

Autolus

Developing Next Generation Programmed T Cell Therapies

April 2023



Disclaimer

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Welcome and opening remarks

Dr Christian Itin, Chief Executive Officer
Autolus

Autolus

Capital Markets Day
April 27 2023

Capital Markets Day

Agenda

3pm BST

Session 1: Welcome and opening remarks

Dr Christian Itin
Chief Executive Officer, Autolus

3.10pm BST *

**Including 5 mins
for Q&A*

Session 2: The treatment landscape for ALL

Dr Lori Muffly, MD - Associate Professor, Blood and Marrow
Transplantation and Cellular Therapy, Stanford University

3.35pm BST

Session 3: FELIX programme update

Dr Claire Roddie, Associate Professor Haematology,
Cancer Institute, UCL

3.50pm BST

Session 4: Living with ALL

CAR T Patient Video

4.05pm BST

Session 5: Broader market overview and economics

Dr Matthew Gitlin, BluePath Solutions

4.25pm BST

Session 6: Commercial Roadmap

Christopher Vann, Chief Operating Officer, Autolus

4.40pm BST

Session 7: Moderated Q&A and final remarks

Dr Christian Itin

5.00pm BST

Event concludes

Today's speakers



Dr Christian Itin
Chief Executive Officer
Autolus

Christian has been CEO of Autolus since the Company's inception

Autolus



Dr Lori Muffly
Associate Professor,
Blood and Marrow
Transplantation and
Cellular Therapy
Stanford University



Dr Claire Roddie
Associate Professor
Haematology,
Cancer Institute
UCL



Dr Matthew Gitlin
BluePath Solutions



Christopher Vann
Chief Operating Officer
Autolus

Chris leads commercial activities at Autolus

Autolus

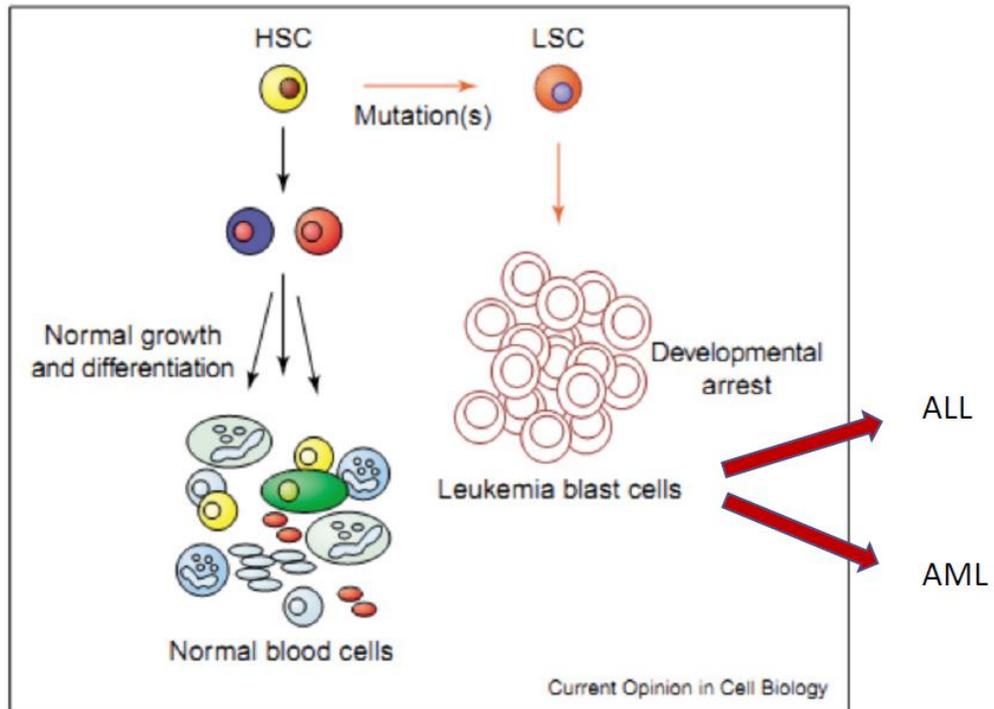


The treatment landscape for ALL

Dr Lori Muffly, Associate Professor, Blood and Marrow
Transplantation and Cellular Therapy
Stanford University

Acute Leukemia is an aggressive disease that can evolve rapidly

Acute leukemia arises from leukemia stem/progenitor cells (LSC)



- Both ALL and AML are characterized by massive proliferation of leukemic blast cells which leads to suppression of normal hematopoiesis
- Resulting in low numbers of normal white blood cells (with an increased rate of infections), low red blood cells (leading to anemia) and low platelets (leading to increased rates of bleeding complications)
- B-cell acute lymphoblastic leukemia is the most common type of ALL, accounting for approx. 85% of childhood ALL cases and 75% of adult cases

Adult patients with relapsed/refractory B-ALL have a poor outcome

Unmet need remains high in adult population

- The majority of adult patients affected by B-ALL will relapse after an initial response, while approximately 20% will display primary resistant disease
- Patients suffering from relapsed/refractory B-ALL have a very poor outcome with median OS ranging from 6-11 months
- With the advancement of possible new therapies such as T cell engaging antibodies, ADCs CAR T cells, survival is improving
- However, there remains significant unmet need for long term durable treatment options

Treatment landscape is changing with the introduction of immuno-therapies

However, allo SCT continues to be 'Gold Standard' for long term remission and/or curative therapy

BLINATUMOMAB

Standard of Care

A bi-specific CD19-directed CD3 T-cell engager (BiTE)

