Autolus

Second Quarter Financial Results and Operational Progress

August 3, 2023

Disclaimer

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Agenda

- Welcome and Introduction: Julia Wilson, Communications Consultant
- Operational Highlights: Dr. Christian Itin, CEO
- Financial Results: Dr. Lucinda Crabtree, CFO
- Upcoming Milestones and Conclusion: Dr. Christian Itin, CEO
- Q&A: Dr. Christian Itin and Dr. Lucinda Crabtree

Obe-cel highlights

Continued progress against strategic and operational goals

Clinical Data

- **obe-cel in relapsed / refractory (r/r) adult ALL**
  - FELIX data presented at ASCO and EHA in June from all patients treated showed 76% of patients achieved a response (CR/CRi) with very low levels of high-grade CRS and ICANS
  - Long term follow up data from ALLCAR19 were presented at the Tandem Meeting with 35% of r/r adult ALL patients in ongoing remission with a median f/u of 36 months (range 24 to 47 months)
  - Longer follow up and subgroup analysis from FELIX expected at ASH in late 2023, as well as at medical conferences in H1 2024

Manufacturing

- **Robust manufacturing process and state of the art commercial manufacturing**
  - FELIX data showed product released for 94% of leukapheresed patients and a median vein to release of 21 days
  - Qualification and validation of the Nucleus Facility is on track for commencement of Good Manufacturing Practice Operations in H2 2023

Regulatory

- **Filing of Biologics License Application (BLA) to the US Food and Drug Administration (FDA) on track for end of 2023**

Commercial Readiness

- **Continuing to build out Autolus' commercial capability and infrastructure**
  - First-in-class Depot model: Cardinal Health selected as specialty distributor partner and instilling core distribution capabilities to support commercial launch
  - Engagement with treatment centers and initiating on-boarding

Pipeline highlights

Continued progress against strategic and operational goals

Obe-cel and AUTO1/22

- **Expanding the obe-cel opportunity**
  - Company sponsored Phase 1 dose confirmation study in refractory systemic lupus erythematosus (SLE) to start in early 2024
  - ALLCAR19 extension study of obe-cel in r/r B-NHL and CLL will complete enrolment in 2023 and will be submitted for publication in a peer-reviewed journal
  - Publication in Nature Medicine demonstrating that long-term CAR T cell persistence is associated with durable responses in B-ALL
- **CD19 and CD22 dual targeting in pediatric ALL**
  - CARPALL Phase 1 trial of AUTO1/22 in pediatric ALL – updated data presented at EBMT in April 2023 showing molecular ORR of 83% and no indication of antigen loss-driven relapses

Other Product Candidates

- **LibrA T1 Phase 1 trial of AUTO4 in Peripheral T Cell Lymphoma**
  - Data presented at ICML in June showed at the highest dose 4 out of 4 patients achieved a response with on-going complete metabolic responses in 2 out of 4 patients at 15 and 18-months post-dosing.
  - AUTO4 was well tolerated with no dose limiting toxicities
- **MCARTY Phase 1 trial of AUTO8 in Multiple Myeloma continues to enroll patients with first data expected end 2023**
- **Phase 1 trial of AUTO6NG in Neuroblastoma, first patient expected to be dosed in 2023**

Strengthening the Autolus team

Dr Robert Iannone
Non-Executive Director

- EVP, Global Head of R&D of Jazz Pharmaceuticals plc.
- Broad experience in drug development and registration from his long career in Oncology
- Immunomedics, AstraZeneca, Merck&Co

Rob Dolski
Chief Financial Officer

- Prior CFO of Checkmate Pharmaceuticals driving the sale to Regeneron
- More than 20 years of diversified experience as a life sciences financial executive
- Prior leadership and operational roles at Moderna, HGS and Amgen

Dr Veronica Hersberger
SVP, Medical Affairs

- Prior CMO at TargImmune Therapeutics AG
- Long career in oncology development and medical affairs
- Prior Global Product Leader for Calquence and Lumoxiti at AstraZeneca
- Prior Global Head of Medical Affairs for the Hematology Franchise at Roche

Miranda Neville
SVP, Project Management

- Prior Partner at AllianceBio supporting development and capital projects at various pharmaceutical companies
- Prior program leader for Benlysta at HGS driving the approval in SLE

LEAD CLINICAL PROGRAM

Obe-cel

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

FELIX data at ASCO and EHA 2023

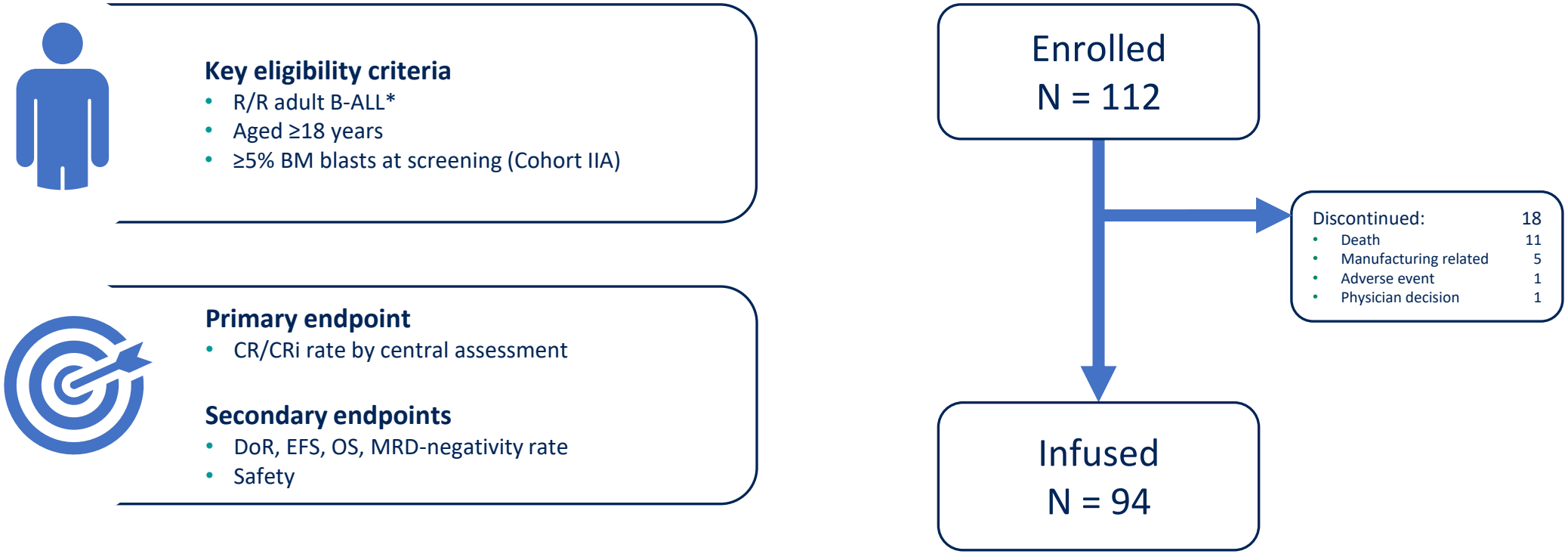
eligibility, endpoints, and disposition

84% of enrolled patients were infused with obe-cel

Key eligibility criteria
- R/R adult B-ALL*
- Aged ≥18 years
- ≥5% BM blasts at screening (Cohort IIA)

