Autolus

Developing Next Generation Programmed T Cell Therapies

November 2023

Disclaimer

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

Established excellence in R&D and Manufacturing; scaling company toward commercialization

Obe-cel approaching regulatory submission

- Potentially best-in-class CAR T for r/r adult ALL
- Met primary endpoint in pivotal Phase 2 trial; plan to file BLA with FDA by year-end 2023 and with EMA H1 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
- Vein-to-delivery time at launch of ~16 days

Strategic collaborations

- Established technology collaborations with Moderna, BMS and Cabaletta
- Longstanding academic collaboration with University College London
- Partnering opportunities on pipeline programs and platform technology

Strong cash position

- Cash $256.4M (Q3 2023)
- Runway into 2025
- Enables execution on current strategy through 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

LEAD CLINICAL PROGRAM

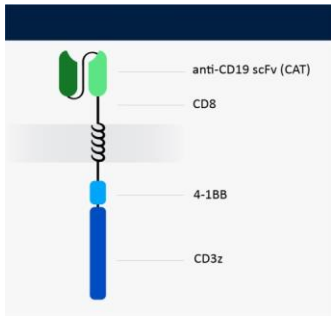
Obe-cel

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

Obe-cel has a unique mechanism of action

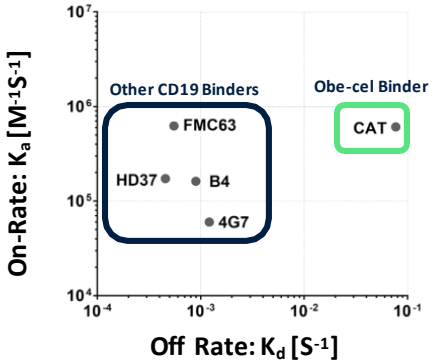
Designed for increased activity and reduced toxicity

Differentiated CD19 binder



CD19 binder with fast off-rate

Fast off-rate



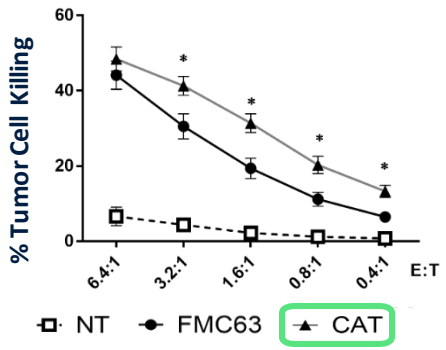
Shorter half-life of interaction compared to binders used in approved products

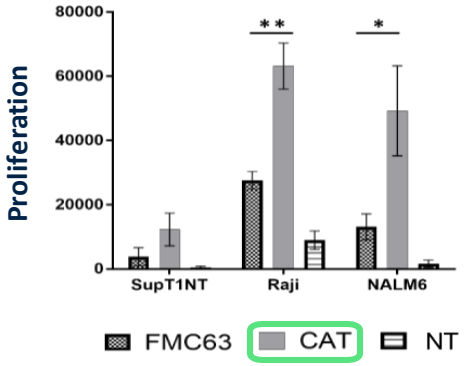
- obe-cel = 9.8 seconds
- Kymriah® = 21 minutes

Potential for improved potency, reduced toxicity

- Avoids over-activation of CAR T cells → Reduced toxicities
- Increases CAR T peak expansion → Improved persistence
- Avoids exhaustion of CAR T-cells → Improved engraftment, Improved persistence

Enhanced cytotoxicity and proliferation





Ghorashian et al. *Nature Medicine 2019*

FELIX data at ASCO and EHA 2023

Trial design and patient baseline characteristics

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

84% of enrolled patients were infused with obe-cel

Enrolled: N = 112
Infused: N = 94

Discontinued: n=18
- Death 11
- Manufacturing related 5
- Adverse event 1
- Physician decision 1

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

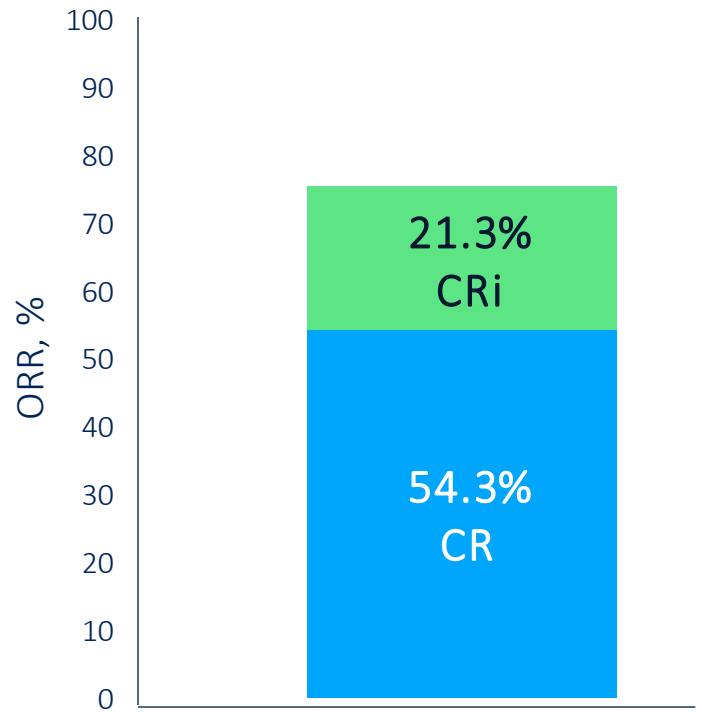
Baseline Characteristics	Total infused (N = 94)
Age years, median (range)	50 (20–81)
Gender male/female, n	47/47
Philadelphia chromosome-positive, n (%)	25 (26.6)
Prior therapies, median (range) ≥3 prior lines, n (%)	2 (1–6) 29 (30.9)
Refractory to last prior line of therapy, n (%)	50 (53.2)
Prior allogeneic 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)

* 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: disease response per IRRC assessment