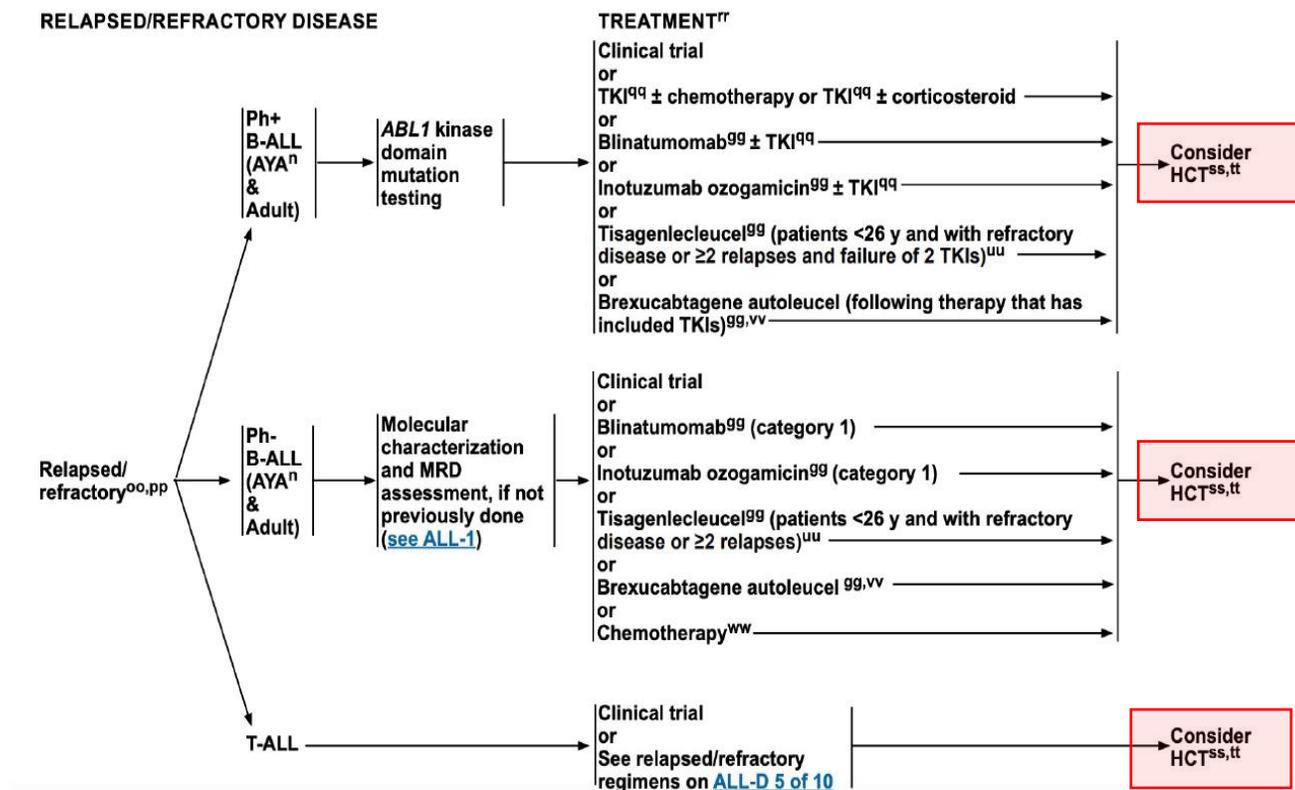
INOTUZUMAB OZOGAMICIN

A CD22-directed Antibody-drug conjugate with calicheamicin

BREXUCABTAGENE AUTOLEUCEL

Recently approved

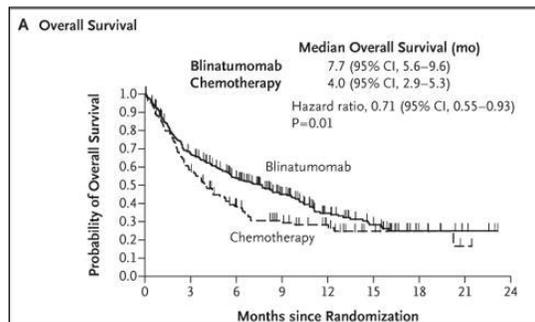
A CD19-directed autologous CAR T cell immunotherapy



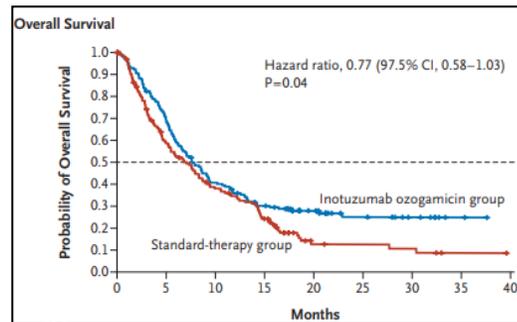
Standard of Care Therapies: Blinatumomab and Inotuzumab

Provides good response rates, but with limited durability and associated toxicities

Blinatumomab



Inotuzumab



Drug	Study	No. of Patients	ORR (%)	MRD Rate (%)	Median OS (Months)
Inotuzumab	Kantarjian <i>et al.</i> [17]	218	81	78	7.7
Inotuzumab	Jabbour <i>et al.</i> [18]	59	78	82	11.0
Blinatumomab	Kantarjian <i>et al.</i> [33]	405	44	76	7.7
Blinatumomab	Topp <i>et al.</i> [32]	189	43	82	6.1

Frequently used as bridge to transplant:

Highly active and initial response rate, however durability remains a challenge with median OS < 8 months

Toxicity profile seen in both therapies:

- Blinatumomab: high level of neurologic toxicities
- Inotuzumab: may cause hepatotoxicity and is associated with higher post-transplant non-relapse mortality

Recently approved CAR T cell therapy: Brexucabtagene autoleucel

High initial response rate, but notable toxicities

Tecartus™¹
(brexucabtagene autoleucel)

N	54
ORR	65%
CRS \geq Grade 3	26%
Neurotox any Grade	87%
Neurotox \geq Grade 3	35%
Other notable observations	40% vasopressor use ²

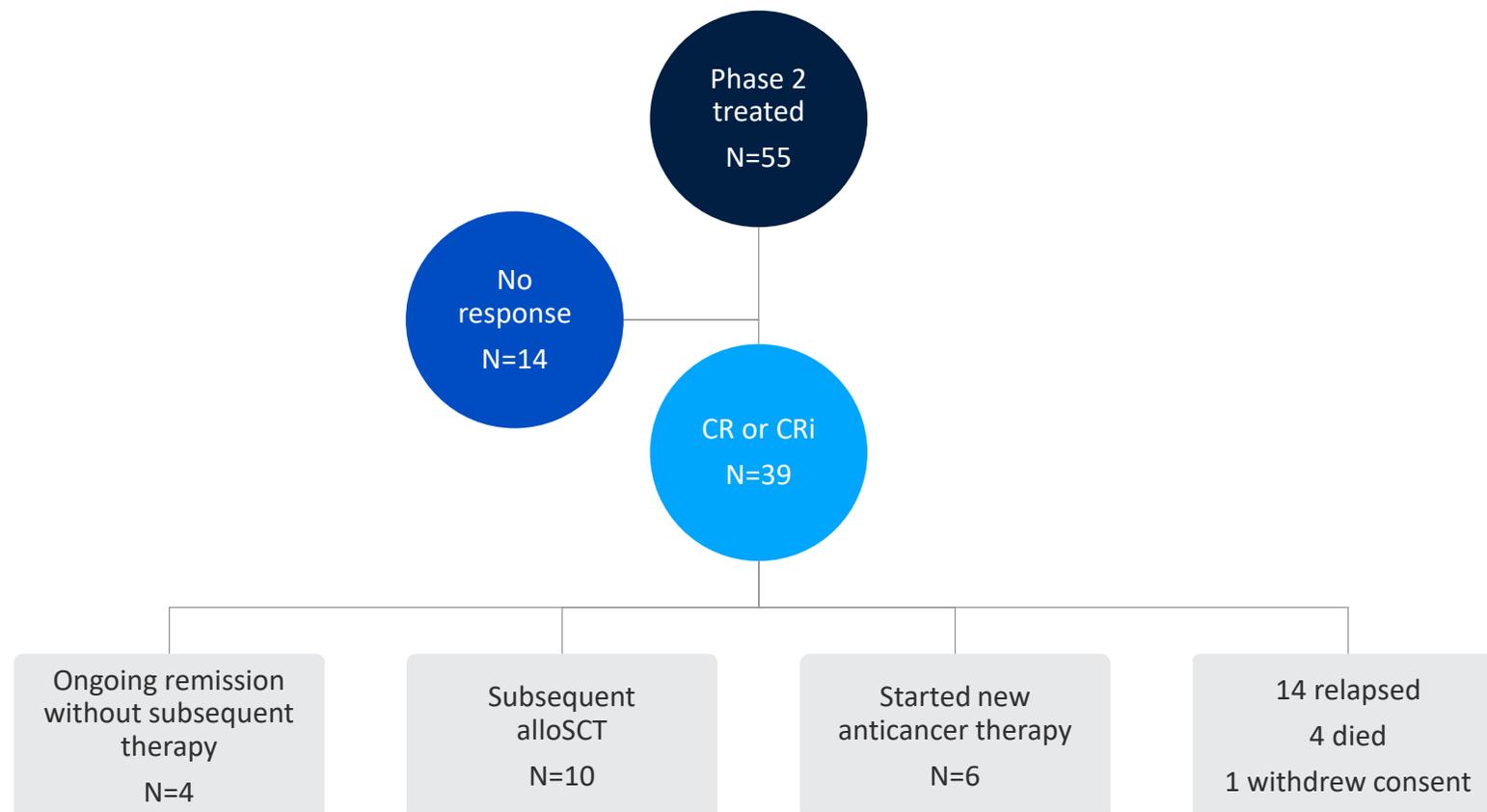
FDA Approved in October 2021, based on the ZUMA-3 trial with 55pts dosed (54pt evaluable)

