Autolus

Developing Next Generation Programmed T Cell Therapies

May 2025



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Autolus is positioned for value creation

Obe-cel product franchise supports multiple growth opportunities

- Highly active, fast off-rate CD19 CAR T therapy with well managed safety profile
- Commercial presence in 60 US centers by end 2025
- Approved in US and UK, EU approval under review
- Developing early-stage pipeline of novel CAR-T therapies

In-house, purpose-built manufacturing facility

Product	Indication	Target	Preclinical	Phase 1	Phase 2/Pivotal	Approved
AUCATZYL®	Adult ALL	CD19				
obe-cel	Lupus Nephritis	CD19				
obe-cel	Progressive Multiple Sclerosis	CD19				
obe-cel	Pediatric ALL	CD19				

Commercial execution and market expansion supported by:

Build









H Bristol Myers Squibb

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AUTOLUS' FIRST APPROVED PRODUCT AUCATZYL®

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

AUCATZYL[®] now FDA and MHRA approved

AUCATZYL indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (B-ALL)

- Highly active, fast off-rate CD19 CAR T therapy with a well managed safety profile
- First FDA-approved CAR T therapy without a REMS obligation building on a substantial safety data base
- First and currently only approved CAR T therapy with customized, tumor-burden guided dosing
- Established infrastructure for manufacturing and commercialization
- Commercial presence in key US centers building to 60 centers in H2 2025
- Expect to add UK and select EU countries in upcoming 12 months





The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukemia

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 <u>Prescribing Information</u>, including **BOXED WARNING** and Medication Guide.

We believe AUCATZYL[®] has a unique mechanism of action

Clinical data show increased activity and reduced toxicity



On-Rate: K_a [M⁻¹S⁻¹]

CAT19 fast off-rate binder²

CD8-derived hinge region/ transmembrane domain²

> **4-1BB co-stimulatory domain**^{1,4} Shown to enhance CAR T-cell expansion and reduce exhaustion compared with CD28 CARs in preclinical studies

CD3Z activation domain¹



Fast off-rate

Off Rate: K_d [S⁻¹]

Potential for improved potency, reduced toxicity

Avoided over-activation of CAR T cells	\rightarrow	Reduced toxicities
Increased CAR T peak expansion	\rightarrow	Improved peak activity and persistence
Avoided exhaustion of CAR T-cells	\rightarrow	Improved engraftment Improved persistence

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

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

AUCATZYL was approved based on results from the FELIX trial



Background

- Open-label, 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 highgrade CRS and ICANS
- Timely and reliable clinical product supply and logistics despite COVID-19 pandemic restrictions
- 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

FELIX trial published in New England Journal of Medicine¹

Favourable response rate and tolerability, despite challenging patient population

High overall response rate with deep molecular responses

 Durable responses, particularly in patients with a low-tointermediate bone marrow burden

Response by disease status at lymphodepletion	Overall Remission Rate (CR/CRi)
All patients (n=127)	77%
Morphological disease (n=91)	75%
Measurable residual disease (n=29)	96%
Isolated extramedullary disease (n=7)	71%

Excellent tolerability profile

- Very low rates of high-grade immunotoxicities
- No high-grade events in low disease burden patients

Safety by disease burden at lymphodepletion	Grade ≥3 CRS	Grade ≥3 ICANS
All patients (n=127)	2%	7%
>75% Blasts (n=40)	2%	12%
5-75% Blasts (n=51)	4%	8%
<5% Blasts (n=36)	0%	0%

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FELIX trial: Tumor burden impact on event-free survival in adult ALL

Survival outcomes show potential of long-term plateau with 12-month EFS rates 49.5%



FELIX trial: Tumor burden impact on overall survival in adult ALL

Estimated 6- and 12-month overall survival rates were 80.3% and 61.1%, respectively



In all patients, the median OFS ٠ was 15.6 months

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1. Roddie C, et al "Obecabtagene autoleucel in B-cell acute lymphoblastic leukemia" N Engl J Med 2024; DOI: 10.1056/NEJMoa2406526

AUTOLUS' FIRST APPROVED PRODUCT AUCATZYL[®] Launch progress

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

Strong momentum in first quarter of the U.S. AUCATZYL[®] launch

Q1 2025 AUCATZYL Net Product Sales

\$9.0 million

Physician interest based upon product profile and unmet patient need is driving encouraging uptake