76% of infused patients achieved CR/CRi



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

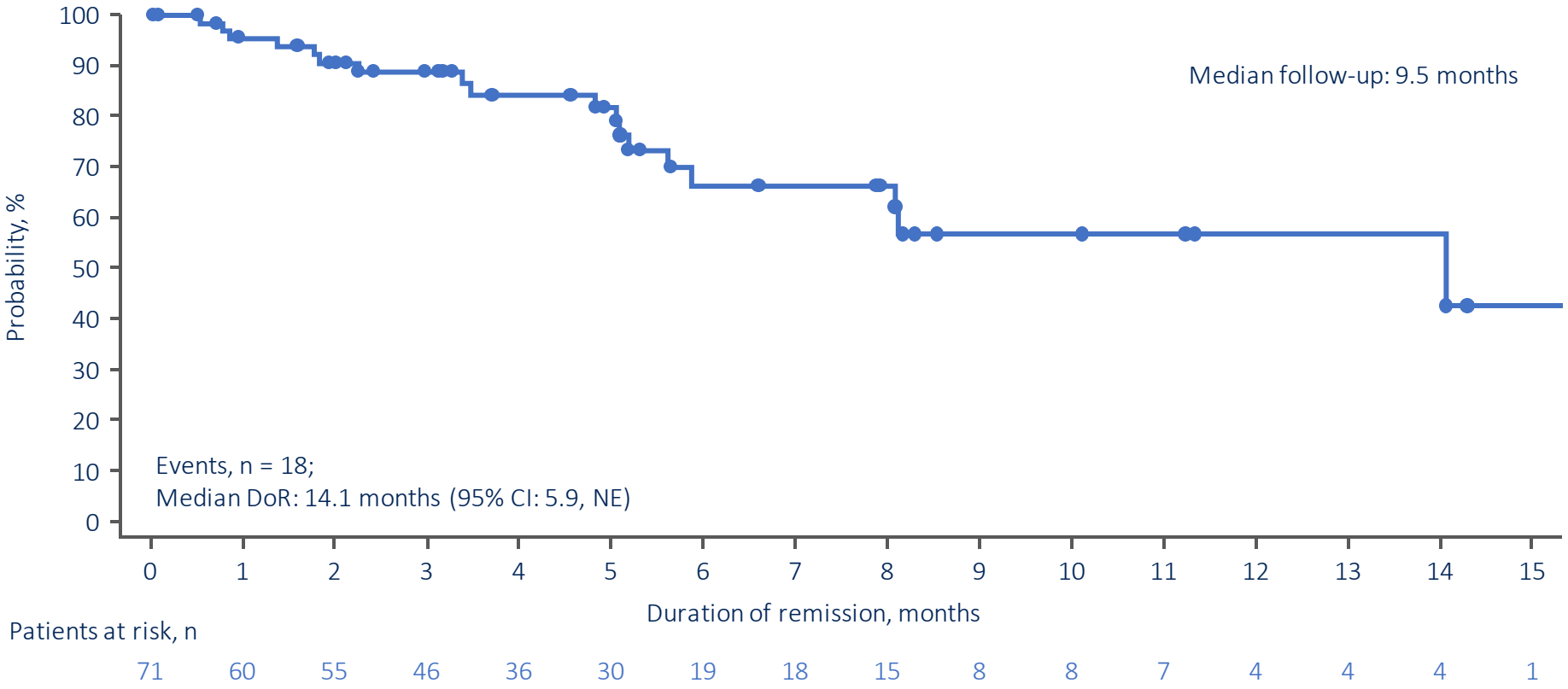
97% of responders with evaluable samples were MRD negative at 10^{-4} level by flow cytometry

*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

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

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

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

FELIX: CRS and ICANS profile

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

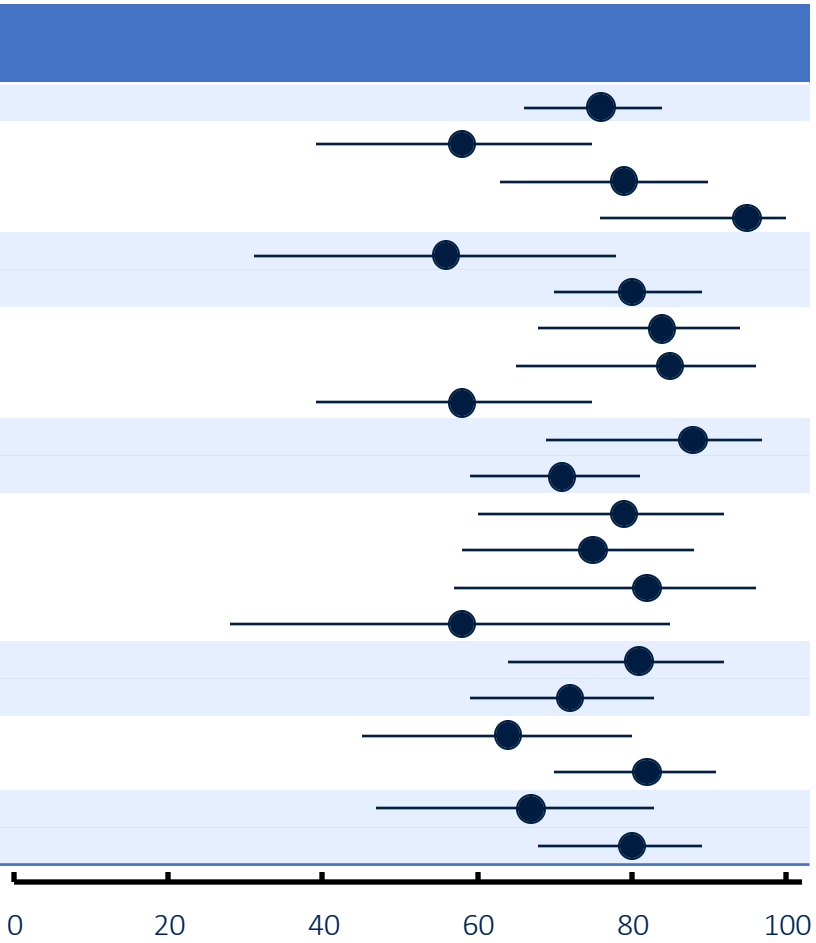
CRS, cytokine release syndrome; ICANS, immune effector cell associated neurotoxicity syndrome