- Demonstrate better overall activity and response rate versus Blinatumomab (cross-trial comparison)
- However, at the cost of high toxicity including 35% pt experience grade 3 or above Neurotoxicity events
- High use of Vasopressors

High initial response rate but are the responses sustained?

Recently approved CAR T-cell therapy: Brexucabtagene autoleucel

Responses are not durable



Outcomes of Phase 2 responders after 38.8 months of median follow-up (range 32.7-44.6mths)

Durability of response: only 4/55 patients (7%) remaining in ongoing remission without subsequent therapies including alloSCT.

Allo SCT may provide a cure for ALL; however, is associated with risks

- A stem cell transplant (SCT) is an intensive and complex treatment that can cause life-threatening side effects
- A second SCT is associated with an even higher risk. Outcomes are poor, with only 14% overall survival and 7% GvHD-free RFS at 5 years, with very high relapse incidence. Importantly, the non-relapse mortality after second SCT is ~24% at 2 years¹
- During a SCT chemotherapy \pm total body irradiation are used to eradicate leukemic cells in the bone marrow. Following this treatment, the patient receives a transplant of donor stems cells to restore bone marrow function
- Success of a SCT is markedly increase in those patients who tested negative for bone marrow minimal residual disease (MRD) before transplant
- The life expectancy, survival rate and quality of life have improved considerably with more accurate genetic matching with donors and improved post-transplant care. However, several risk factors remain, including:
 - Graft versus host disease (GvHD) and side effects due to its prevention
 - Infections
 - Non-relapse mortality

¹Nagler A et al, British Journal of Haematology, 2019, 186, 767–776

What next for the adult ALL patients?

Despite new therapeutic agents there remains significant unmet need in patients with ALL

Brexucabtagene Autoleucl CART cell therapy provides an alternative treatment option with high response rate and toxicities

However, durability of response and severe toxicities remains a hurdle

SoC therapies Blinatumomab and Inotuzumab Ozogamicin, provide high response rates with limited toxicities but also limited durability

Predominantly used to support patients as a bridge to Allo SCT

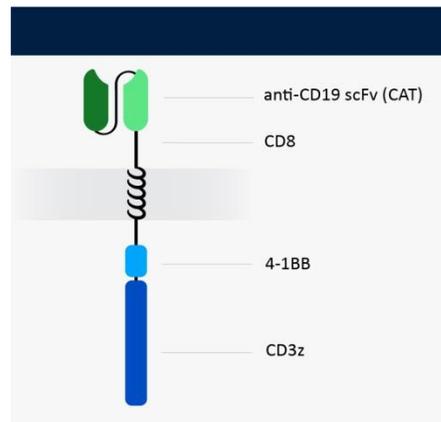
Newer therapies may provide an opportunity to address some of these limitations, without the subsequent need for transplant



FELIX program update

Dr Claire Roddie, Associate Professor
Haematology, Cancer Institute, UCL

Obe-cel has a unique mechanism of action



CD19 binder with fast off-rate

Improved potency, reduced toxicity

Avoided over-activation of CAR T cells

-> Reduced toxicities

Increased CAR T peak expansion

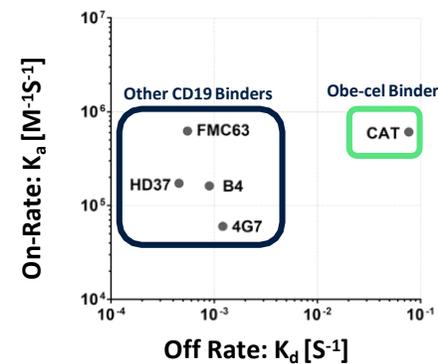
-> Improved persistence

Avoided exhaustion of CAR T cells

-> Improved engraftment

-> Improved persistence

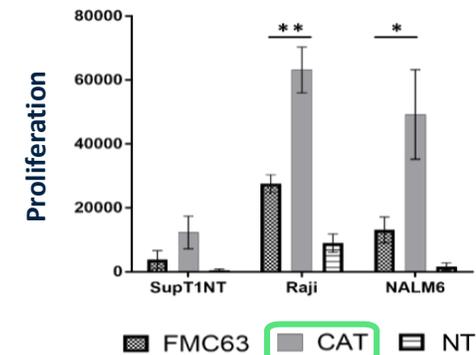
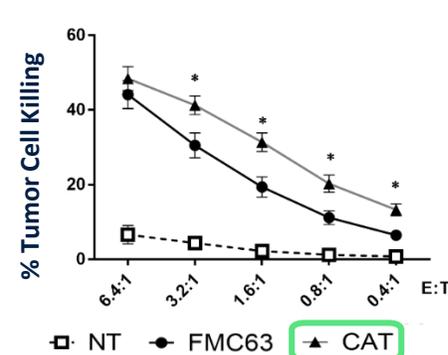
Fast off-rate