Primary endpoint
- CR/CRi rate by central assessment

Secondary endpoints
- DoR, EFS, OS, MRD-negativity rate
- Safety



Median duration of follow-up: 9.5 months (1.9–19.0)

*** R/R B-ALL: Primary refractory; First relapse if first remission ≤12 months; R/R disease after ≥2 lines of systemic therapy; R/R disease after allogeneic transplant; R/R Philadelphia chromosome-positive ALL if intolerant to/failed two lines of any TKI or one line of second-generation TKI, or if TKI therapy is contraindicated**
Enrollment: all eligibility criteria met and the leukapheresate accepted for manufacturing

Roddie et al., ASCO 2023, data cut-off date: March 16, 2023

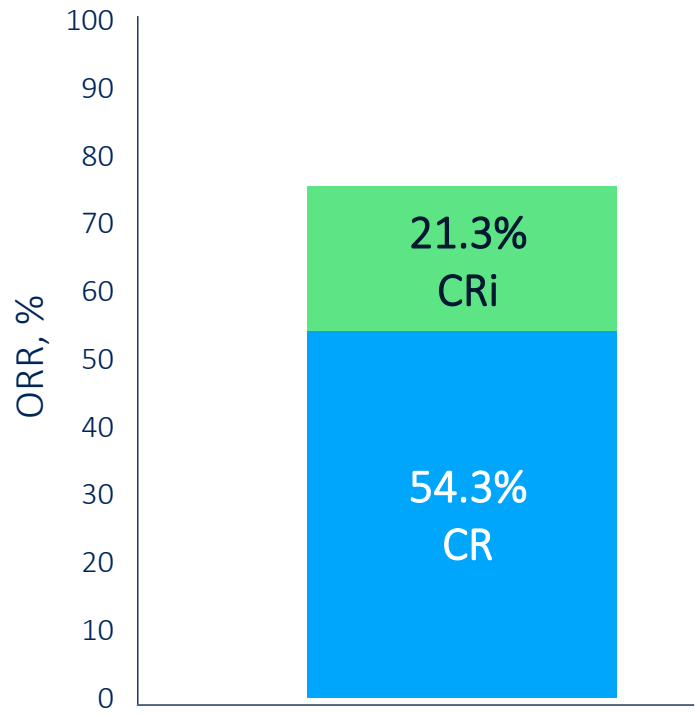
FELIX: baseline characteristics

Heavily pre-treated patients with high disease burden

	Total infused (N = 94)
Age years, median (range)	50 (20–81)
Gender male/female, n	47/47
Philadelphia chromosome-positive, n (%)	25 (26.6)
Prior therapies, median (range) ≥3 prior lines, n (%)	2 (1–6) 29 (30.9)
Refractory to last prior line of therapy, n (%)	50 (53.2)
Prior allogeneic SCT, n (%)	36 (38.3)
Prior blinatumomab, n (%) Prior inotuzumab, n (%) Prior blinatumomab and inotuzumab, n (%)	33 (35.1) 30 (31.9) 15 (16.0)
BM blasts % at screening, median (range)	49.5 (6–100)
BM blasts % at pre-conditioning, median (range)	41.1 (0–100)
Extramedullary disease at pre-conditioning, n (%)	18 (19.1)

FELIX: disease response per IRRC assessment

76% of infused patients achieved CR/CRi



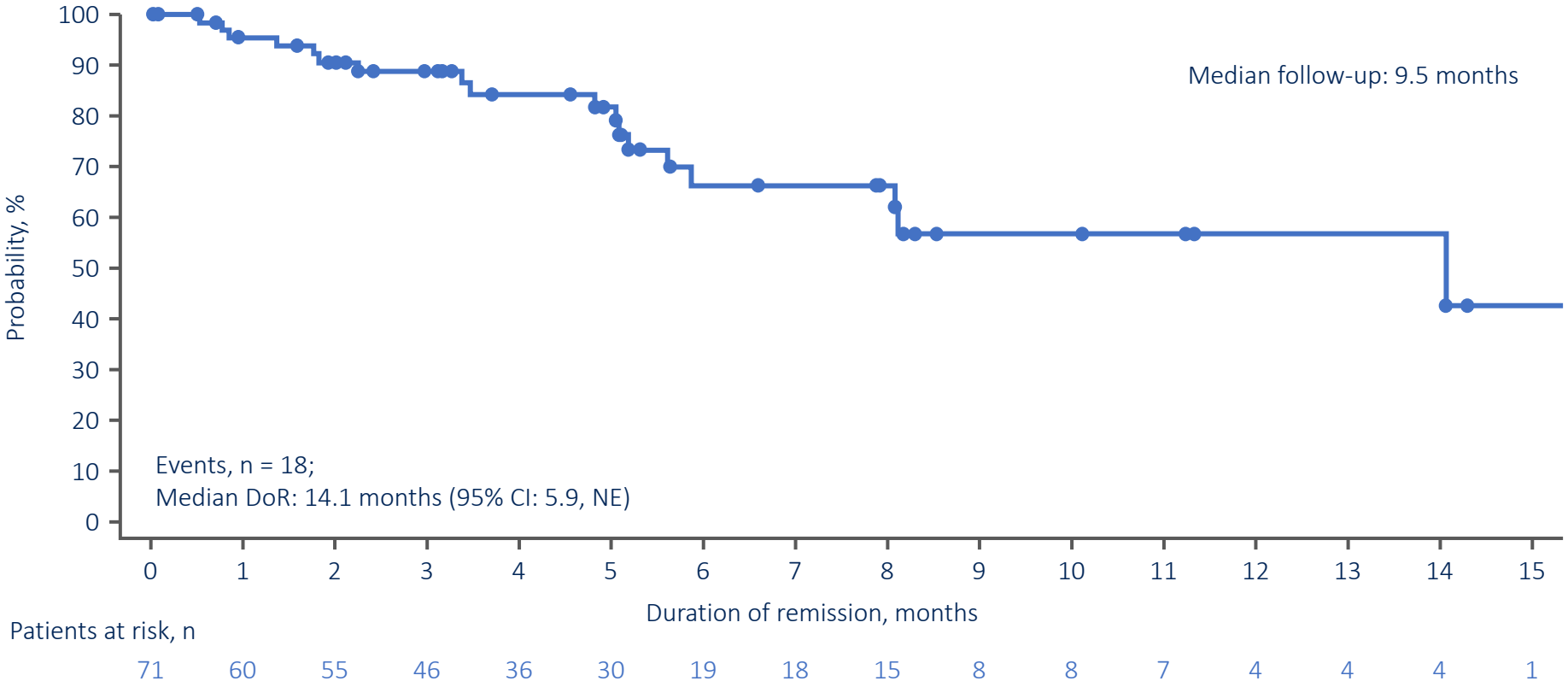
ORR: 76%
95% CI (66, 84)
p<0.0001*

97% of responders with evaluable samples were MRD negative at 10^{-4} level by flow cytometry

*One-sided p-value from the exact test on H0: ORR ≤40% vs H1: ORR >40%
CR, complete remission, CRi, CR with incomplete blood count recovery; IRRC, independent response review committee; MRD, minimal residual disease; ORR, overall remission rate

