# Autolus

# Developing Next Generation Programmed T Cell Therapies



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#### **Autolus Overview**

#### Building a fully integrated CAR T company



- Lead product obe-cel potentially best-inclass for relapsed/ refractory adult acute lymphoblastic leukemia (ALL)
- Phase 2 FELIX ALL initial data expected H2 22
- Updated exploratory data in NHL from Phase 1 studies expected in 2022



- Pipeline built on modular innovation addressing cancers with limited treatment options
- AUTO1/22 in paediatric ALL
- AUTO4 /5 in T cell lymphoma
- AUTO6NG in neuroblastoma
- AUTO8 in multiple myeloma



- In house cell manufacturing for clinical trial conduct
- Commercial fit-forpurpose cell manufacturing facility under construction with planned annual capacity of 2000 patient products



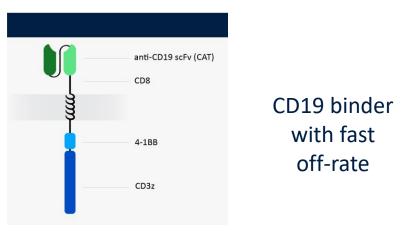
- Collaboration with Blackstone Life Sciences to develop obe-cel in adult ALL
- Moderna granted exclusive license for binders to up to four IO targets
- Pipeline programs not partnered



# LEAD CLINICAL PROGRAM Obe-cel

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

### obe-cel has a unique mechanism of action



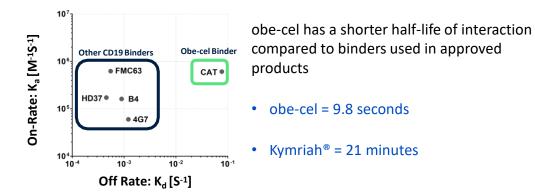
Improved potency, reduced toxicity .

> Avoids over-activation of CAR T cells -> Reduced toxicities

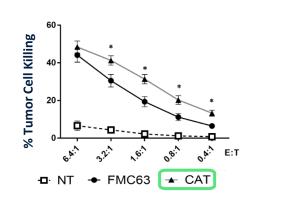
Increased CAR T peak expansion -> Improved persistence

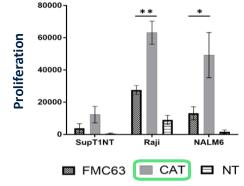
Avoids exhaustion of CAR T cells -> Improved engraftment -> Improved persistence

Fast off-rate 



**Enhanced cytotoxicity and proliferation** ۲





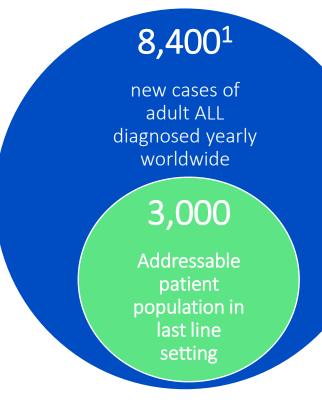
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Ghorashian et al. Nature Medicine 2019

# obe-cel for adult Acute Lymphoblastic Leukemia (ALL): high unmet need

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<sup>®</sup> and Tecartus<sup>™</sup>
  - Therapies are highly active, but require subsequent allograft to achieve durability
  - Notable toxicity with high incidences of severe CRS and cases of fatal neurotoxicity
- Opportunity to expand the addressable patient population in earlier lines of therapy



## obe-cel is a potentially transformational therapy for adult ALL

Unique CAR T design drives differentiated product profile

- Unique mechanism of action built on a fast off-rate from CD19 target antigen
- High Overall Response Rate (ORR) across all patient populations evaluated<sup>1</sup>
- Sustained morphological Event Free Survival (EFS) of 46% with a median followup of 29.3 months<sup>2</sup>
- Long term CAR T persistence drives durability of effect
- Favorable safety profile:
  - No high-grade Cytokine Release Syndrome (CRS)
  - Limited immune effector cell-associated neurotoxicity syndrome (ICANS)

en	obe-cel
	Orphan Drug designation by FDA for B-ALL
low-	Orphan Medical Product designation by EMA in ALL
	<b>RMAT designation</b> by FDA in R/R B-ALL
)	Prime designation by EMA in R/R B-ALL
	ILAP designation by MHRA in Adult R/R B-ALL

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#### NOTES

1. FELIX study

ALLCAR19 study

## obe-cel shows consistent clinical profile across three clinical studies

Data from 3 studies - range of ages and patient conditions

 obe-cel has a favourable safety profile with no high-grade CRS and limited ICANS

	CARPALL <sup>#1</sup> Peds ALL	ALLCAR19 <sup>#2</sup> Adult ALL	FELIX 1b <sup>#3</sup> Adult ALL
n	14	20	16
ORR (CR & CRi) (95% CI)	86% (57%, 98%)	85% (62%, 97%)	75% (48%, 93%)
CRS <sup>1</sup> ≥ Grade 3	0%	0%	0%
CRS <sup>1</sup> any grade	93%	55%	56%
Neurotox <sup>2</sup> <u>&gt;</u> Grade 3	7%	15%	6%
Neurotox <sup>2</sup> any Grade	50%	20%	13%
Median Age	9	42	42
Bone marrow blast >20% at LD	21%	60%	75%
Bone marrow blast <5% at LD	71%	35%	25%
Prior blinatumomab	7%	25%	56%

<sup>1</sup> CRS grading based on Lee et al (2014) for CARPALL and ALLCAR19, and ASTCT grading (Lee et al 2019) for FELIX