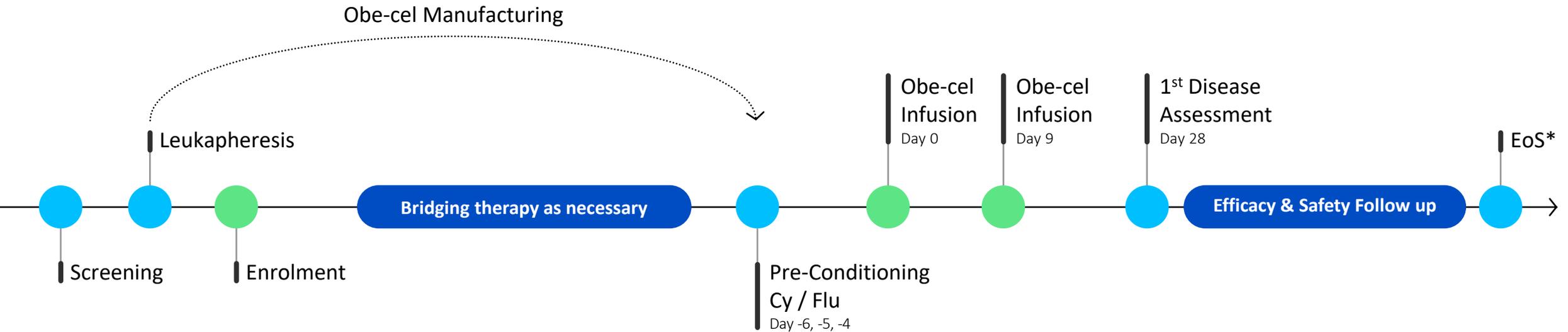
Obe-cel has a shorter half-life of interaction compared to binders used in approved products

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

Enhanced cytotoxicity and proliferation



ALLCAR19 Phase 1 study overview



Indication	LD	Day 0 Dose 1 (x10 ⁶ CAR T-cells)	Day 9 Dose 2 (x10 ⁶ CAR T-cells)
B-ALL	Cy / Flu	10/100*	400/310*

*Dose dependent on patient disease burden. (total dose 410m CAR T-cells)

Roddie et al., *Journal of Clinical Oncology* 2021

Obe-cel: ALLCAR19 study - initial experience in r/r adult ALL

Very low rates of high-grade CRS and ICANS in challenging patient population

ALLCAR19	(N=20)
CRS	
(any grade)	11 (55%)
Grade 2	8 (40%)
≥ Grade 3	0
ICANS	
(any grade)	4 (20%)
Grade 1	0
Grade 2	1 (5%)
≥ Grade 3	3 (15%)

Cytokine Release Syndrome

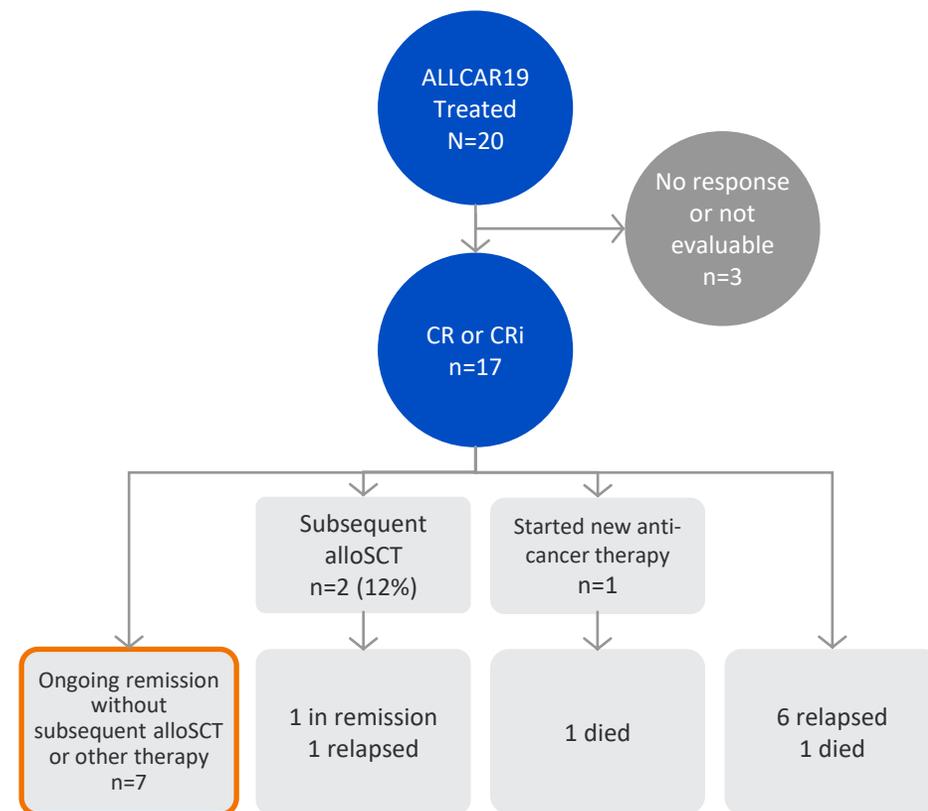
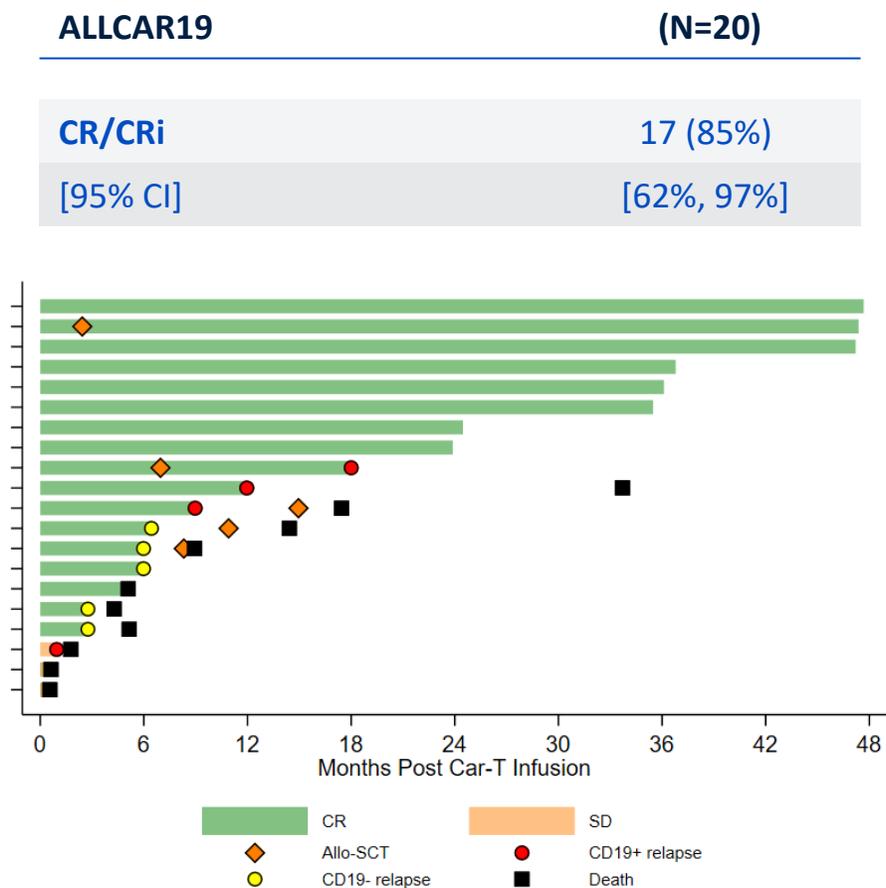
- No patients experienced ≥ Grade 3 CRS
- Tocilizumab was used in 7/20 patients (35%) all of which had grade 2 CRS
- No steroid use required for management of CRS

