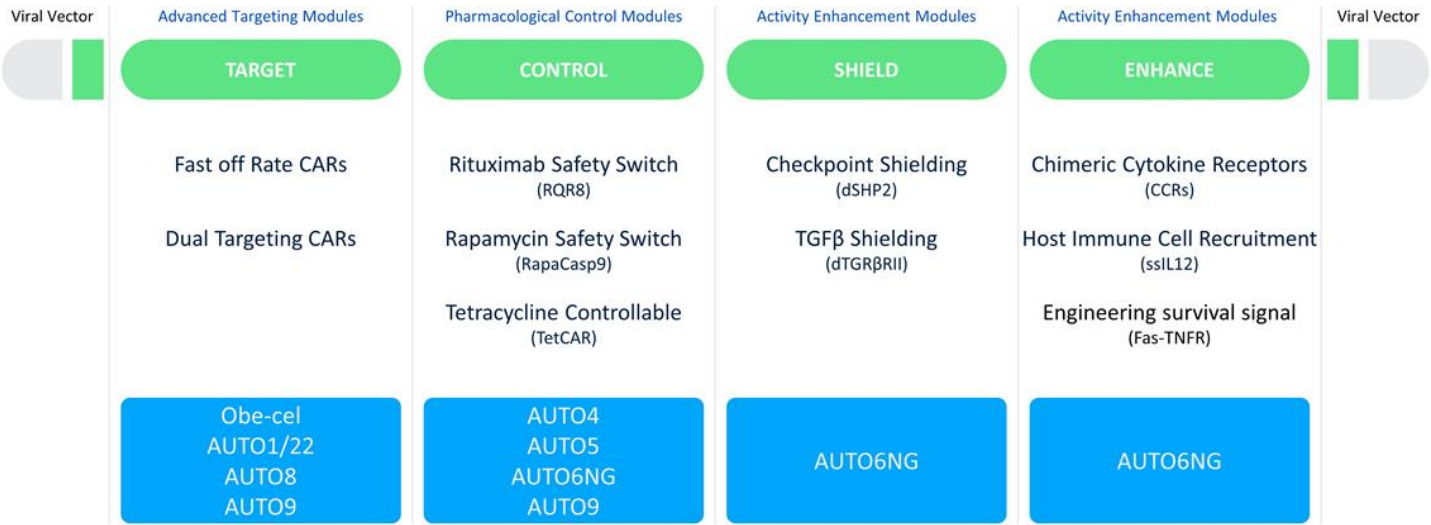
Oncology

Autoimmune

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

A broad toolkit which is core to our strategy of modular innovation

Advanced T cell programming



Underpinned by a broad and robust patent estate of more than 80 global patent families

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



Leveraging technology platform for BioNTech's programs



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



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

The image features a dark blue background with two large, overlapping, semi-transparent circles. One circle is a vibrant blue and is positioned on the left side, while the other is a darker shade of blue and is located in the upper right corner. The text 'Upcoming news flow' is written in a white, sans-serif font, centered horizontally and positioned between the two circles.

Upcoming news flow

Autolus planned news flow

Anticipated Milestone or Data Catalysts	Anticipated Timing
Obe-cel in autoimmune disease – refractory SLE Phase 1 study initiation	Early 2024
Obe-cel Marketing Authorization Application (MAA) to EMA	First half 2024
Potential MHRA approval of Nucleus site	First half 2024
Obe-cel FELIX data update at EHA & ASH 2024	June & December 2024
FDA PDUFA target action date	November 2024



Summary

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

Scaling company toward commercialization



Obe-cel potentially best in class CAR T for r/r adult ALL

- FELIX pivotal trial showed high ORR, encouraging EFS and favorable tolerability with low levels of high-grade CRS and ICANS
- PDUFA date 16 Nov 2024
- EMA submission planned for 1H 2024



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 \$256.4M (Q3 2023)
- Runway into 2025*
- Enables execution on current strategy through expected approval of obe-cel

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

*Does not include proceeds from BioNTech

Thank you