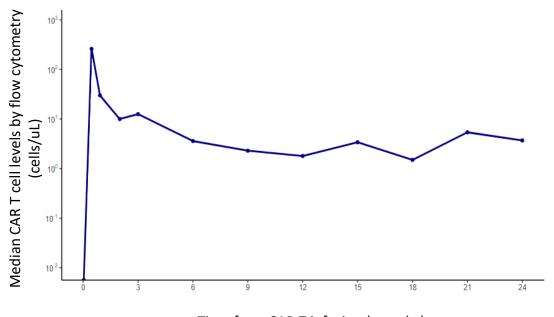
<sup>2</sup> Neurotoxicity grading based on CTCAE v4.03 for CARPALL and ALLCAR19, and ASTCT ICANS grading (Lee et al 2019) for FELIX

#1 Ghorashian et al. Nature Medicine 2019#2 Roddie et al. J Clin Oncol, 2021#3 Culshaw et al, ASH 2021, abstract #477

#### obe-cel shows sustained event-free survival beyond 30 months

Long term CAR T persistence drives durability of effect

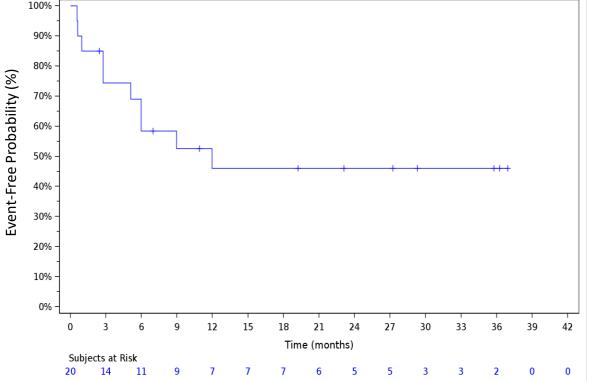
#### Median CAR T cell levels in peripheral blood



Time from CAR T infusion (months)

# 70%

**ALLCAR19 Event-Free Survival** 



#### Median (range) follow-up time: 29.3 months (range 0.6 – 41.5)

Median (95% CI) EFS: 12 months [2.8, NE] EFS starting from Month 12 going forward: 46% (95% CI [23%, 67%])

Data cut for ALLCAR19 study: 15-OCT-2021; Patients were received SCT post obe-cel infusion are censored at date of SCT

#### Unmet medical need in r/r adult ALL despite approved agents

Current standard of care and recently approved agents in r/r adult ALL

	Stand	ard of Care	Recently FDA approved
	<b>Blincyto</b> <sup>1</sup>	Besponsa <sup>2</sup>	Tecartus <sup>3</sup>
Ν	271	109	54
ORR	44%	81%	65%
EFS/PFS	31% @ 6m ~10% @ 18m	~45% @ 6m ~20% @ 18m	~65% @ 6m ~25% @ 18m
median DoR	7.3m	4.6m	13.6m
median OS	7.7m	7.7m	18.2m
CRS <u>&gt;</u> Grade 3	5%	Not reported	26%
Neurotox any Grade	65%	Not reported	87%
Neurotox ≥ Grade 3	13%	Not reported	35%
Subsequent SCT post treatment	24%	41%	18%
Other notable observations	NA	14% Hepatic VoD	40% vasopressor use

1. Kantarjian et al., 2017/ USPI (product label) 2. Kantarjian et al., 2016/ USPI (product label) 3. Shah et al. Lancet 2021/ USPI (product label) The estimates of EFS/PFS are read from the KM curves. The efficacy data in ZUMA-3 are based on the modified ITT population while the blinatumomab and inotuzumab data are based on the ITT population. 10

**Reported Blincyto<sup>®</sup> sales<sup>1</sup>** 

# obe-cel could launch into an expanding ALL market

Blincyto<sup>®</sup>, current market leader, shows annual revenue growth of 25%

#### 500 **472**<sup>1</sup> 450 +25%400 379<sup>1</sup> + 21% H2 2021 350 257 312<sup>1</sup> Global Sales \$m 300 H2 2020 192 250 H2 2019 165 200 150 H1 2021 H1 2020 100 215 H1 2019 187 147 50 0 FY 2019 FY 2021 FY 2020

- Blincyto<sup>®</sup> sales price estimated to be \$178k<sup>3</sup> (for 2 cycles) supporting approx. >2,000 commercial adult ALL patients, growing at a rate of 25%
- Kymriah<sup>®</sup> is priced at \$475k in pediatric ALL. Breyanzi<sup>®</sup> is priced at \$410k in DLBCL<sup>4</sup>. Tecartus<sup>™</sup> is priced at \$399k for adult ALL.
- Breyanzi<sup>®</sup> and other CAR T cell therapies are expanding delivery center footprint
- Tecartus<sup>™</sup> is expected to establish CAR T use in adult ALL
- obe-cel has the potential to be best-in-class curative therapy expanding use beyond academic transplant centers

#### NOTES

- 1. As per Amgen quarterly SEC filings
- 2.H2 2021 is not yet reported, this is just an extrapolation based on H1 2021 reported sales 3.https://www.medscape.com/viewarticle/836879
- 4. Bristol Myers finally wins FDA approval for cancer cell therapy | BioPharma Dive
- Komodo Health 2015 2020

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### Next steps: obe-cel initial data (FELIX) expected in H2 2022

obe-cel is the first Autolus program to move into a pivotal program: full data in H1 2023



#### Data in MRD population will enable obe-cel to maximise outcomes from the study

- Autolus plans to evaluate a separate cohort of up to 50 additional patients with Minimal Residual Disease (MRD)
- Patients to be recruited in parallel to the main Felix cohort
- The additional data aims to establish the profile of obe-cel in patients across all levels of disease burden in adult ALL
- Data from the population has potential to support adoption as earlier line treatment