Neurotoxicity

- In patients with Grade 3 ICANS all had ≥ 50% blasts
- All cases rapidly resolved within 24 - 72 hrs of treatment with steroids

High initial response rates and high levels of sustained remissions

35% of patients in long term remission w/o additional anti-leukemia tx at a median f/u of 36 months (range 24-48 months)



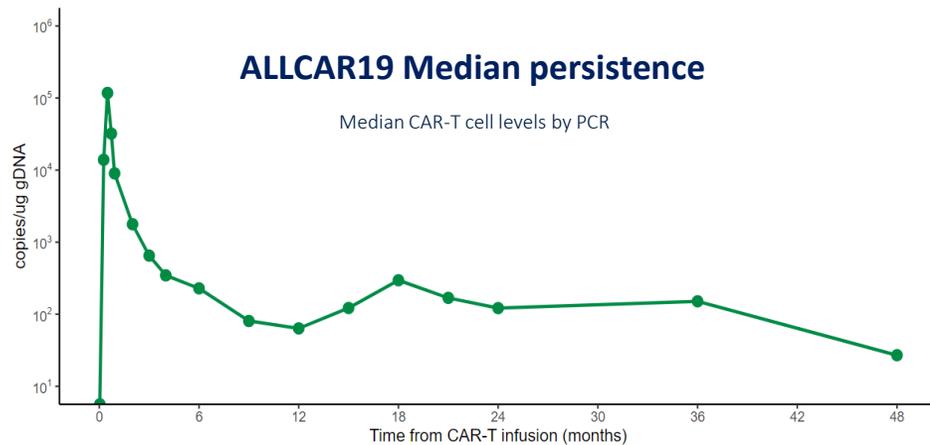
- 35% (7/20) patients remain in CR with no further therapy

Median FU 36 months (IQR 24-47)

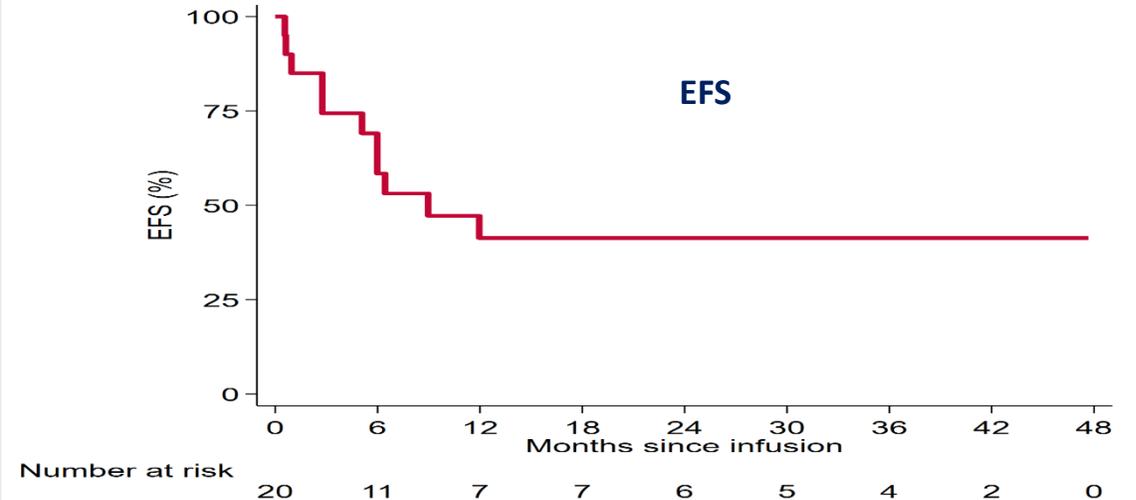
Roddie et al., ASH 2022, abstract #3318
 Roddie et al., *Journal of Clinical Oncology* 2021

Long term persistence of CAR T cells

Differentiated OS and EFS



- CAR T cells persist at last assessment in all patients that maintain remission without any further therapy



- EFS achieving a plateau at month 12, with no further relapse events

FELIX Phase 2 Study Overview

Interim analysis completed Q4 2022 – **met primary endpoint** – next data readout expected mid 2023

FELIX



Pivotal Phase 2 trial in adult ALL
ongoing since mid-2021

Phase 2 has up to 100 relapsed/refractory adult ALL patients with morphological disease:

- 34 sites in US, UK and Spain
- Phase 1b run-in study – completed Q4 2021
- Phase 2 study interim analysis completed in Q4 2022 – primary end point reached
- Phase 2 cohort fully enrolled Q4 2022

Mid 2023
Data at medical
conference

**Primary
endpoint**
overall
complete
response rate
(CR/CRi)

**Secondary
endpoints**
include MRD-
negative CR,
EFS and DoR

Obe-cel FELIX Phase 2 data track ALLCAR19 data at interim analysis

Efficacy Assessment (50 pts)

- Phase 2 pivotal FELIX study of obe-cel in r/r adult ALL has met its primary endpoint, defined as ORR (CR + CRi)
- Obe-cel demonstrated ORR of 70% in interim analysis of 50 patients with r/r ALL
- Encouraging tolerability data observed, with 3% ≥Grade 3 Cytokine Release Syndrome (CRS) and 8% ≥Grade 3 Immune effector cell-associated neurotoxicity syndrome (ICANS) in 92 patients evaluable for safety

FELIX P2 Interim Analysis (N=50)

ORR (=CR + Cri) – n (%)	35 (70.0%)
[95% CI]	[55.4%, 82.1%]

FELIX P2 Interim Analysis (N=92)

CRS¹ > Grade 3	3%
ICANS² > Grade 3	8%
ICANS² any Grade	23%

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

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

Obe-cel data consistent across independently conducted studies

	CARPALL¹ Peds B-ALL Phase 1	ALLCAR² Adult B-ALL Phase 1	FELIX⁴ Adult B-ALL Phase 1b	FELIX⁵ Adult B-ALL Pivotal
N	14	20	16	50/92
ORR (95% CI)	86% (57%, 98%)	85% (62%, 97%)	75% (48%, 93%)	70.0% (55.4%, 82.1%)
CRS \geq Grade 3	0%	0%	0%	3.3%
ICANS > Grade 3	7%	15%	6%	7.6%
ICANS any Grade	50%	20%	13%	n/a