FELIX: duration of remission

61% responders in ongoing remission without subsequent anti-cancer therapies



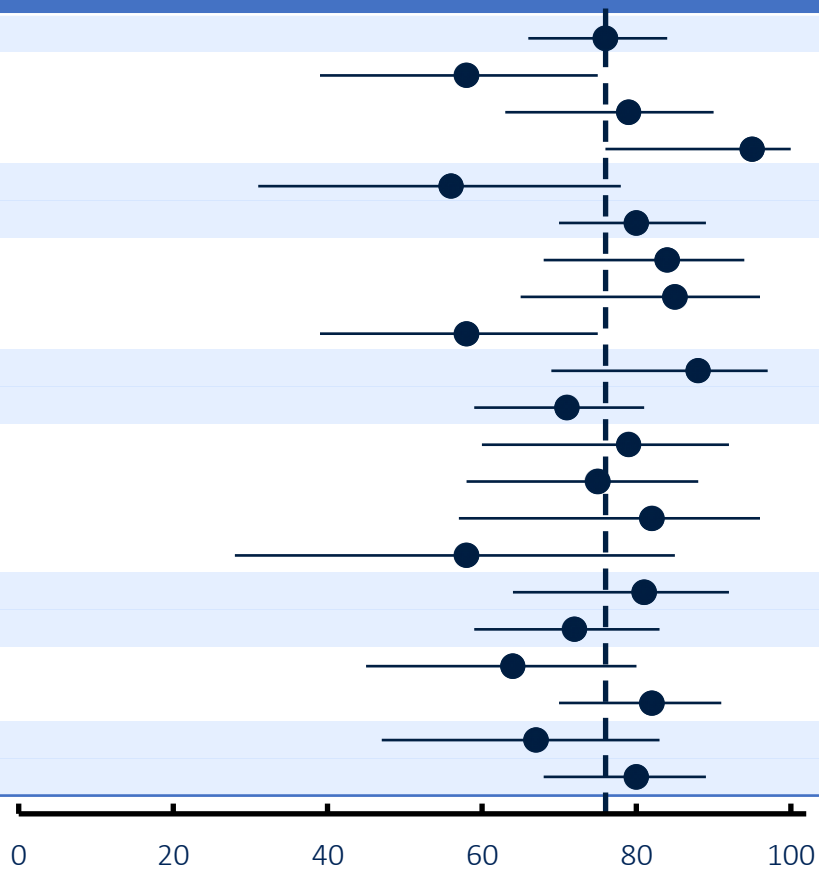
13% responders who proceeded to SCT while in remission were censored at the time of SCT

NE, not estimable

FELIX: subgroup analysis of CR/CRi (IRRC assessment)

High risk subgroups include EMD and high BM blasts at pre-conditioning

Subgroup		Total N (%)	ORR % (95% CI)
Overall		94 (100)	76 (66, 84)
Age, years	18–39	31 (33)	58 (39, 75)
	40–64	42 (45)	79 (63, 90)
	≥65	21 (22)	95 (76, 100)
EMD prior to pre-conditioning	Yes	18 (19)	56 (31, 78)
	No	76 (81)	80 (70, 89)
BM blasts % prior to pre-conditioning	≤20	37 (39)	84 (68, 94)
	>20–75	26 (28)	85 (65, 96)
	>75–100	31 (33)	58 (39, 75)
Philadelphia chromosome	Yes	25 (27)	88 (69, 97)
	No	69 (73)	71 (59, 81)
Previous lines of therapy	1	29 (31)	79 (60, 92)
	2	36 (38)	75 (58, 88)
	3	17 (18)	82 (57, 96)
	≥4	12 (13)	58 (28, 85)
Previous allogeneic SCT	Yes	36 (38)	81 (64, 92)
	No	58 (62)	72 (59, 83)
Previous blinatumomab	Yes	33 (35)	64 (45, 80)
	No	61 (65)	82 (70, 91)
Previous inotuzumab ozogamicin	Yes	30 (32)	67 (47, 83)
	No	64 (68)	80 (68, 89)



CR, complete remission; CRi, CR with incomplete blood count recovery; EMD, extramedullary disease; IRRC, independent response review committee; ORR, overall remission rate

FELIX: safety – CRS and ICANS

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

	BM blasts ≤20% at pre-conditioning (N = 37)	BM blasts >20% at pre-conditioning (N = 57)	All infused patients (N = 94)
CRS			
Any grade, n (%)	24 (64.9)	47 (82.5)	71 (75.5)
Grade ≥3, n (%)	1 (2.7)	2 (3.5)	3 (3.2)
ICANS			
Any grade, n (%)	5 (13.5)	19 (33.3)	24 (25.5)
Grade ≥3, n (%)	1 (2.7)	6 (10.5)	7 (7.4)

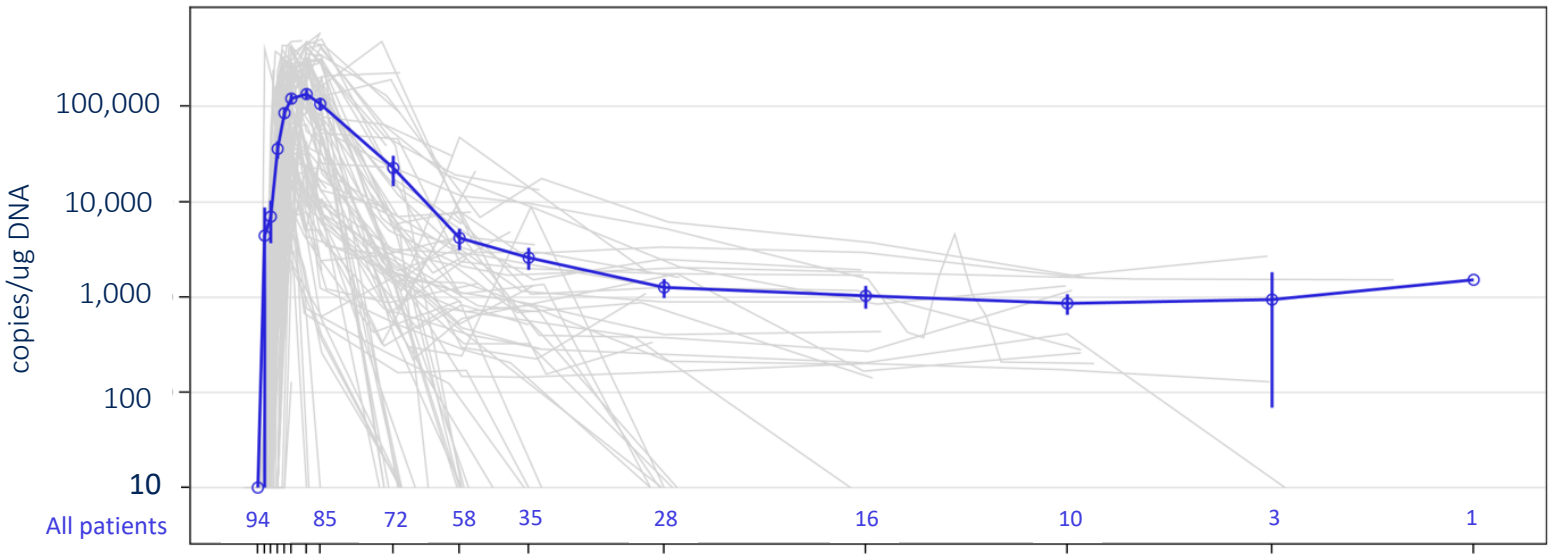
- Tocilizumab and steroid was used to treat CRS in 53/94 (56%) and 16/94 (17%) patients, respectively
- 3/94 (3%) patients required vasopressor for treatment of CRS
- 6/7 (86%) Grade ≥3 ICANS were observed among patients with >75% BM blasts at pre-conditioning