# Building obe-cel into a franchise

Deep value program with broad applicability

#### Capitalising on the unique profile of obe-cel

#### Clinical data supports differentiated product profile

- High degree of activity and persistence -> drives long term outcomes
- Potential best-in-class safety profile -> will drive adoption of obe-cel in all clinical settings
- Initial NHL data is consistent with this profile

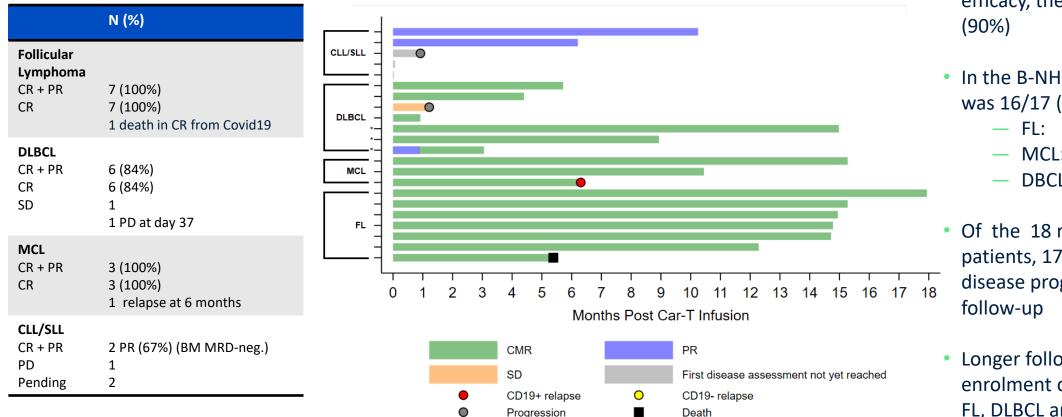
#### • Solid foundation for onward development

PRODUCT	INDICATION	TARGET	STUDY NAME	PHASE
obe-cel	Adult ALL	CD19	FELIX	Pivotal
obe-cel	B-NHL & CLL	CD19	ALLCAR19*	Phase 1
obe-cel	Primary CNS Lymphoma	CD19	CAROUSEL*	Phase 1
AUT01/22	Pediatric ALL	CD19 & CD22	CARPALL*	Phase 1
B Cell Malignancie	15			* Collaboration with UCL

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# EHA data: encouraging efficacy and duration of response in NHL/CLL

Long term persistence drives durable outcomes



Median (Range) Follow-Up Time:

- FL/DLBCL: 9.2 Months (Range 1.9-19.1)
- MCL/CLL: 8.9 Months (Range 0.0-19.7) ٠

Of 20 patients evaluable for efficacy, the ORR was 18/20

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- In the B-NHL cohorts the CRR was 16/17 (94%)
  - 7/7
  - MCL: 3/3
  - DBCL: 6/7
- Of the 18 responding patients, 17/18 are without disease progression at last
- Longer follow-up and enrolment of additional MCL, FL, DLBCL and CLL/SLL patients is ongoing

DLBCL\* = transformed follicular lymphoma

Data Cutoff: 12-May-2022

#### Primary CNS Lymphoma: favorable tolerability profile

- No grade high grade CRS was observed using IV or intraventricular obe-cel administration
- 2 cases of grade 3 ICANS were reported following IV infusion
  - 1 patient improved with steroids / toci
  - 1 patient had several neurological deficits consistent with progressive disease and didn't respond to steroids / toci
- 2 patients died from progressive PCNSL

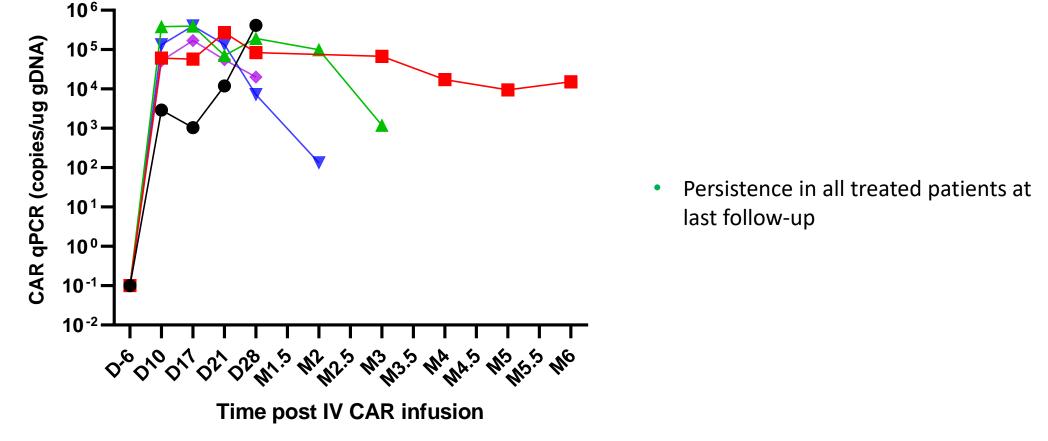
#### Adverse Events of Special Interest

Event N = 6 patients	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
CRS*	6	2	4**	0	0
ICANS	3	1	0	2	0

\*CRS grading by grading by ASTCT consensus criteria, Lee et al 2019 \*\*Grade 2 CRS in 3 patients with IV AUTO1 and 1 patient with I-VEN AUTO1