1. [Ghorashian et al., Nature Medicine 2019](#),
2. [Roddie et al., Journal of Clinical Oncology 2021](#)
3. [Roddie et al., ASH 2022, abstract #3318](#)
4. Culshaw et al., ASH 2021, abstract #477
5. Company Data Phase 2 Interim Analysis (50pt evaluable for efficacy and 92pts evaluable for safety)

Conclusions

- Obe-cel is a differentiated CD19 CAR T cell treatment candidate for adult ALL, based on its novel mechanism of action, driven by a fast off rate
- The ALLCAR19 study has demonstrated CAR T cell persistency is correlated with long term patient response:
 - All 7 patients in ongoing remission having CAR T cells present at the last assessment
 - All patients with CD19 positive relapse have lost CAR T cell persistency prior to relapse
- Obe-cel has a favourable safety profile with no grade ≥ 3 CRS (Roddie C et al., JCO 2021)
- Interim analysis of FELIX study suggests consistent safety and efficacy profile
- The FELIX study is generating consistent data as seen on ALLCAR19 in terms of initial efficacy and safety profile
 - Longer term data from the FELIX study will be released in December 2023, with an initial release at ASCO and EHA (June 2023)



Living with ALL

CAR T Patient Video



Market overview and economics

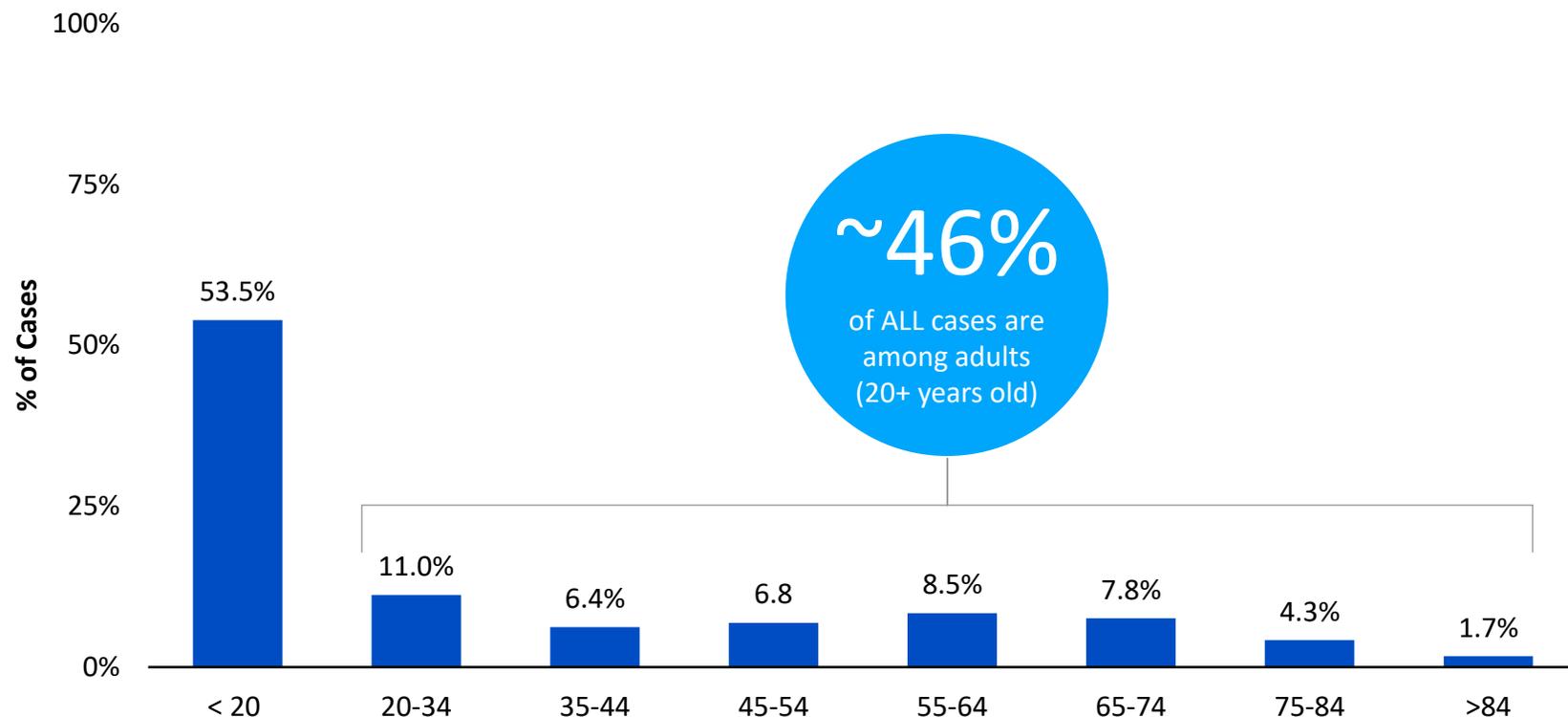
Dr Matthew Gitlin
BluePath Solutions

Epidemiology of adult ALL in the US

Surveillance, Epidemiology and End Results (SEER) Registry

In 2023, a total 6,540 new cases of ALL (all ages) are estimated¹

- Incidence rate of ALL (all ages) was 1.8 per 100,000 persons per year
- In 2020, there was an estimated prevalence of 111,425 (all ages) people living with ALL
- Relapse/refractory (R/R) ALL has an estimated incidence 0.19 cases per 100,000 persons²