CRS, cytokine release syndrome; ICANS, immune effector cell associated neurotoxicity syndrome

FELIX: obe-cel expansion and persistence

CAR T cellular kinetics are consistent with the ALLCAR19 study[1]

Mean (SE) for CAR-T therapy by PCR in peripheral blood



	FELIX (N = 94)	ALLCAR19 (N = 20)
C_{max}, copies/ug Geo-Mean, CV%	114,982 (287.6)	127,152 (109.7)
T_{max}, days Median, range	14 (2–55)	13 (7–21)
$AUC_{0–28d}$, copies/ug×d Geo-Mean, CV%	1,139,380 (225.4)	1,251,802 (108.9)

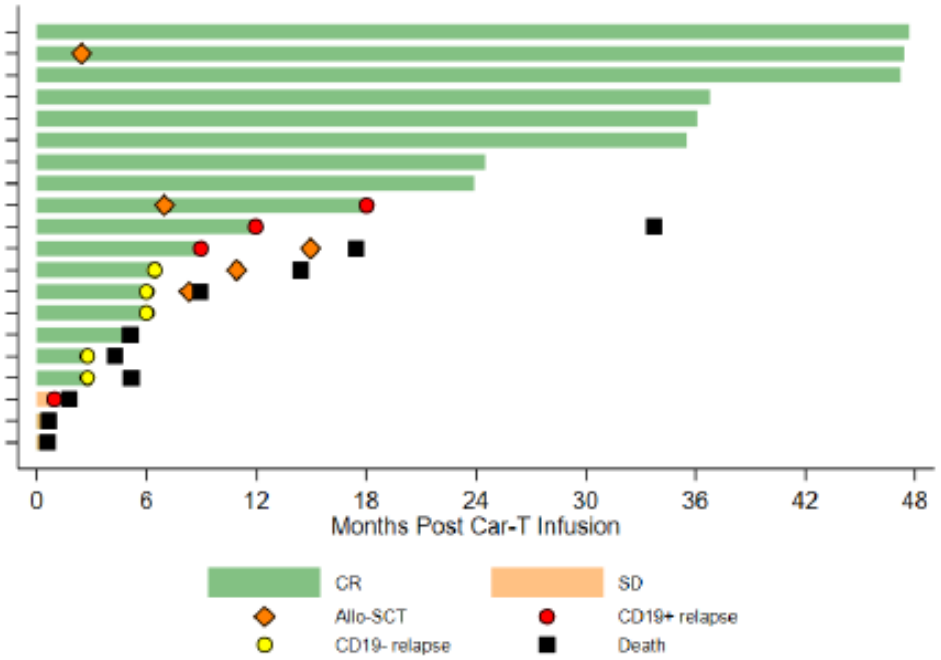
AUC, area under the curve; CV, coefficient of variation; Geo, geometric; PCR, polymerase chain reaction; SE, standard error

1. Roddie C et al., J Clin Oncol 2021;39(30):3352–63

Obe-cel - Tandem Meeting - long term follow up from Phase 1 ALLCAR19 study

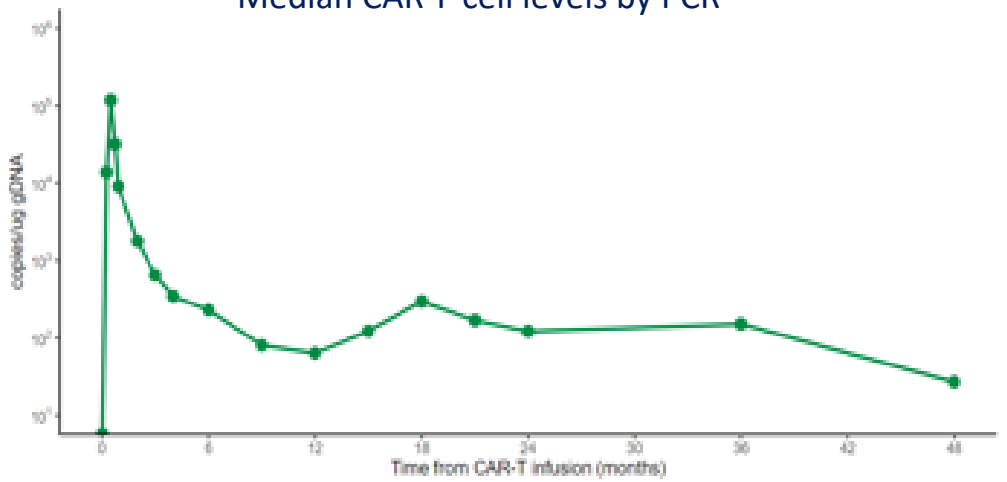
'Long-Term Follow-up of AUTO1, a Fast-Off Rate CD19 CAR, in Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia and Factors Associated with Durable Response'

ALLCAR19 Swim plot



ALLCAR19 Median persistence

Median CAR T-cell levels by PCR



- Of the 20 infused B-ALL patients, 7/20 (35%) are in ongoing CR at a median FU of 36 months (IQR 24-47) post obe-cel
- All patients with long term remissions have long term persisting CAR T cells

Roddie et al., Tandem Meeting 2023, data cut-off date: November 2, 2022

FELIX: conclusions

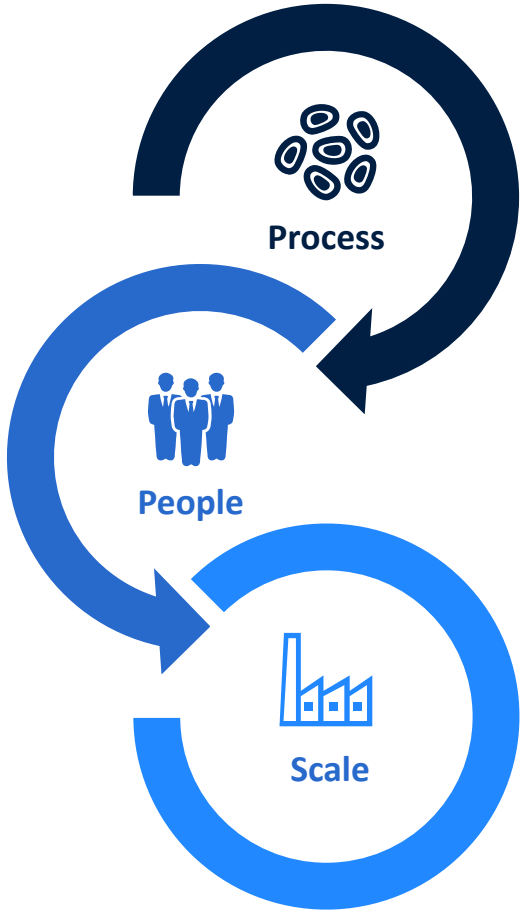
- Obe-cel infusion resulted in a CR/CRi rate of 76%, with 97% of responders becoming MRD negative
  - With a median of 9.5 months' follow-up, 61% of responders remain in remission
- Obe-cel infusion resulted in very low rates of Grade ≥3 CRS (3.2%) and low rates of Grade ≥3 ICANS (7.4%)
  - In total, obe-cel was evaluated in 94 patients with r/r B-ALL
  - 31% of patients had received ≥3 prior lines of therapy and 33% had >75% marrow burden at infusion
- Robust manufacturing process, with product released for 94% of leukapheresed patients and a median vein to release of 21 days
  - 84% of enrolled patients received obe-cel
- Excellent CAR T-cell engraftment with C_{max} of 114,982 copies/ug DNA and T_{max} at 14 days