#### obe-cel shows excellent T cell expansion and engraftment

Persistence of obe-cel demonstrated by qPCR



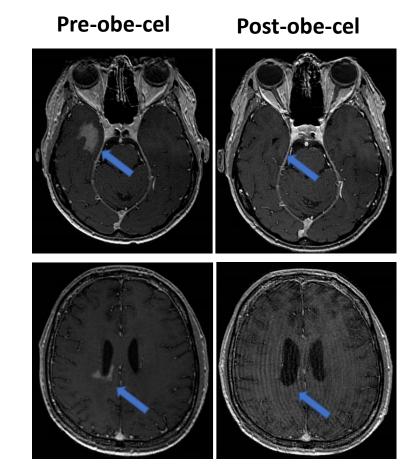
CAR, chimeric antigen receptor; VCN, vector copy number; qPCR, quantitative polymerase chain reaction

## obe-cel shows encouraging initial efficacy and durability in PCNSL

Overall response rate was 4/6 (67%) and these patients are without disease progression at last follow up

							N (%)	)					
			CR + CR PR	PR		2		%) %) (1					
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					<u></u>	SD		<b>•</b>		CR			
					× +	Death Patient n	ot treat	ed		Dose 2			

Median Follow-Up Time: 4.7 Months (Range 1-10)



Disease assessment by MRI imaging

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### Summary and next steps for obe-cel

Building a franchise through broad applicability

- Favourable and consistent safety profile demonstrated across all indications
- ✓ Of patients evaluable for efficacy across MCL, DLBCL, FL and CLL the ORR was 18/20 (90%)
- ✓ In the B-NHL cohorts, the CRR was 16/17 (94%)
- In the CLL cohort a best response of a PR was achieved in 2/3 patients, notably both achieved MRD-negativity in their marrow and both remain in PR at 10 and 6 months respectively
- Of the responding MCL, DLBCL, FL and CLL patients, 17/18 (94%) are without disease progression at last follow-up
- Encouraging initial data in PSNSL with 4/6 patients (2 CR and 2 PR) in ongoing responses at last follow up



• Longer follow-up and enrolment of additional MCL, FL, DLBCL and CLL/SLL patients is ongoing

# Pipeline

A broad portfolio of next generation modular T cell therapies

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

Advanced T cell programming

Viral Vector	Advanced Targeting Modules	Pharmacological Control Modules	Activity Enhancement Modules	Allogeneic Programming Modules	Viral Vector
	TARGET	CONTROL	SHIELD	ENHANCE	
	Fast off Rate CARs	Rituximab Safety Switch (RQR8)	Checkpoint Shielding (dSHP2)	Chimeric Cytokine Receptors (CCRs)	
	Dual Targeting CARs	Rapamycin Safety Switch (RapaCasp9)	TGFβ Shielding (dtgrβrii)	Host Immune Cell Recruitment (ssIL12)	
		Tetracycline Controllable (TetCAR)			
	obe-cel AUTO1/22 AUTO8	AUTO4 AUTO5 AUTO6NG	AUTO3NG AUTO6NG	AUTO3NG AUTO6NG	

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# Pipeline

Designed to address limitations of current T cell therapies

PRODUCT	INDICATION	TARGET	STUDY	PRE CLINICAL	PHASE 1	PHASE 2/ PIVOTAL	BLA
obe-cel	Adult ALL	CD19	FELIX				
obe-cel	B-NHL & CLL	CD19	ALLCAR19 Ext*				
obe-cel	Primary CNS Lymphoma	CD19	CAROUSEL*				
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL*				
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1				
AUTO5	TRBC2+ Peripheral TCL	TRBC2					
AUTO6NG	Neuroblastoma; Other tumour types	GD2					
AUTO8	Multiple Myeloma	BCMA & CD19	MCARTY*				

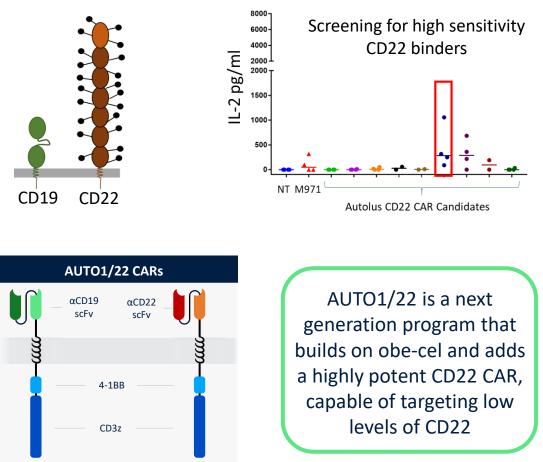
\*Collaboration with UCL

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CD19 negative antigen escape is a common cause of treatment failure

CARPALL Study						
n	14					
CR Rate	86%					
EFS 12m	52% (95% CI, 16% to 72%)					
No. of CD19 negative relapses	5/6					
CRS ≥ G3	0%					

- obe-cel (AUTO1) in r/r pALL is highly active and has a favourable safety profile - CARPALL study<sup>1,2</sup>
- Medical need in pALL is to minimize rates of antigen-loss– driven relapses and improve long-term outcomes – points to need for a dual targeting CAR T