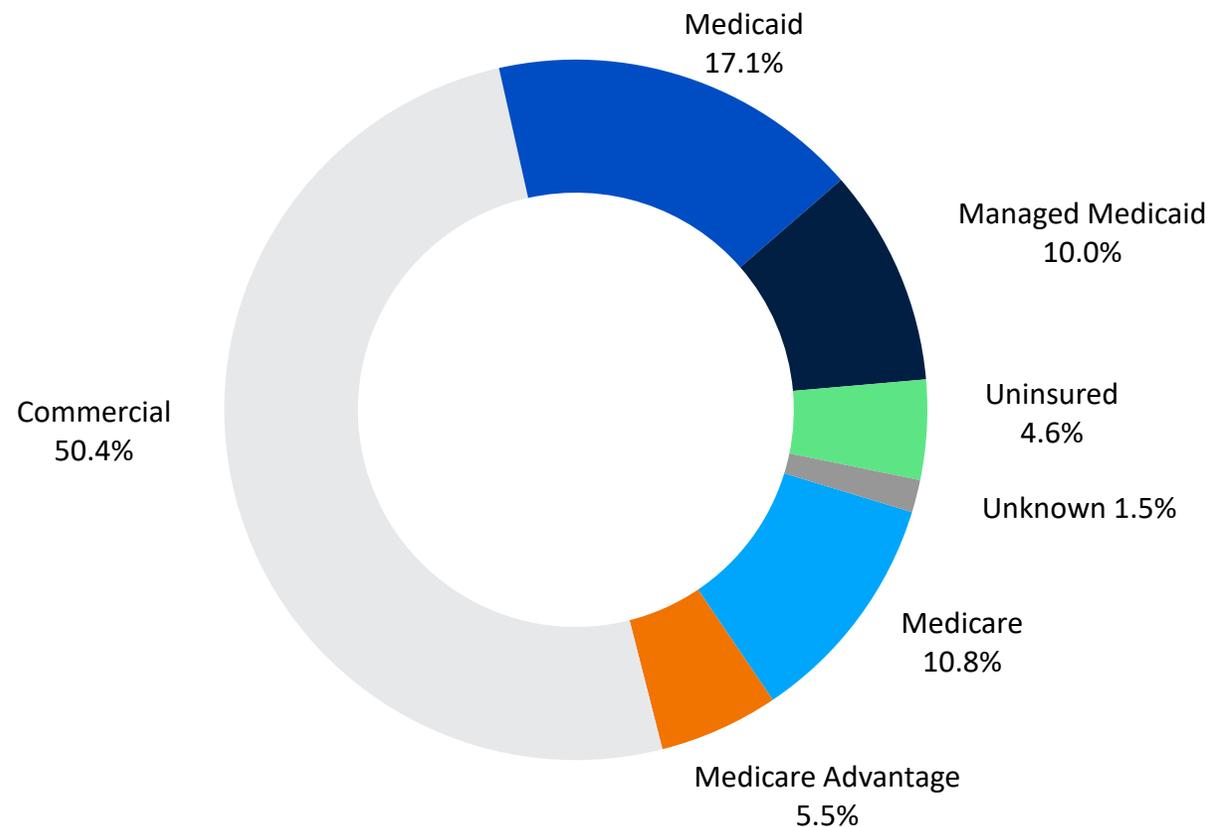


1. <https://seer.cancer.gov/statfacts/html/aly1.html>.

2. Spoorendonk J, Feng C, Shah D, et al. PCN183 global incidence, prevalence, and survival in relapsed/refractory (R/R) adult acute lymphoblastic leukemia (aALL): a systematic literature review (SLR). Value Health. 2020;23:S455.

ALL adult population is predominately commercial

ALL 5-Year Prevalent Population by Insurance Type^{1,2,3}



ALL = acute lymphoblastic leukemia

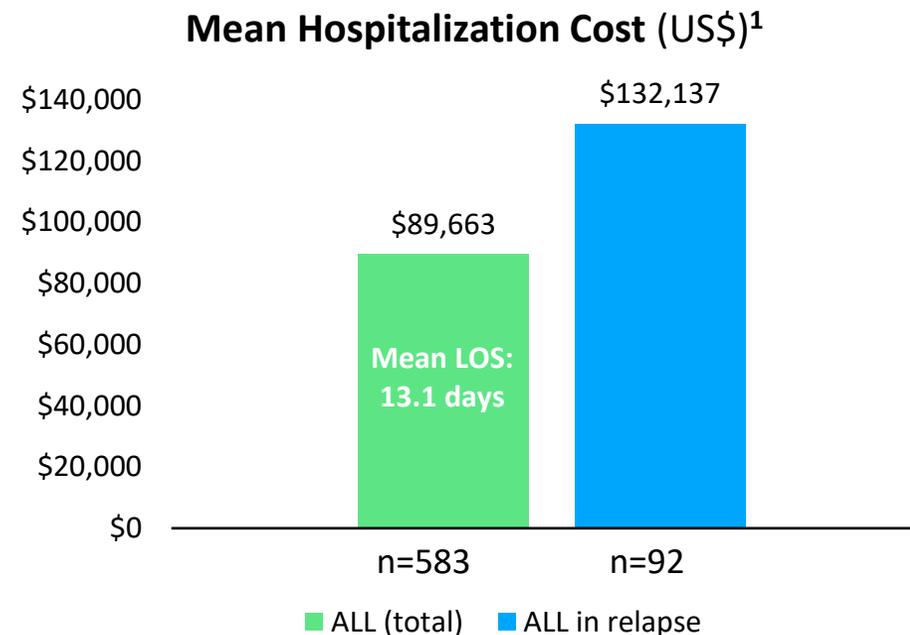
1. Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER*Stat Database: Incidence - SEER 18 Regs Research Data + Hurricane Katrina Impacted Louisiana Cases, Nov 2018 Sub (2000-2016) <Katrina/Rita Population Adjustment> - Linked To County Attributes - Total U.S., 1969-2017 Counties, National Cancer Institute, DCCPS, Surveillance Research Program, released April 2019, based on the November 2018 submission. 2. Medical Insured Lives for 2017. Decision Resources Group, July 2017, Data on File. 3. Jacobson G, et al. Kaiser Family Foundation. 2018. <https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/>

R/R adult ALL patients spend >50% of their treatment time in the hospital

Chemotherapy administration is the primary reason for hospitalization (44.9%)¹



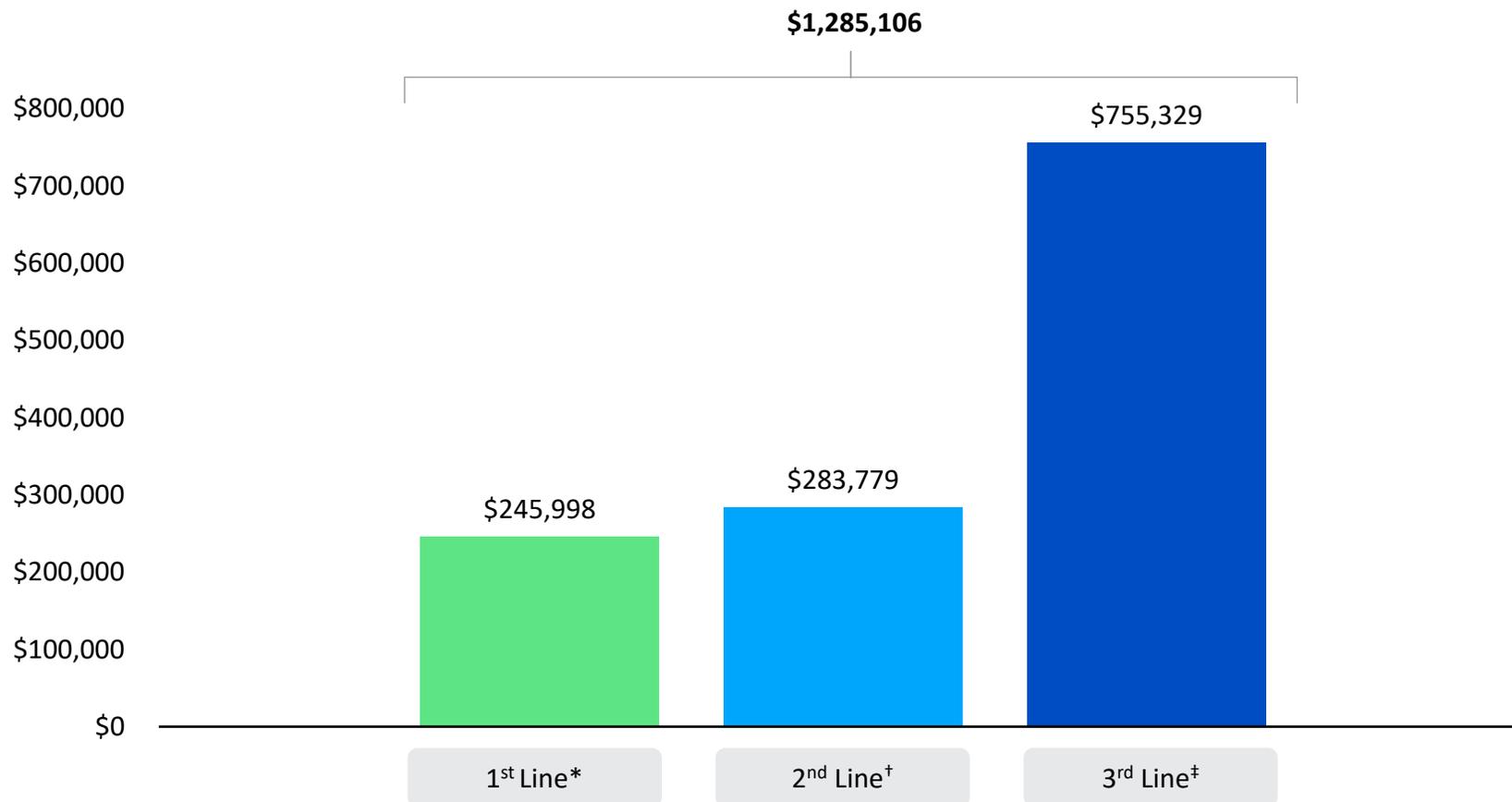
Higher hospitalization costs for relapse ALL likely reflect greater salvage chemotherapy treatment expense¹