39 Treatment Centers Authorized as of 05/07/25



- ~90% of total U.S. medical lives covered
- CMS published HCPCS coding determinations and OPPS payment rates, making AUCATZYL eligible for reimbursement for patients on government programs

AUCATZYL growth opportunities in ALL

Expansion

Near-Term New Markets	 Conditional marketing authorization in the UK received April 25, 2025 EMA decision expected in 2H 2025 Country-by-country launches planned based on pricing and reimbursement decisions 				
	Strong data from the FELIX study, support indication expansion opp	and experience in the market to-date, ortunities:			
ALL Potential Indication Expansion	 Adult ALL in frontline: Explore by investigator sponsored trials 	 Pediatric ALL: Ongoing P1 study with plans to report data in 2H 2025 and review regulatory path with FDA 			

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
- 1st line therapy is based on high dose chemotherapy cycles given over a period of 12 – 36 months
- In 1st line therapy approx. 90% of patients achieve a CR, but most patients relapse
- Blincyto[®] is incorporated into frontline therapy as an additional component
- Aucatzyl[®] offers opportunity as a standalone therapy for patients in 2nd and subsequent lines of therapy



AUCATZYL[®] is poised to fill the unmet need for r/r ALL patients

- We believe AUCATZYL is a transformative product in the r/r B-ALL space
- Unique MOA designed to deliver potency and persistency that results in deep and durable efficacy
- Favorable tolerability profile
- Customized tumor-burden guided dosing
- Well-positioned to deliver therapy globally with Autolus' proven reliable manufacturing



Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

The obe-cel product family and franchise opportunity

Potential value-creation through multiple life-cycle management and market expansion opportunities



MOA and established commercial capabilities are key differentiators

Obe-cel is the only CD19 CAR with an FDA approval outside of autoimmune disease

Autolus Potential Advantage



Favorable tolerability to drive acceptability in non-oncology indications



Deep cut into the CD19+ B and plasma cell



Robust, economical and scalable manufacturing and established commercial infrastructure



Potential for accelerated clinical program



Only FDA-approved CAR-T therapy in development for autoimmune indications

Supports differentiated approach and potential for obe-cel in autoimmune disease areas

Initial data from CARSLYLE SLE P1 trial in patients with severe disease

Baseline SLEDAI-2K score ranges from 16 to 28

Severe patient population

- Patients aged 19 to 50 years had 3 to 23 years of disease history and exhausted prior therapy options
- All patients had prior B-cell depleting agent exposure, 2 also BAFF inhibitors, 3/6 also calcineurin inhibitors
- Lupus nephritis: 5/6 patients had a class IV disease, 4/6 had also a class V component
- Kidney function was significantly impaired in 4 of 6 patients (<60 ml/min/SA)

No high-grade CRS, No ICANS observed No DLTs observed

Transient hypertension, including G3, due to abnormal kidney function prior to start of therapy according to PI's judgement nor pre-existing hypertension (3/6)

TEAE, Grade	#1	#2	#3	#4	#5	#6	Patients, n (%)	
CRS	_	_	1	-	1	1	3 (50%)	
ICANS	_	-	-	-	-	-	0 (0%)	

Highest grade of treatment-emergent adverse event observed by patient:

Preliminary CARLYSLE results; additional follow up planned for H2 2025

10+ point drop in SLEDAI-2K scores and 3 of 6 patients with renal CRs by month 3





- All patients benefited significantly from obe-cel
- Skin: rash, alopecia and mucosal ulcers resolved by M3
- Musculoskeletal: Arthritis resolved by M1
- Complement normalized in all patients by M1
- 3 of 6 patients with complete renal response by M3
- Two patients had only one month follow up

Lupus nephritis development strategy

Leveraging a fast to market strategy

Development Rationale

- LN is assessed by quantitative lab- parameter based endpoints (CRR) vs. SLE with a composite endpoint depending on clinical assessments
- Current guidelines require for Class III/IV LN triple therapy including B-cell modifier or CNI, without any treatment options for those being refractory to both
- Lack of SOC for refractory LN opens the possibility to single arm trial path for initial approval
- Outcome of refractory LN single arm trial serves as good predictor for RCT in earlier LN vs. SOC