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

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

Benefits observed across all patient subgroups; 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)

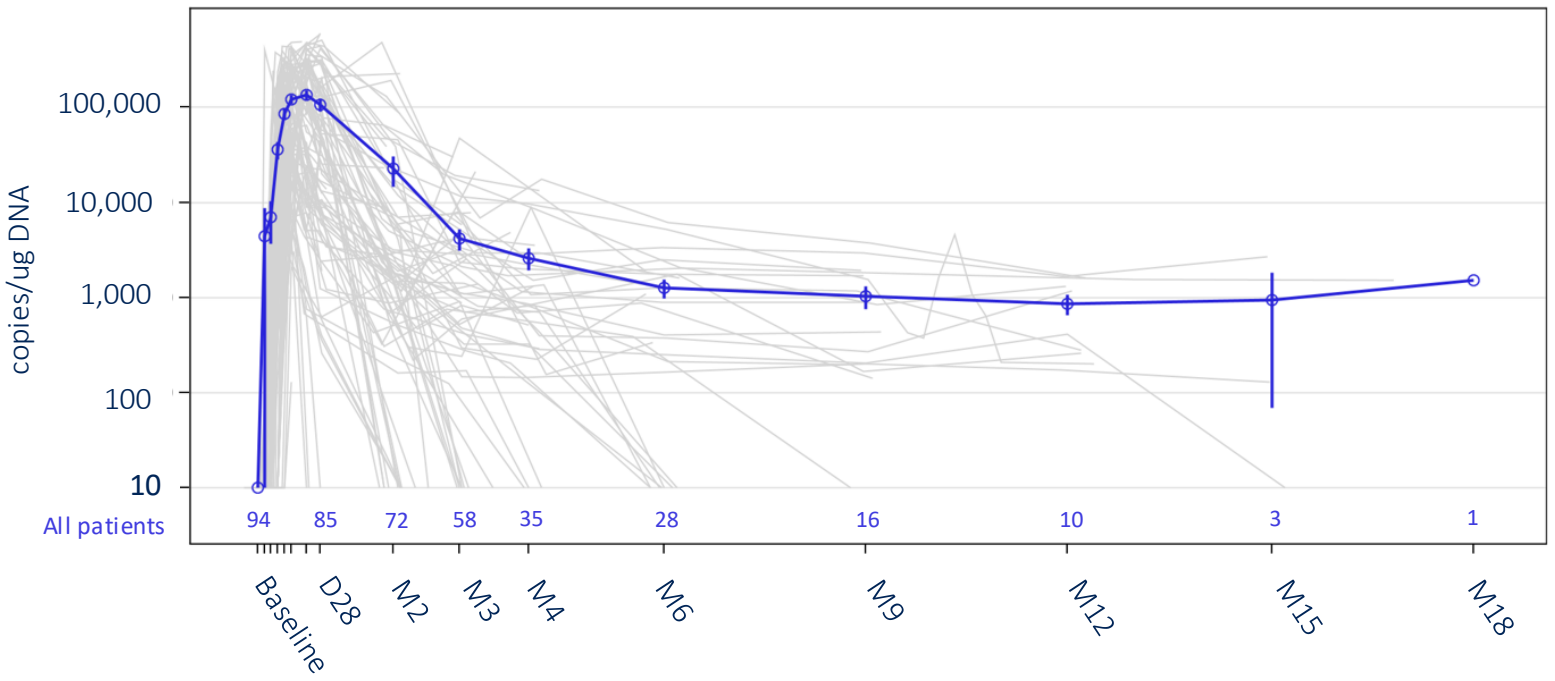


CR, complete remission; CRi, CR with incomplete blood count recovery; EMD, extramedullary disease; IRRC, independent response review committee; ORR, overall remission rate

FELIX: 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

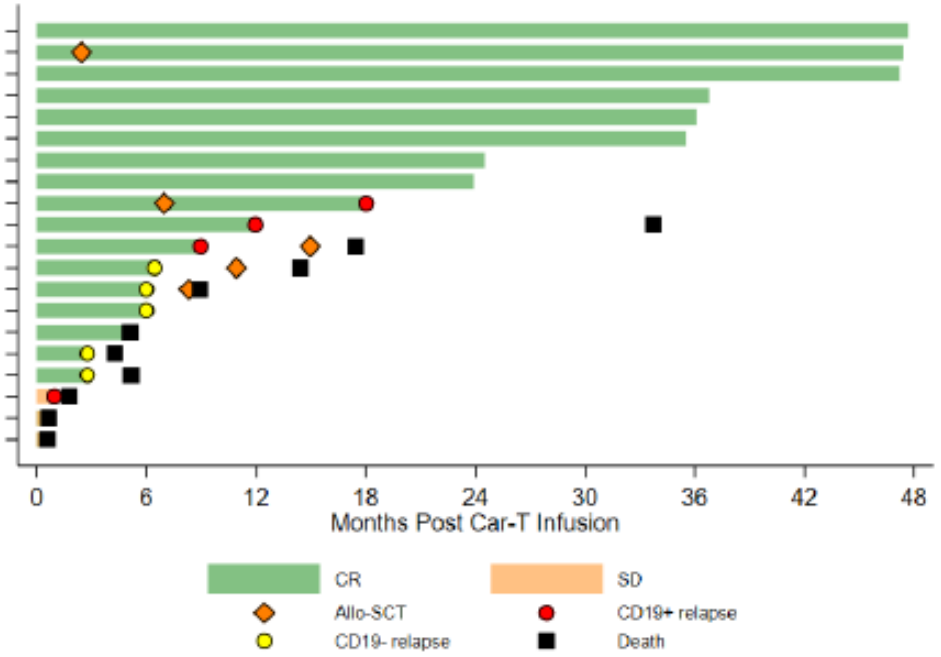
1. Roddie C et al., J Clin Oncol 2021;39(30):3352–63