• AUTO1/22 is being evaluated in Phase 1 in r/r paediatric patients

# AUTO1/22 in pediatric Acute Lymphoblastic Leukemia

Patient characteristics

<b>Total</b> Median age at registration	<b>n=11 (%)</b> 12 yrs (range = 3.7-20.5)
Indication Post SCT relapse 1st relapse 2 <sup>nd</sup> relapse >2 <sup>nd</sup> relapse Median number of lines of prior Rx Prior Inotuzumab/Blinatumomab Prior CD19 CAR T cell therapy CD19-ve disease	<b>6 (55%, 3 isolated extramedullary)</b> 2 (18%) 8 (73%) 1 (9%) <b>3 (range 2-6)</b> 6 (55%) 4 (36%) 3 (27%)
BM status pre-lymphodepletion Morphological relapse (>5% blasts) MRD 2-5% MRD 10 <sup>-2</sup> -10 <sup>-5</sup> MRD negative	4 (36% + 1 NE with 6% mol MRD) 1 (9%) 3 (27%) 2 (18%)

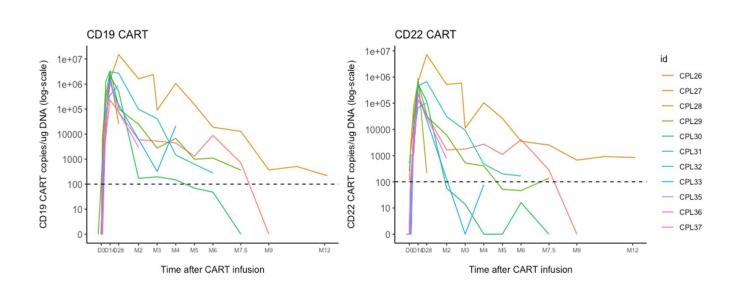
None eligible for Kymriah (4 previous Kymriah, 5 EM disease, 3 CD19-ve component at enrolment)

#### Autolus.com

### EHA data: AUTO1/22 in pediatric Acute Lymphocytic Leukemia

Phase 1 trial: Dose escalation trial – safety profile

#### qPCR (blood)

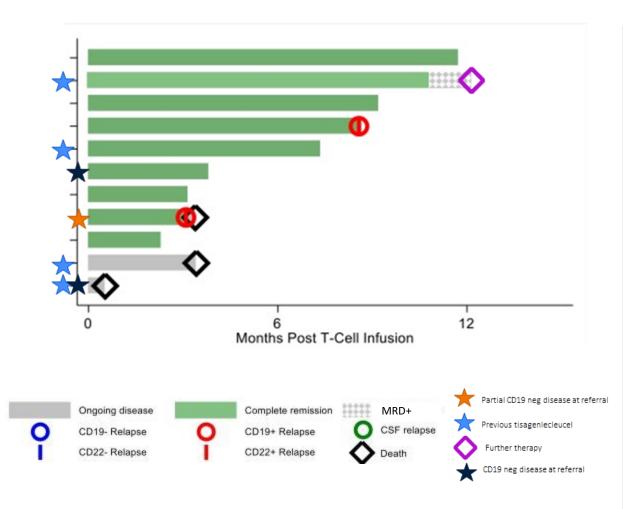


- AUTO1/22: reproducibly generate product balanced in CD19 vs CD22CAR with predominantly central memory phenotype
- Safety profile acceptable to date: no severe CRS, 1 Grade 4 ICANS but atypical
- Excellent CAR T expansion 4 patients have lost CAR T persistence

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# AUTO1/22 in pediatric Acute Lymphoblastic Leukemia

Efficacy data



Total	N=11
Molecular MRD neg CR/Cri by d60	9 (82%)
Disease progression	2 (18%)
Events in responders	3
Emergence of molecular MRD	1
CD19+/CD22+ relapse	2

- No antigen-ve relapse was seen in responding patients
- At median follow up of 8.7 months, 6 of 9 responding patients were in MRD-ve complete response (1-12 mo)

# Summary for AUTO1/22 phase 1 study in r/r pALL

Initial data presented at EHA, June 2022

- ✓ CD19/CD22 targeting CAR T cells generated by co-transduction show robust expansion and persistence
- Favorable safety profile demonstrated, with no severe CRS
- Demonstration of efficacy of CD22 CAR
- Early efficacy in a heavily pre-treated cohort with 9/11 (82%) MRD negative CR rate
- To date with limited follow-up we have not observed antigen negative relapse

Next steps:

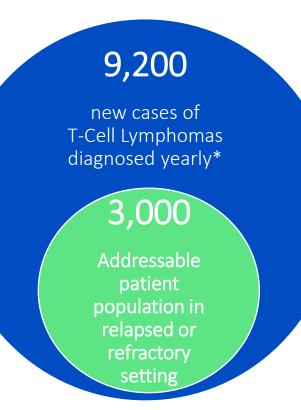
- Enrol additional patients
- Longer follow-up

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## AUTO4 and AUTO5 for Peripheral T-Cell Lymphoma