Anticipate dosing first patient in Phase 2 pivotal trial by year end 2025

Refractory lupus nephritis is a high unmet medical need

- Kidneys are one of the most common organs involved in SLE -30% – 40% are lupus nephritis patients
- High disease activity is associated with inflammatory processes
- Uncontrolled inflammation leads to high chronicity due to accumulated kidney damage
- Despite treatment advances including regulatory approvals of belimumab and voclosporin the goal to sufficiently improve short and long-term outcomes in patients with LN remains unmet

• There are no treatment options for refractory patients



Multiple sclerosis development strategy

Establish Phase 1 Clinical Proof of Concept in MS

3 x 6 dose escalation design - a higher dose may be required for CNS effect

Biomarker readouts to provide nearer term
evidence of biological effect at 6 months +



Initiate Phase 2/3 study in progressive MS patients exhibiting PIRA

- Anticipate a randomised phase 2/3 study design as path to approval
- Phase 1 clinical PoC is derisking for initiation of development in other neurology indications

Anticipate dosing first patient in Phase 1 trial by year end 2025

Progressive multiple sclerosis is a high unmet medical need



1: GlobalData MS Market Forecast 2020-2030 April 2023

Partnerships, pipeline programs and technologies

A broad portfolio of potential next generation modular T cell therapies

Pipeline supports growth with multiple development opportunities

Product	Indication	Target	Preclinical	Phase 1	Phase 2/Pivotal	Approved	Status
AUCATZYL®	Adult ALL	CD19					FDA & MHRA licensed, EMA under review
obe-cel	Lupus Nephritis	CD19					Enrolling H2 2025
obe-cel	Progressive Multiple Sclerosis	CD19					Enrolling H2 2025
obe-cel	Pediatric ALL	CD19					Initial data H2 2025

	Product	Indication	Target	Preclinical	Phase 1	Status
es	obe-cel*	B-NHL & CLL	CD19			Data in peer reviewed journal
niti	obe-cel*	Primary CNS Lymphoma	CD19			Data in peer reviewed journal
age ortu	AUTO8	Multiple Myeloma	CD19 & BCMA			Phase 1 Enrolling
eline oppo	AUTO8	Light chain Amyloidosis	CD19 & BCMA			CTA approved; first patient expected by YE 2025
	AUTO1/22*	Pediatric ALL	CD19 & CD22			Initiating new cohort in Q2 2025
	AUTO6NG*§	Neuroblastoma	GD2			Patient dosing ongoing; preliminary data expected in 2026
Pip	AUTO4/5	TRBC1/2+ Peripheral TCL	TRBC1/2			Moving back into translational research
	AUTO9*	Acute Myeloid Leukemia	CD33,123,CLL1			Preclinical work ongoing

*UCL Collaboration **#UCL** § BioNTech holds option to co-fund and co-commercialise **BIONTECH**

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

Upcoming milestones

Antic	Anticipated Timing	
obe-cel	Longer-term follow up from FELIX clinical trial	Mid-Year
obe-cel	Notification from EU regarding MAA decision in adult r/r ALL	H2 2025
obe-cel	Initial data from PY01 trial in pediatric ALL	H2 2025
obe-cel	SLE Phase 1 trial presentation at medical conference	Q4 2025
obe-cel	First patient dosed in Phase 2 trial in lupus nephritis	YE 2025
obe-cel	First patient dosed in progressive MS Phase 1 trial	YE 2025
AUTO8	First patient dosed in AL amyloidosis Phase 1 trial (UCL collaboration)	YE 2025

Oncology Autoimmune/B-cell mediated disease

Summary

Autolus is positioned for commercial execution and market expansion

Obe-cel product franchise supports multiple growth opportunities

- Highly active, fast off-rate CD19 CAR T therapy with well managed safety profile
- Commercially approved in US and UK, EU approval under review
- Commercial presence in 60 US centers by end 2025
- Developing early-stage pipeline of novel CAR-T therapies



Commercial execution and market expansion supported by:



In-house, purpose-built manufacturing facility Design Build



Operations

Strategic collaborations and strong cash position \$517M* as of Q1 2025 BIONTECH Moderna (I) Bristol Myers Squibb



Thank you

Autolus.com



Appendix

Autolus.com

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://cww.bts.gov/data-spotlight/commercial-aviation-2020-downturn-airline-passengers-employment-profits-and-flights"/https://covid19.who.int/ Accessed October 2023; 2World Health Organization COVID–19 dashboard [online]. Available at: https://cww.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://cww.bts.gov/data-spotlight/commercial-aviation-2020-downturn-airline-passengers-employment-profits-and-flights Accessed October 2023

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

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

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