Manufacturing

Product supply

Critical success factors for a personalized cell therapy

Reliable and timely delivery of every batch with consistent quality is critical for each patient



- Process
  - Consistent manufacturing process performance over a wide range of patient cell material
  - Consistently short turnaround time
  - A semiautomated production platform enabling product consistency and economies of scale
- People
  - Leadership to drive outcome
  - Highly trained and motivated work force - training center and program implemented
  - Culture of continuous improvement - continuing operational excellence program
- Scale of operation
  - Capacity to match demand
  - Right sized and scalable capacity to realize attractive COGS

Supply of FELIX study pressure tested all aspects of product delivery

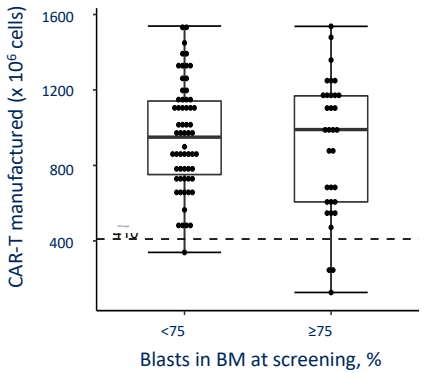
New approach to manufacturing – requires new thinking to be successful

- Semi-automated manufacturing process optimized to manage wide range of apheresis materials
- Efficient and precise in process controls and release analytics
- Training center in place enabling the build and maintenance of the operating workforce
- 2 shifts / 7 days per week commercial manufacturing operations implemented
- Operational excellence program in place driving ongoing optimization of manufacturing operations and COGS
- Transatlantic logistics operated for 24 US clinics during COVID restrictions (flights as low as 5% of pre-pandemic levels)

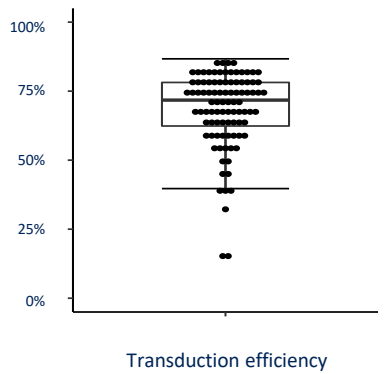
CliniMACS **Prodigy®**

Miltenyi Biotec

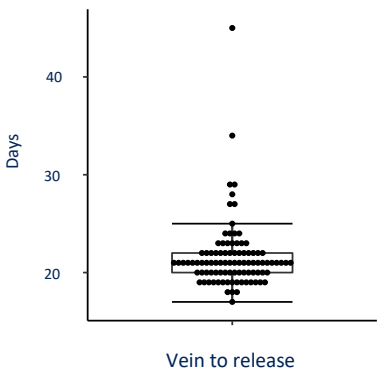
96% of products reached target dose



Median transduction efficiency of **72%**



Median **21 days** from vein to release

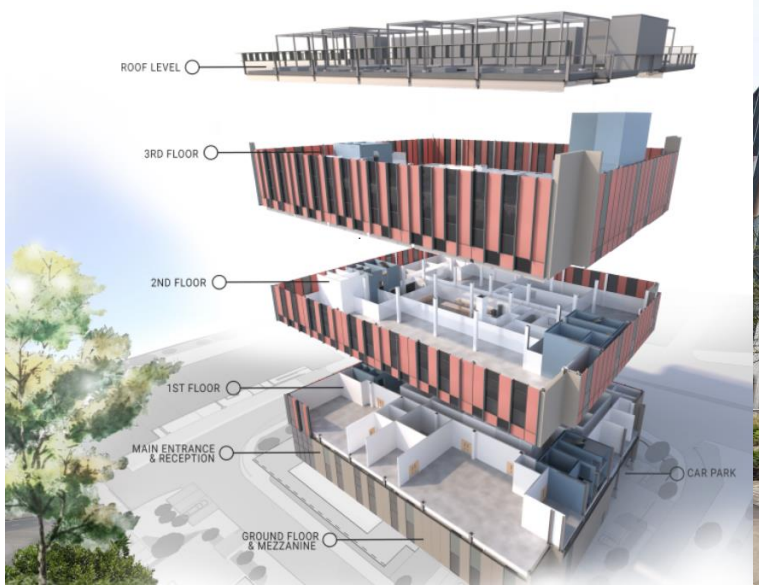


Roddie et al., ASCO 2023, data cut-off date: March 16, 2023

The Nucleus

State of the art design and operations established – validation on track

Design



- ~70,000 sq ft facility
- Modular build using PAMs
- 70% built off-site
- 60% Reduced build time

Build

- Nov 8, 2021 ground breaking
- Nov 25, 2022 first clean room in operation

Operations

- Dec 14, 2022 first Prodigy operational
- May 2023 capacity challenge
- Designed for 2,000+ batches per year
- Target vein to delivery time 16 days at launch

Preparing for obe-cel commercial launch

Deep value program with potentially broad applicability

Obe-cel next steps to commercialization

Data and path to approval

- Filing of Biologics License Application (BLA) to US Food and Drug Administration (FDA) planned for end of 2023
- Filings of EU and UK marketing authorization applications planned for H1 2024

Manufacturing

- Bespoke commercial manufacturing facility built in Stevenage, UK
- Operational start up in H1 2023 (qualification and validation)
- Facility designed for a capacity of 2,000+ batches per annum; sufficient for global demand in ALL

Commercialization

- Focus in 2023 on Medical affairs, HTA dossier compilation and center onboarding
- Focus in 2024 on launch preparation and execution
- Consider EU partner for launch

Selection of Cardinal Health as US distribution partner

Covers three key elements of obe-cel commercialization in the US

Distribution

Standard suit of services including:

- “Flash ordering”
- Center checks
- Government price reporting

Essential pre-requisite for efficient ordering process

Order-to-Cash

Includes collection of US Revenues

Autolus does not need to internalize this capability

Depot Model

Maintain custody and storage closer to US treatment centers while completing product release

Facilitates reduction in vein to delivery time

Building the obe-cel opportunity and other pipeline highlights

The obe-cel product family and franchise opportunity

Obe-cel
CD19

- Optimal CD19 CAR design
- Potential best-in-class efficacy and safety profile
- Supported by state-of-the-art manufacturing
- Supported by mature FELIX clinical/CMC package

→ B-ALL and B-NHL
→ B-cell mediated autoimmune disease

AUTO1/22
CD19/CD22

- Dual CD19 & CD22 Targeting
- Designed to prevent antigen negative escape
- Supported by Phase 1 data in pediatric B-ALL