T-Cell Lymphoma is an aggressive disease with a very poor prognosis

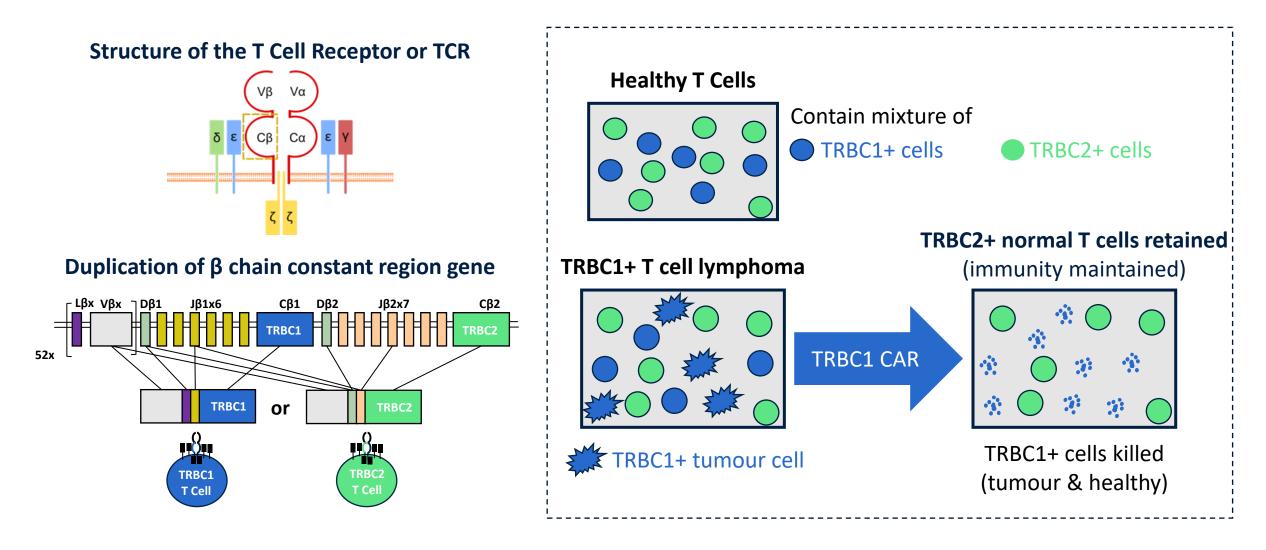
- A large portion of T-Cell Lymphoma patients are refractory/relapse following first-line treatment (68%)<sup>3</sup>
- Standard of care is variable and often based on high-dose chemotherapy and stem cell transplants:
  - $-\,$  Median 5 yrs OS: 32%  $^1$
- Relapsed/refractory patients have a worse prognosis
  - Median PFS approximately 3 months/ Median OS < 6 months<sup>2,3</sup>
- Brentuximab survival benefit restricted to CD30 positive ALCL subtype<sup>4</sup>
  - approx. 12% of total PTCL patient population<sup>4,5</sup>
- T cell lymphoma has not benefited from advances in immunotherapy
  - Pan T-cell depletion highly toxic; few/no tumor-specific antigen targets



\*Japan, US and EU5 (DRG Epidemiology Data)

#### Mature T cells express either TRBC1 or TRBC2

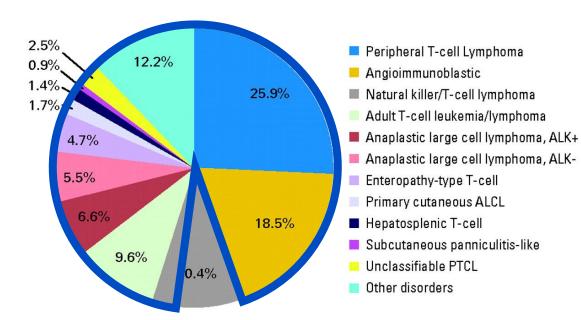
T-Cell Lymphomas are also clonal and express either TRBC1 or TRBC2



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## TRBC1/TRBC2 targeting approach applicable to 95% of TCL subtypes

#### Distribution of cases by subtype



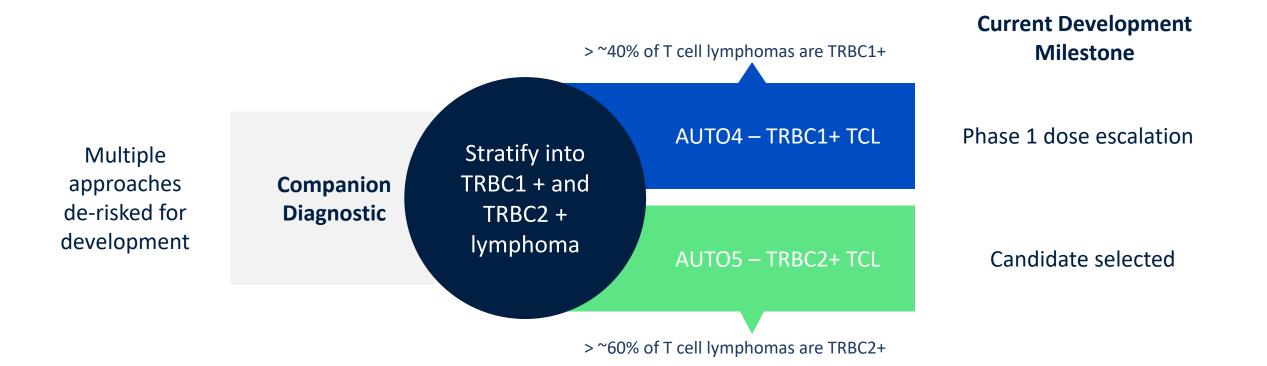
#### Subtypes that are TRBC1 or TRBC2 positive

- High and homogeneous expression of TRBC1 or TRBC2 is seen in the majority of TCL subsets 95% of cases
- TRBC1 and TRBC2 will not be expressed in NK cell lymphomas or rare gamma delta t-cell lymphomas
- Other potential TCL targets:
  - Highly restricted in their expression
  - High and homogenous expression of CD30 is restricted to ALCL subset 12% of cases
  - Widely expressed on normal T cells and therefore come with a significant risk of toxicities

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#### Three key elements to address T-Cell Lymphomas