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

Obe-cel Phase 1 long term follow up demonstrates durable responses

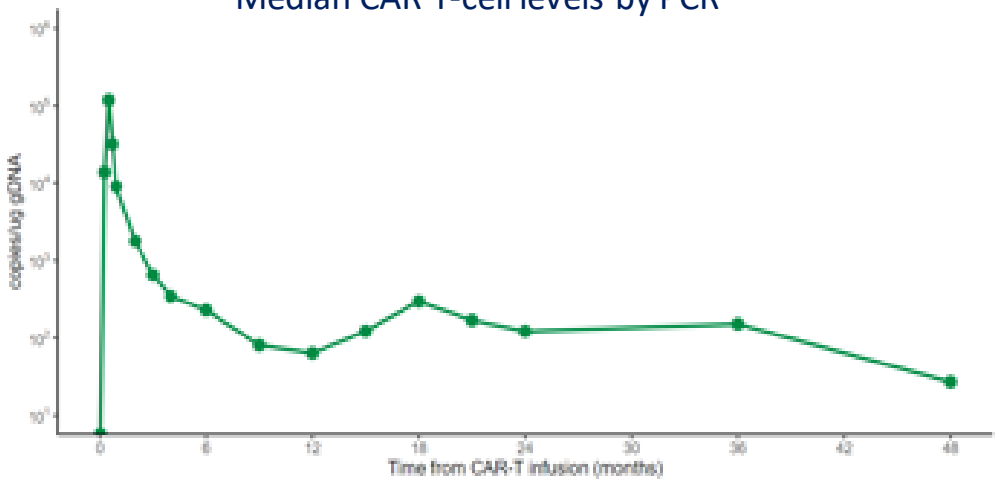
Long term follow up from Phase 1 ALLCAR19 study in r/r ALL of up to 4 years

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

- **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
- **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**
  - 84% of enrolled patients received obe-cel
  - Median vein to release of 21 days
- **Excellent CAR T-cell engraftment**
  - C_{max} of 114,982 copies/ug DNA and Tmax at 14 days

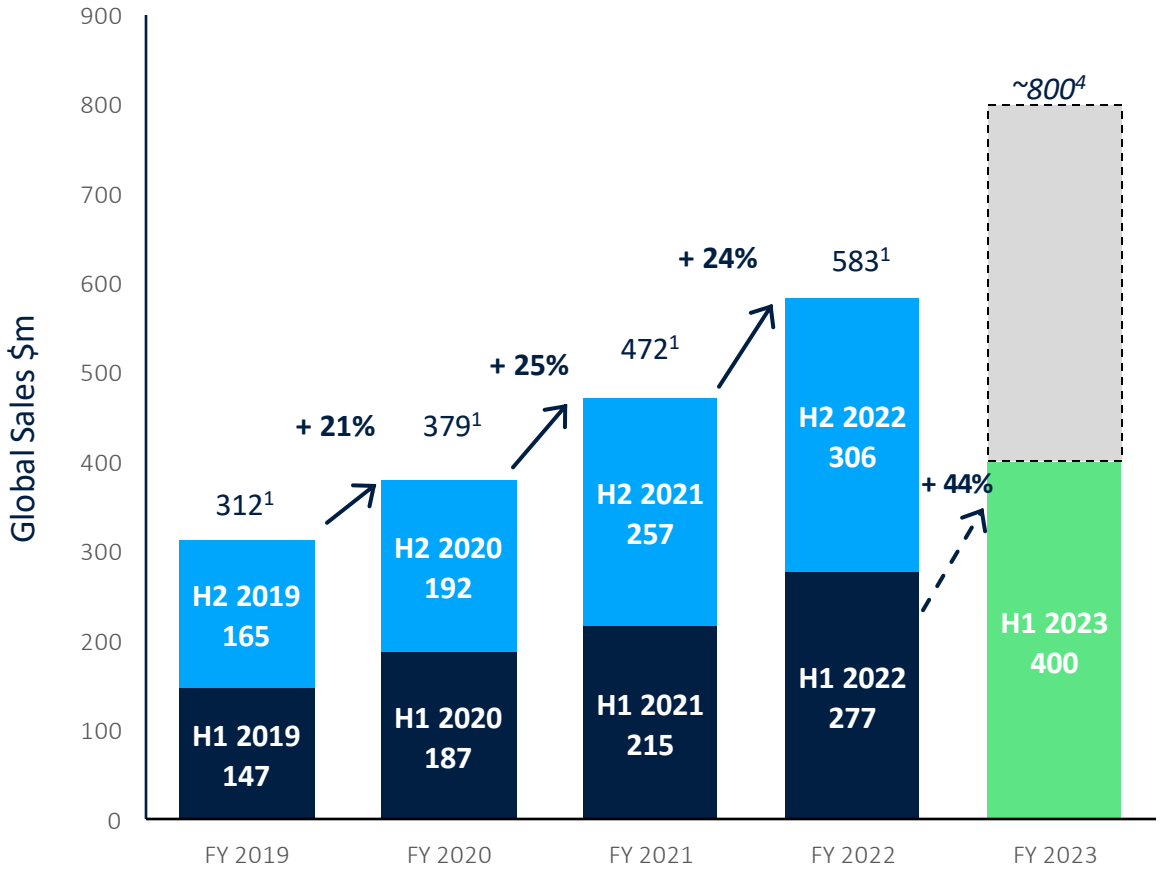
Roddie et al., ASCO 2023, data cut-off date: March 16, 2023

ALL: unmet need and market overview

Obe-cel could launch into an expanding ALL market if approved

Blincyto®, current market leader, sales increased 48% year-over-year to $206 million for the second quarter 2023

Reported Blincyto® sales[1]