→ B-ALL and B-NHL

AUTO8
CD19/BCMA

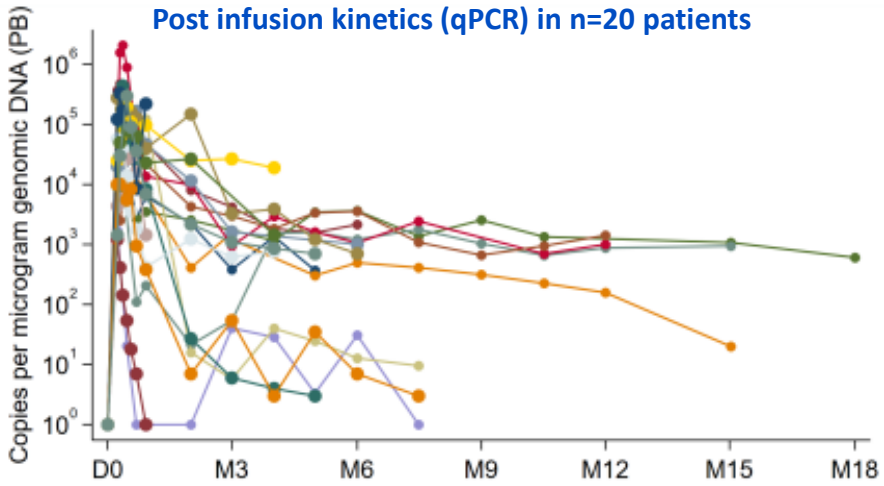
- Dual CD19 & BCMA Targeting
- Designed to induce deep and durable responses
- Phase 1 data expected end 2023

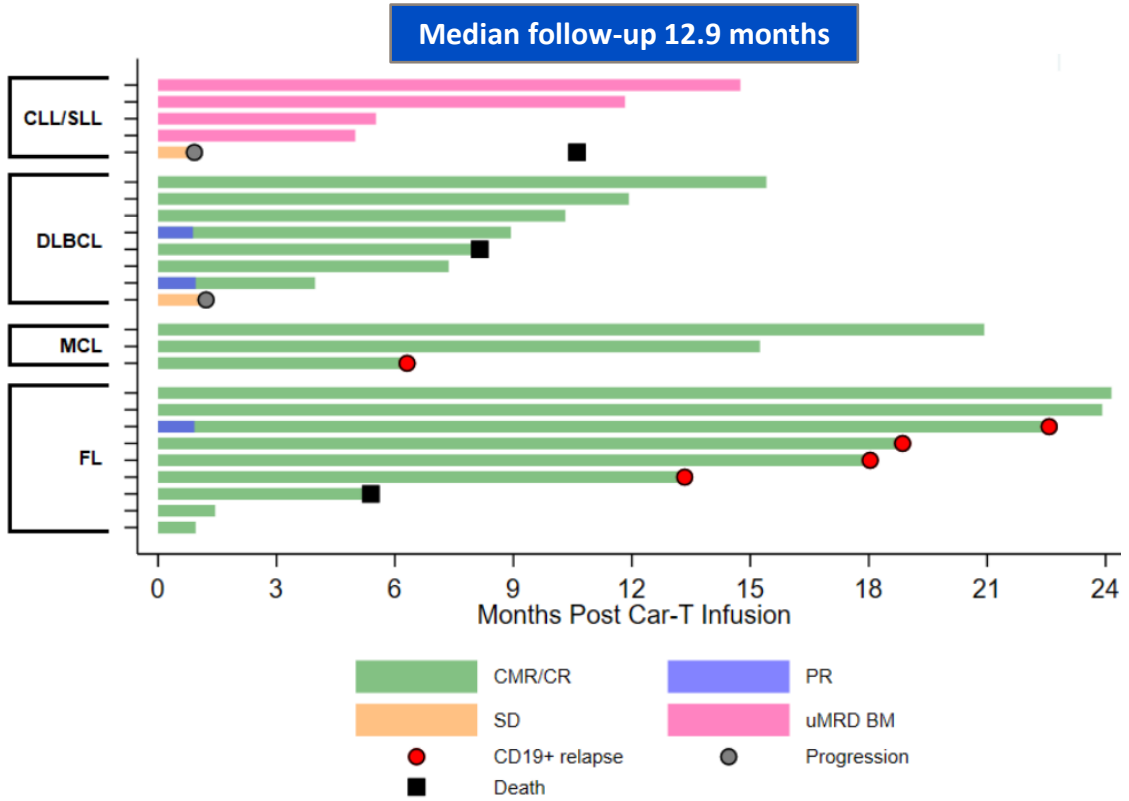
→ Multiple Myeloma
→ B-cell and plasma cell mediated autoimmune

Obe-cel in B-NHL/CLL: High level clinical activity with durable outcomes

Long term persistence driving durable outcomes

ALLCAR19 – B-NHL and CLL	
N	25
ORR	
All patients	92%
Follicular Lymphoma	100%
Mantle Cell Lymphoma	100%
DLBCL	88%
CLL/SLL	80%





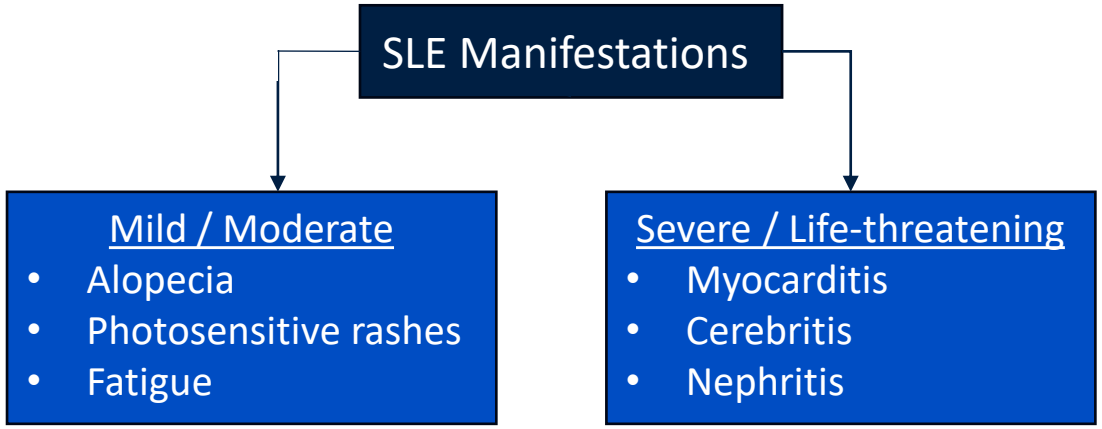
- No ≥ grade 3 CRS and ICANS reported
- 2 deaths in remission from COVID19; 1 death from PD

Roddie et al., ASH 2022, data cut-off date: November 2, 2022

Obe-cel: expanding into B-cell mediated autoimmune disease

Systemic Lupus Erythematosus (SLE)

- SLE is a multi-organ systemic autoimmune disease that affects approximately 160K - 320K patients in the US[1]
- Characterised by activation of autoreactive B-cells, production of autoantibodies and immune complex formation causing tissue injury and organ damage



Rationale for obe-cel in SLE

- High unmet need remains, with the efficacy of B-cell depleting mAbs limited due to persistence of autoreactive B-cells in lymphatic organs and inflamed tissues
- Proof-of concept data published by the Erlangen Group[2] showed a transformational treatment effect of CD19 CAR T-cell therapy in patients with severe SLE with a very well tolerated safety profile
- With the improved profile of obe-cel we expect we will be well positioned in the treatment of severe SLE