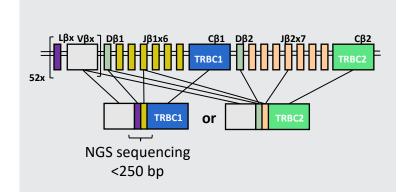
A companion diagnostic: AUTO4 and AUTO5



#### **Companion Diagnostic**

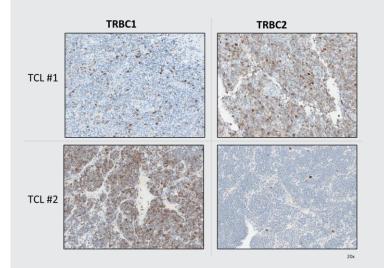
Multiple approaches de-risked for development

#### **Next Generation Sequencing**



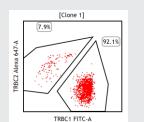
#### T cell clonality NGS assay currently used in AUTO4 Phase 1



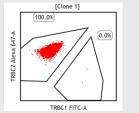


FFPE specific antibodies can discriminate between TRBC1 and TRBC2 patient tumors

#### **Flow Cytometry**



TRBC1 positive T-cell Prolymphocytic Leukemia



TRBC2 positive small Sezary cell cutaneous T-Cell Lymphoma

Flow specific antibodies can discriminate between TRBC1 and TRBC2 in patient tumors

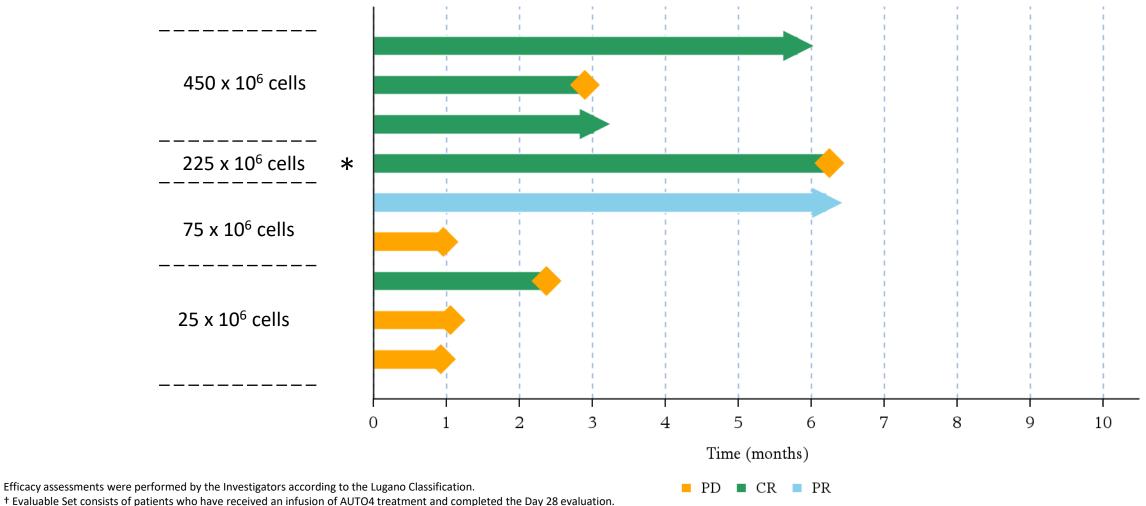
## EHA data: Key Safety Data

AUTO4 findings / clinical data

	Cohort 1 25x10 <sup>6</sup> cells (N = 3)	Cohort 2 75x10 <sup>6</sup> cells (N = 2)	Cohort 3 225x10 <sup>6</sup> cells (N = 1)	Cohort 4 450x10 <sup>6</sup> cells (N = 4)	Total (N = 10)
Dose Limiting Toxicity (DLT)	0	0	0	0	0
Grade 3 or 4 TEAE within 60 days	3 (100%)	2 (100%)	1 (100%)	4 (100%)	10 (100%)
Neutropenia	3 (100%)	2 (100%)	0	3 (75%)	8 (80%)
Infections and Infestations	0	0	0	0	0
Serious TEAE	2 (67%)	0	0	2 (50%)	4 (40%)
Any grade CRS	0	0	0	4 (100%)	4 (40%)
Grade 3 CRS	0	0	0	1 (25%)	1 (10%)
Any grade ICANS	0	0	0	0	0

#### Initial data encouraging

All patients treated at highest dose level had a complete metabolic response

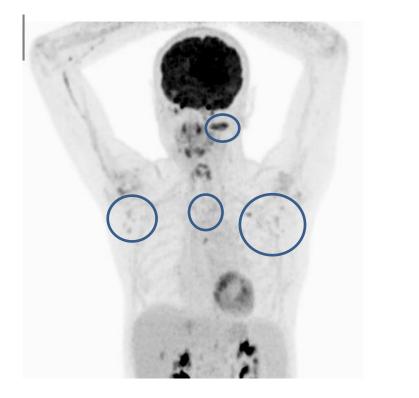


All patients had relapsed/refractory disease at time of Part B screening and enrolment.

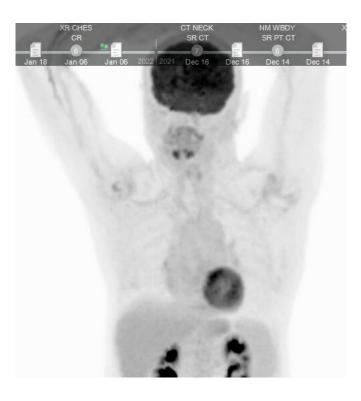
\* Patient was PET-negative at the start of pre-conditioning therapy.