- Blincyto® sales price estimated to be $207k[2] (for 2 cycles) supporting approx. >2,000 commercial adult ALL patients. Sales increased 48% year-over-year to $206 million for the second quarter 2023
- Kymriah® is priced at $508k in pediatric ALL. Breyanzi® is priced at $447k in DLBCL[3]. Tecartus™ is priced at $424k[3] 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

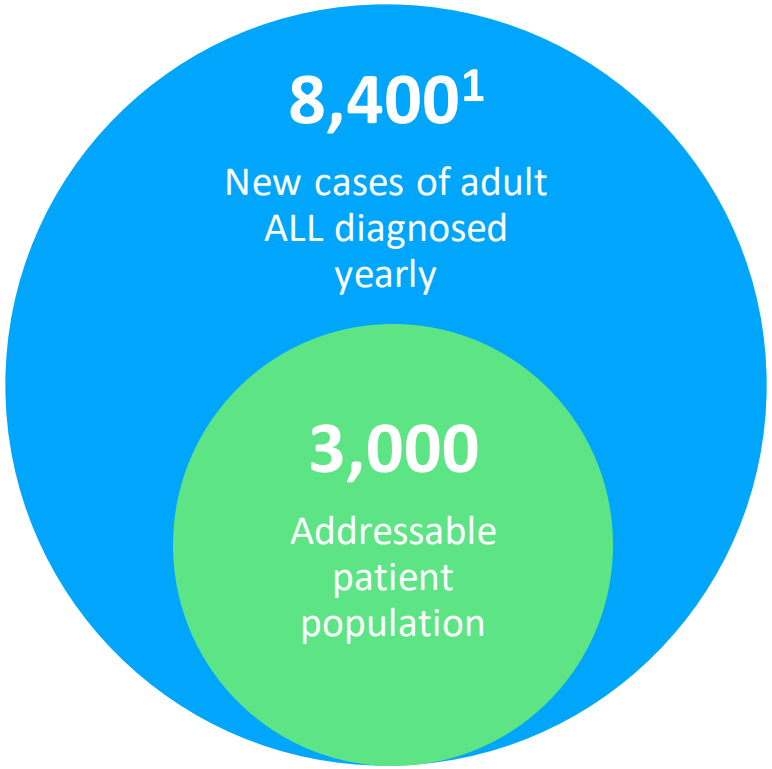
NOTES

1. As per Amgen quarterly SEC filings
2. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files
3. Red Book pricing database https://www.ibm.com/products/micromedex-red-book/pricing
4. Autolus crude extrapolation from Q2 2023, based on sustaining growth in Q3 and Q4 2023

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 market adoption

PRODUCT PROFILE

Durable and robust response

- CR/CRi rate of 76%, with 97% of responders becoming MRD negative[1]
- With a median of 9.5 months' follow-up, 61% of responders remain in remission[1]

Predictable and manageable tolerability

- Very low rates of Grade ≥3 CRS (3.2%) and low rates of Grade ≥3 ICANS (7.4%)[1]

FELIX 19 **Pivotal Phase 2 trial in adult ALL**

TREATMENT EXPERIENCE

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

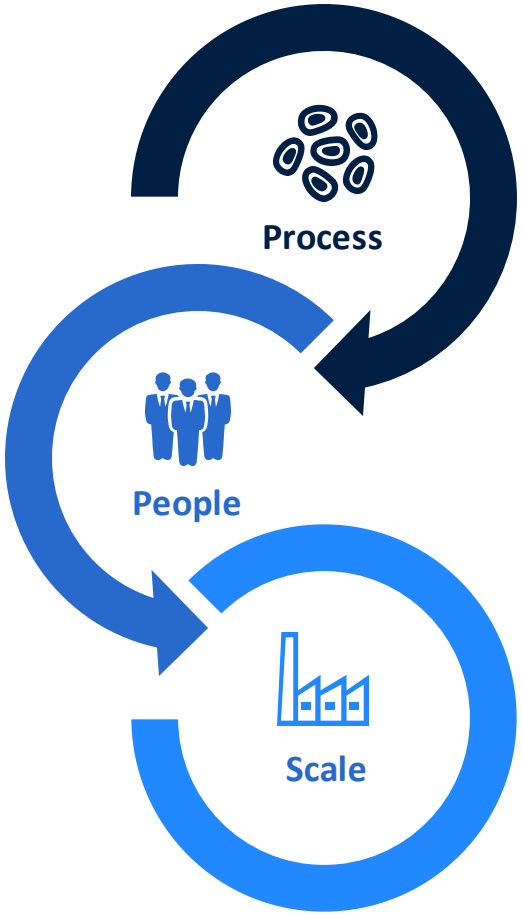
1. Roddie et al., ASCO 2023, data cut-off date: March 16, 2023

Commercial Launch Readiness

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

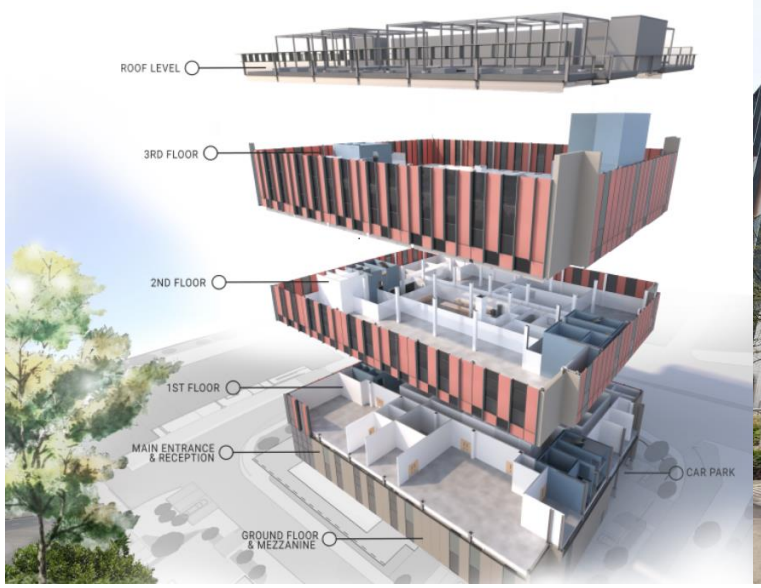


- Process
  - Consistent manufacturing process performance over a wide range of patient cell material
  - Consistently short turnaround time
  - A semiautomated production platform enabling product consistency and economies of scale
- People
  - Leadership to drive outcome
  - Highly trained and motivated 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