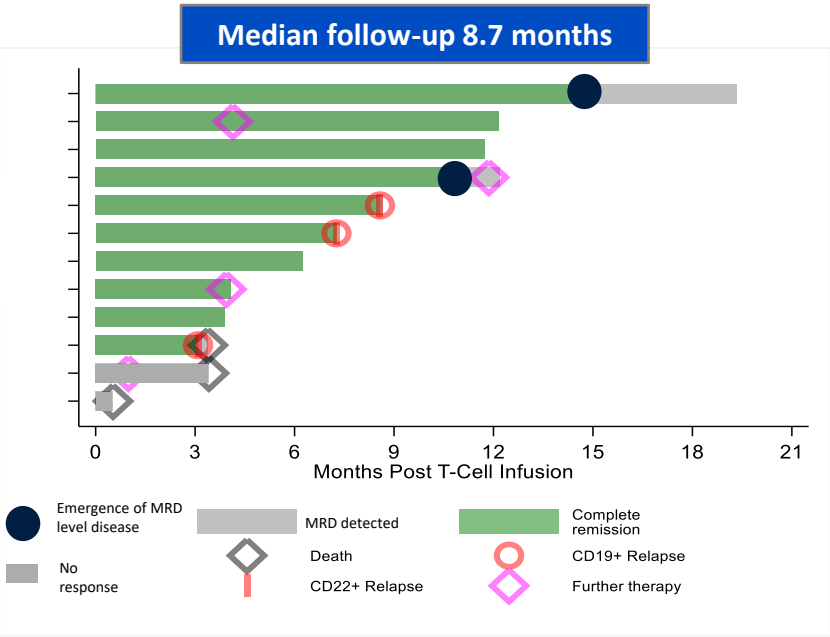
Autolus to conduct a Phase 1 study in patients with severe, refractory SLE with first patient visit planned in early 2024

1. Helmick et al., *Arthritis Rheum.* 2008, 2. Mackensen et al., *Nat Med.* 2022

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



- Favourable tolerability 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 the efficacy of 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

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

BCMA CAR

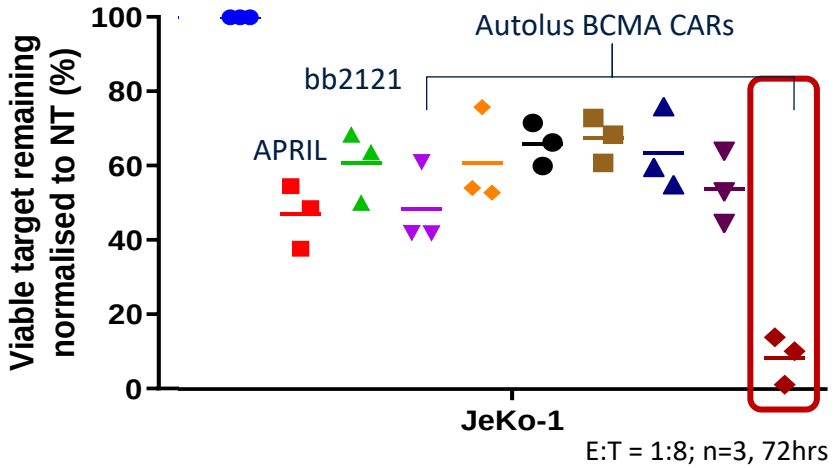
Novel format CAR designed to be highly sensitive to low BCMA density found on malignant plasma cells

CD19 CAR

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

AUTO8

Screening for high sensitivity BCMA binders



E:T = 1:8; n=3, 72hrs

Phase 1 Design

Cohort 1: BCMA CAR — 50MM — 150MM

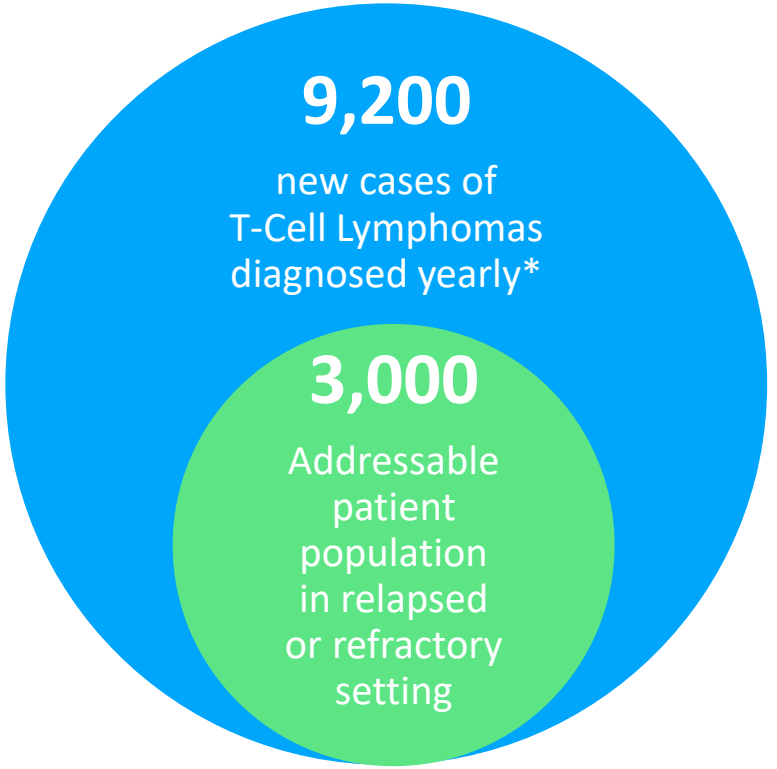
Cohort 2: BCMA CAR + CD19CAR — 50MM — 150MM

Phase 1 study currently enrolling patients with first data expected end 2023

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%)[1]
- Standard of care is variable and often based on high-dose chemotherapy and stem cell transplants:
  - Median 5 yrs OS: 32%[2]
- Relapsed/refractory patients have a worse prognosis
  - Median PFS approximately 3 months/ Median OS < 6 months[1,3]
- Brentuximab survival benefit restricted to CD30 positive ALCL subtype[4]
  - approx. 12% of total PTCL patient population[4,5]
- T cell lymphoma has not benefited from advances in immunotherapy
  - Pan T-cell depletion highly toxic; few/no tumor-specific antigen targets