### PET scans for patient given 450 x 10<sup>6</sup> CAR T cells

Patient refractory to prior therapies achieved a metabolic complete response







Baseline

#### Day 28 post-infusion

#### 3 months post-infusion

35

Data Cutoff: 26 April 2022

#### AUTO4 summary and next steps

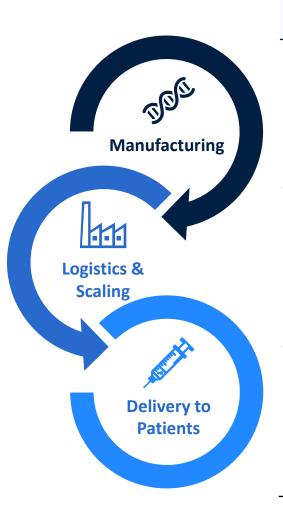
- AUTO4 treatment generally well tolerated
- Early efficacy is encouraging, particularly with all patients responding at higher dose levels
- CAR T-cells detected in lymph node but no expansion observed in peripheral blood
- Study ongoing, with additional patients due to be treated to define recommended Phase 2 dose



# Manufacturing

# Manufacturing capabilities to accelerate assets into the clinic and beyond

Building a fully integrated manufacturing and logistics platform that aims to bring assets to market



#### Product Delivery

- Highly skilled Autolus manufacturing operations housed in UK at the Cell and Gene Therapy Catapult
- Established clinical supply and launch capacity – industrial 4 shift / 7d operation
- Strategic and long term supply arrangements with all critical supply partners
- Purpose built Autolus facility to for commercial scale supply GMP certified by mid-2023
- Pilot systems for product delivery at product launch
- High level of service and scientific engagement at specialised treatment centres

150+ highly skilled manufacturing staff



70,000 sq. foot manufacturing facility



Robust UK/EU/US vein to delivery platform

38



Autolus.com

350 batches p.a.

Commercial capacity of 2000 batches p.a.



In collaboration with treatment centers network

# **Blackstone Collaboration**

Investment of \$100m in equity and up to \$150 million in product financing

- Blackstone agreed to purchase \$100 million of Autolus' American Depositary Shares (ADS') in a private placement, priced at market
- Blackstone also committed to invest up to \$150 million in product financing to support obe-cel development and preparation for commercialization
  - \$50 million paid upon closing of the transaction
  - Remainder payable based on achievement of certain development and regulatory milestones
- Blackstone received a warrant to purchase up to \$24 million worth of Autolus ADSs at an exercise price premium to market
- Autolus to pay Blackstone a capped single digit royalty plus milestone payments based on net sales of obe-cel
- Transaction provides runway into 2024<sup>1</sup>

# Summary

Multiple catalysts in H2 2022

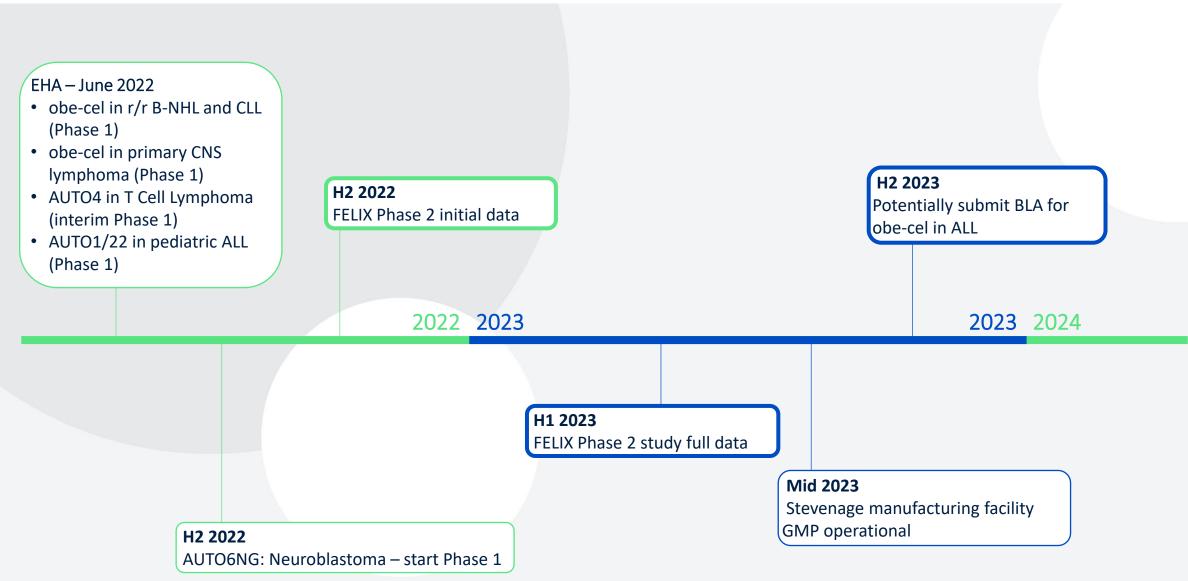
## Autolus poised for potential value inflection

obe-cel pivotal data in adult ALL in 2022

#### • obe-cel

- FELIX Phase 2 study in adult ALL ongoing; initial data expected in H2 2022 and full data in H1 2023
- Evaluation in r/r B-NHL and CLL ongoing
- Evaluation in Primary CNS Lymphoma ongoing
- AUTO1/22
  - AUTO1/22 Phase 1 (CARPALL) study in Pediatric ALL ongoing
  - Longer term follow-up data in H2 2022
- AUTO4 /AUTO5
  - AUTO4 Phase 1 (LibrA T1) study in Peripheral T cell lymphoma ongoing
- Pipeline transitioning to Phase 1 in 2022
  - AUTO8 Phase 1 study has started
  - AUTO6NG in Neuroblastoma start Phase 1 H2 2022
- Cash balance at March 31, 2022, \$268.6 million

## Autolus key newsflow timeline



# Autolus

# Thank you