The Nucleus

State of the art design and operations established – validation completed

Design



- ~70,000 sq ft facility
- Modular build using PAMs
- 70% built off-site
- 60% reduced build time
- BREEAM Excellent rating for sustainability

Build

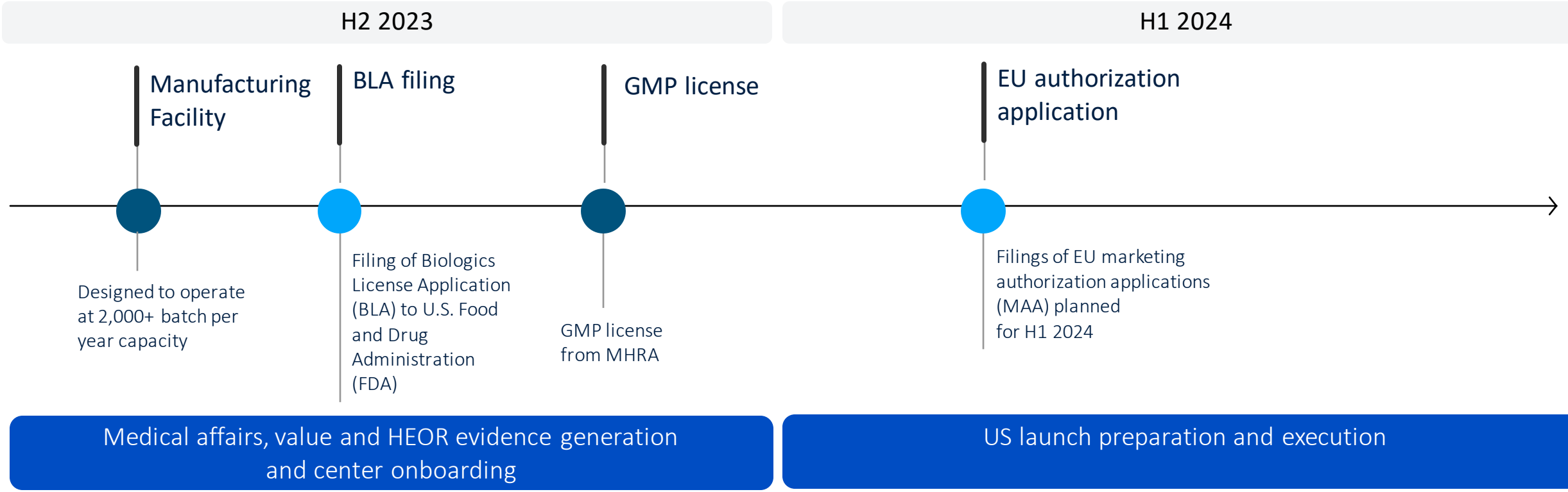
- Nov 8, 2021 ground breaking
- Nov 25, 2022 first clean room in operation
- Facility validation completed in 2H 2023

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

Obe-cel steps to commercialization

Roadmap to a 2024 commercial launch



- Regulatory
- Manufacturing
- Commercialization

Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

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

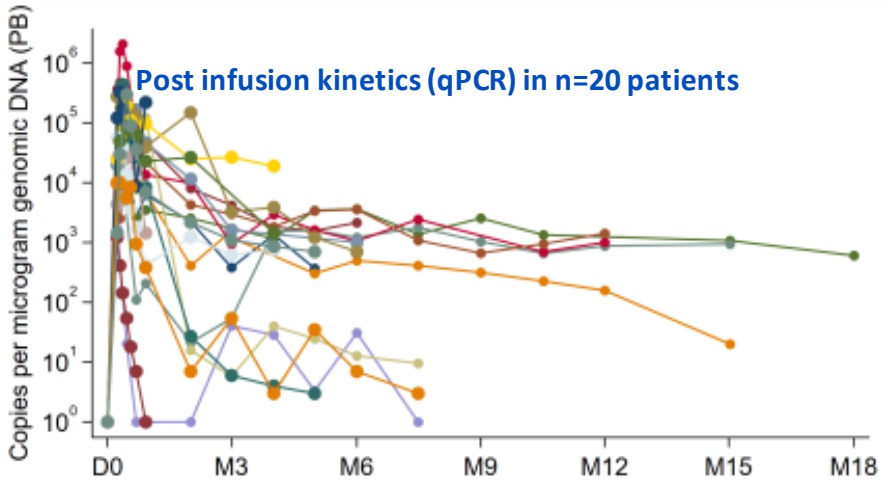
- Dual CD19 & BCMA Targeting
- Designed to induce deep and durable responses
- Phase 1 data expected end 2023