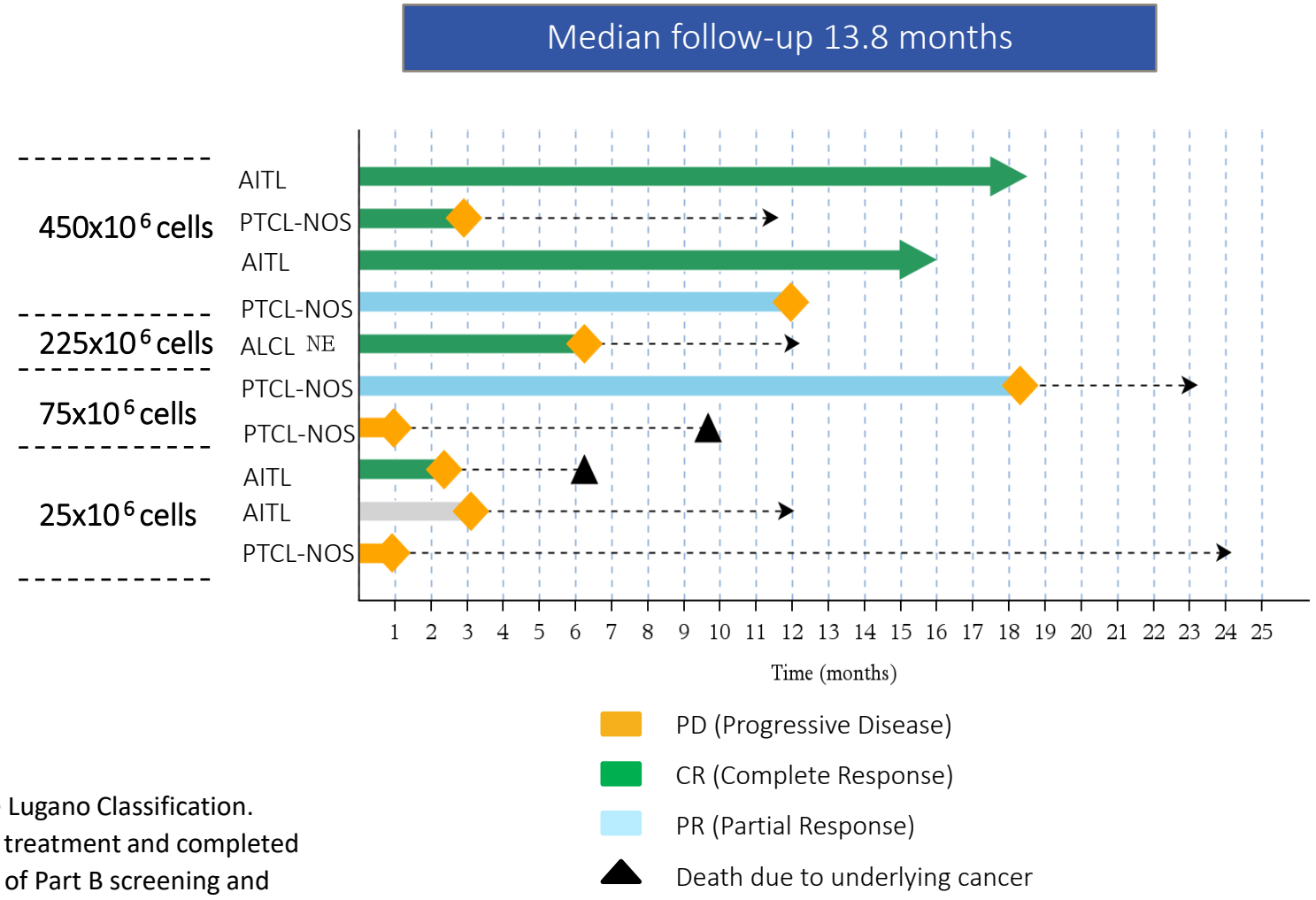
*Japan, US and EU5 (2020 DRG Epidemiology Data)

[1]Bellei M et al, Haematologica 2018, [2] Weisenburger et al., Blood 2011; [3]Mak et al, JCO 2013;, [4]Horwitz et al, Lancet, 2019, [5]Vose et al., JCO 2008

AUTO4 for Peripheral T-Cell Lymphoma: ICML 2023

Process A

- At the highest dose (450x10^6) 4 out of 4 patients achieved a response (Process A)
- On-going complete metabolic responses in 2 out of 4 patients at 15 and 18-months post-dosing
- Presence of CAR T-cells in the lymph nodes of patients suggest fast homing of CAR T-cells to the tumor site, despite absence in the blood
- AUTO4 treatment was well tolerated with no dose-limiting toxicities



Efficacy assessments were performed by the Investigators according to the Lugano Classification. Evaluable Set consists of patients who have received an infusion of AUTO4 treatment and completed the Day 28 evaluation. All patients had relapsed/refractory disease at time of Part B screening and enrolment

NE=not evaluable. Patient achieved CMR post bridging

Cwynarski et al IMCL 2023, data cut-off date: April 28, 2023

Autolus pipeline

PRODUCT	INDICATION	TARGET	STUDY NAME	COLLABORATION	PHASE	UPCOMING CATALYST
Obe-cel	Adult B-ALL	CD19	FELIX		Pivotal	Q4 2023: FELIX data updates Q4 2023: BLA filing with FDA
Obe-cel	Systemic Lupus Erythematosus	CD19	TBD		Preclinical	Q1 2024: Phase 1 initiation
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
Allogeneic obe-cel	B-Cell malignancies	CD19	KCAT19	UCL	Phase 1	-
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL	UCL	Phase1	Data in peer reviewed journal
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1		Phase 1	Data in peer reviewed journal
AUTO5	TRBC2+ Peripheral TCL	TRBC2	-		Preclinical	-
AUTO6 NG	Neuroblastoma	GD2	MAGNETO	UCL	CTA submitted	Q4 2023: Phase 1 initiation
AUTO8	Multiple Myeloma	BCMA & CD19	MCARTY	UCL	Phase 1	Q4 2023: First clinical data
AUTO9	Acute Myeloid Leukemia	CD33, CD123 & CLL1	TBD	UCL	Preclinical	-

Financial Results

Financial summary

Cash runway into 2025

USD	Q2 2023 ($ '000)	Q2 2022 ($ '000)	Variance ($ '000)
Grant Income	-	-	-
License Income	-	-	-
R&D	(36,742)	(38,212)	1,470
G&A	(11,122)	(8,269)	(2,853)
Loss on disposal of property and equipment	(23)	-	(23)
Total operating expense, net	(47,887)	(46,481)	(1,406)
Other income (expense), net	482	(1,331)	1,813
Interest Income	3,403	89	3,314
Interest expense	(5,020)	(1,810)	(3,210)
Income tax benefit	3,470	7,474	(4,004)
Net Loss after tax	(45,552)	(42,059)	(3,493)

USD	Q2 2023 ($ '000)	Q4 2022 ($ '000)	Variance ($ '000)
Cash Balance (including restricted cash)	307,832	382,761	(74,929)

- Foreign currency: 57% of cash at June 30, 2023 held in GBP

Summary

Autolus planned news flow

Obe-cel

- FELIX -Data update expected at ASH 2023
- Biologics License Application (BLA) to FDA by end of 2023
- Longer term follow up data planned for medical conferences in H1 2024

Pipeline

- Update on AUTO 8 planned for 2023
- Multiple academic clinical studies ongoing expected to generate additional news flow in 2024
- Opportunity for news flow related to collaborations and technology licensing

Manufacturing

- Commencement of GMP operations in H2 2023

The Autolus opportunity

Building a fully integrated CAR T company - Expanding excellence in R&D and manufacturing to commercialization

- Deliver on obe-cel opportunity in oncology
  - Potential best in class product candidate
  - Met ORR primary endpoint in adult patients with r/r ALL; low rates of Grade ≥3 CRS and/or ICANS
  - Planned BLA filing end of 2023
  - Additional opportunity in B-NHL indications
- Expand obe-cel into B-cell mediated autoimmune diseases
  - Initiate first clinical study in systemic lupus erythematosus (SLE)
- Early pipeline with potential broad applicability in cancers with limited treatment options
  - Strong ongoing collaboration with UCL exploring multiple tumor types

- Established CAR T process development and manufacturing expertise. Reliable delivery and consistent quality of clinical product during FELIX trial
- New commercial manufacturing facility qualification and validation activities on schedule. Planned capacity to serve global demand in ALL (2000+ batches per year)
- Strong technology foundation, validating collaborations with leading pharma and biotech companies – BMS, Moderna and Cabaletta Bio
- Strong cash position with $307.8m (June 30, 2023)

Autolus

Thank you