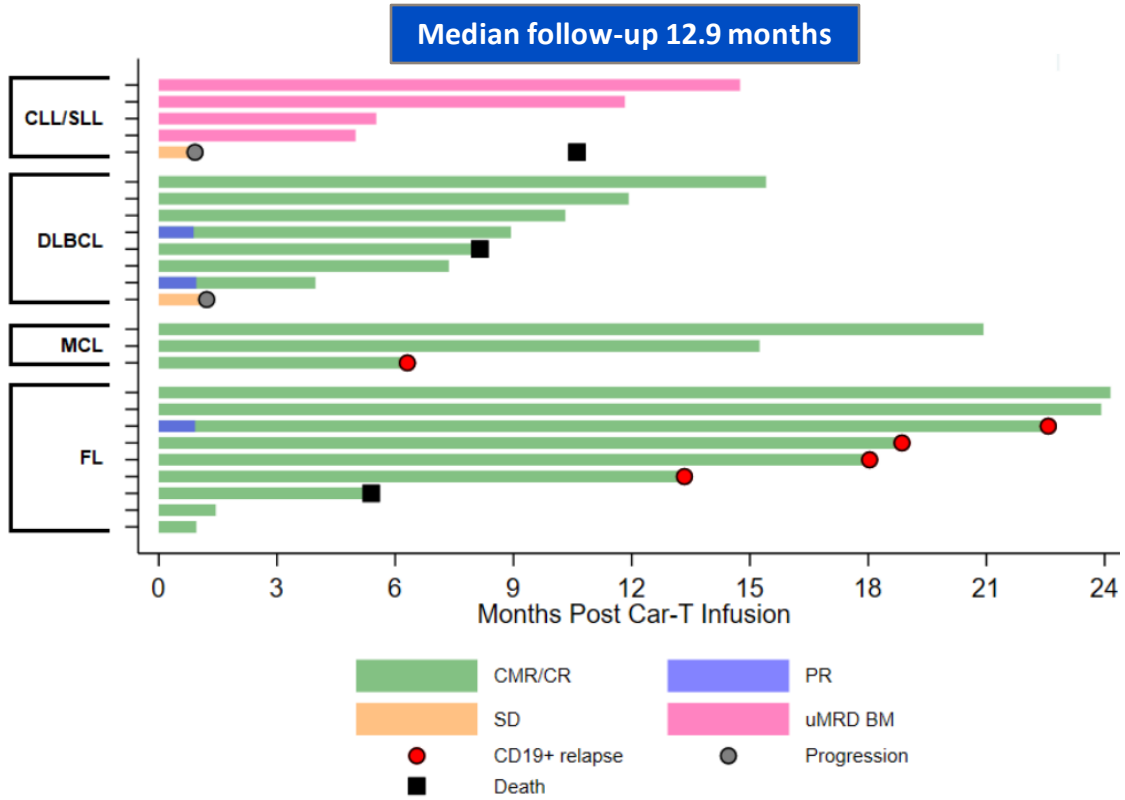
→ Multiple Myeloma
→ B-cell and plasma cell mediated autoimmune

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

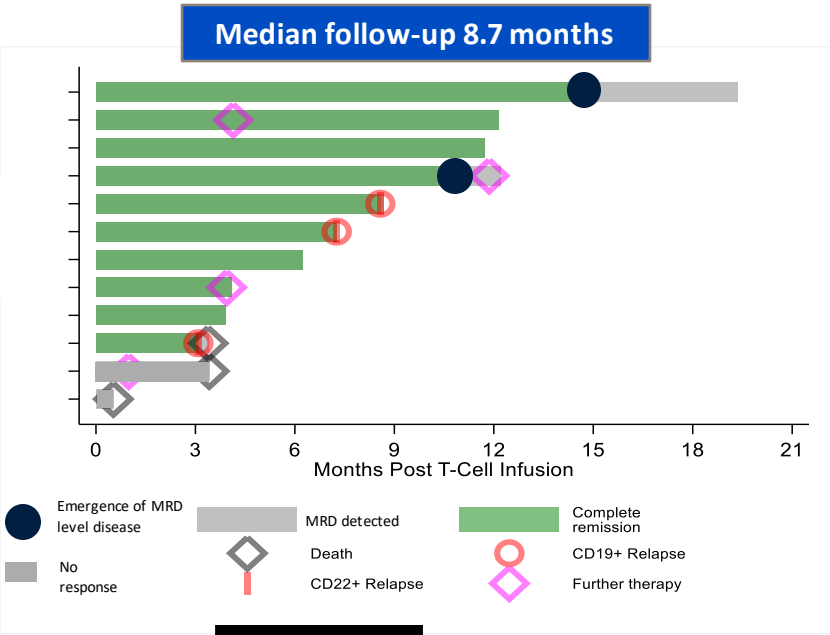
Collaboration with UCL

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



- 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

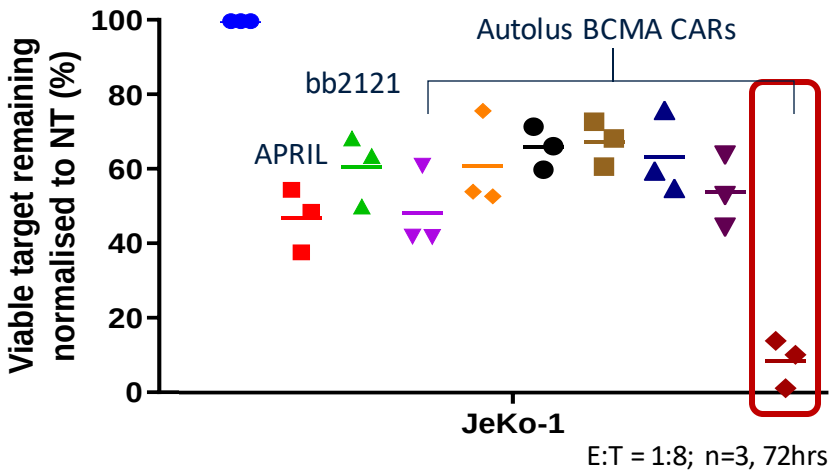
BCMA CAR

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

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

Collaboration with UCL

Uniquely positioned to deliver CAR T therapy in autoimmune disease

Obe-cel's potential advantages	Supporting evidence
Outstanding tolerability to drive physician and patient acceptability in rheumatology settings	✓ Potential best-in-class risk/benefit profile in pivotal FELIX trial in adult ALL ✓ Low rates of high-grade CRS and ICANS across all patients
Deep cut into the CD19+ B and plasma cell compartment to remove all autoreactive clones	✓ Demonstrated in B-ALL with very high rate of MRD negative complete remissions (97% of responders)
Development of robust, economical and scalable manufacturing and commercial infrastructure	✓ Potential approved, commercial manufacturing facility in adult ALL with attractive cost of goods at launch for SLE ✓ Commercial systems and CAR T center services established with potential adult ALL launch
High treatment effect enables smaller clinical program and accelerated regulatory path to launch	✓ Treatment effect demonstrated in Erlangen proof-of concept ✓ Clinical safety data from ALLCAR19 and FELIX as well as potential commercial patient data to supplement SLE pivotal study

Obe-cel ideally positioned as potential best in class and fastest to market

Could offer fastest and lowest risk cell therapy approach for B-cell mediated autoimmune diseases

	Established Tolerability Profile	Established Clinical Profile	Manufacturing Infrastructure	Commercial Infrastructure	Comment
AUTOLUS (obe-cel)	🟢	🟢	🟢	🟢	Potential best-in-class risk/benefit ratio. Established manufacturing and product delivery. ALL commercial infrastructure in place for SLE
BIOTECH: (new CAR T entrants)	🔴	🔴	🔴	🔴	Clinical profile not yet established. Likely use CDMO or local site for manufacturing with unfavorable cost implications
PHARMA: (new CAR T products)	🟡	🟡	🟡	🟢	New products under development. Will need to re-establish efficacy & safety profile and commercial manufacturing for autoimmune
ALLOGENEIC	🔴	🔴	🟡	🔴	Clinical profile not yet established

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	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	Early 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	First clinical data end of 2024
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL	UCL	Phase1	Data in peer reviewed journal
AUTO8	Multiple Myeloma	CD19 & BCMA	MCARTY	UCL	Phase 1	Q4 2023: First clinical data

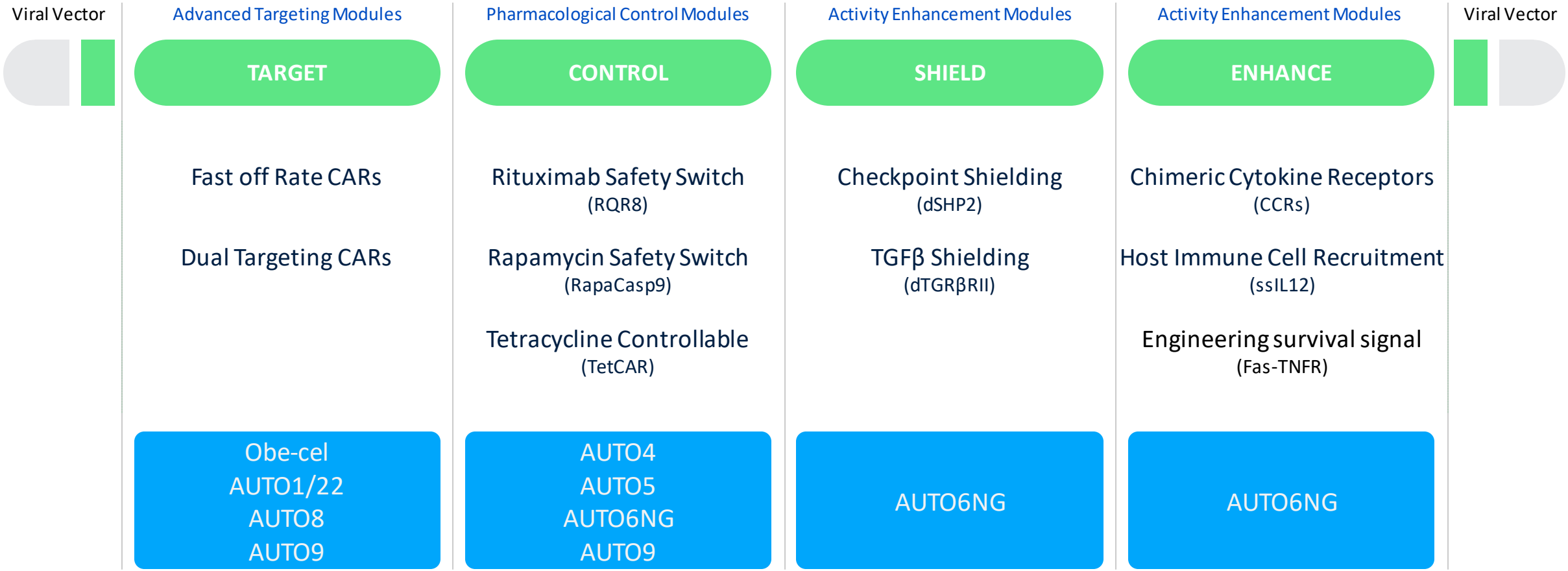
Additional pipeline programs

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	UCL	CTA submitted	Q4 2023: Phase 1 initiation
AUTO9	Acute Myeloid Leukemia	CD33, CD123 & CLL1	TBD	UCL	Preclinical	First clinical data in 2025

Oncology Autoimmune

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

moderna

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

Bristol Myers Squibb

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

Cabaletta Bio®

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

Upcoming news flow

Autolus planned news flow

Milestone or Data Catalysts	Timing
Obe-cel Biologics License Application (BLA) to FDA	**By end 2023**
Obe-cel FELIX data update at ASH	**Dec 2023**
AUTO8 update (MCARTY) at ASH	**Dec 2023**
AUTO6NG Phase 1 study start (MAGNETO)	**By end 2023**
Obe-cel in autoimmune disease – refractory SLE Phase 1 study start	**Early 2024**
Obe-cel Marketing Authorization Application (MAA) to EMA	**First half 2024**

Summary

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

Established excellence in R&D and Manufacturing; scaling company toward commercialization

Obe-cel approaching regulatory submission

- Potentially best-in-class CAR T for r/r adult ALL
- Met primary endpoint in pivotal Phase 2 trial; plan to file BLA with FDA by year-end 2023 and with EMA H1 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
- Vein-to-delivery time at launch of ~16 days

Strategic collaborations

- Established technology collaborations with Moderna, BMS and Cabaletta
- Longstanding academic collaboration with University College London
- Partnering opportunities on pipeline programs and platform technology

Strong cash position

- Cash $256.4M (Q3 2023)
- Runway into 2025
- Enables execution on current strategy through 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

Autolus

Thank you