R/R aALL patients incur a mean of ~2.8 hospitalizations during a mean treatment follow-up period following relapse of 80.2 day

Costs may be >\$1M across lines of therapy for responding patients

Estimated Adult ALL Drug Acquisition Costs by Line of Therapy



General Model Assumptions (Full List in Model¹):

- 1) Patient characteristics are representative of the average adult patients from the study cited or reflective of population norms;
- 2) Any weight-based dosages were determined by the average US body surface area (m²) for age;
- 3) Costs considered are drug acquisition costs;
- 4) Wholesale acquisition costs (WAC) were obtained from IBM Truven Micromedex REDBOOK[®] in May 2019;
- 5) The maximum number of cycles, as allowed by the product's label, was included as the default;
- 6) Costs are reflective of the prescribed dose and do not include drug wastage, and
- 7) Oral capsules and tablet amounts were rounded up to the closest whole number of units.

* Modified hyper-CVAD + rituximab²

† Inotuzumab Ozogamicin (per product label)³

‡ Blinatumomab (per product label)⁴

ALL = acute lymphoblastic leukemia; CVAD = cyclophosphamide, vincristine sulfate, doxorubicin hydrochloride, dexamethasone

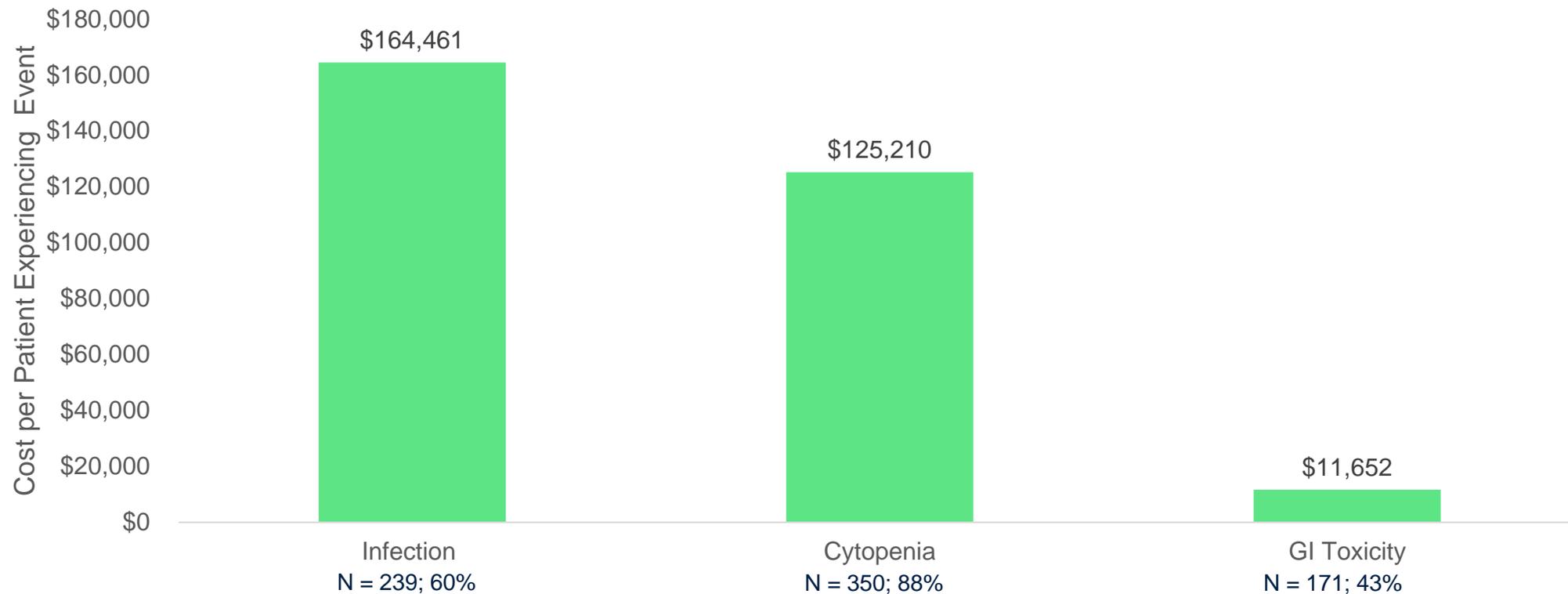
1. Data on File; 2. Thomas DA, et al. JCO. 2010;28(24):3880-3889; 3.

Inotuzumab Ozogamicin Prescribing Information. 2018; 4.

Blinatumomab Prescribing Information. 2019

Management of r/r adult ALL treatment-related SAE is significant

Among a sample of 400 adult R/R ALL Patients, 92.5% had at least 1 adverse event



The cost of adverse events from chemotherapy and monoclonal antibodies can result in significant increases to the total cost of care

The benefits of CAR T efficacy on value comparisons

A recent cost-effectiveness analysis evaluated the most recent CAR T approval (Tecartus™; brexucabtagene autoleucel) versus standard of care for R/R aALL

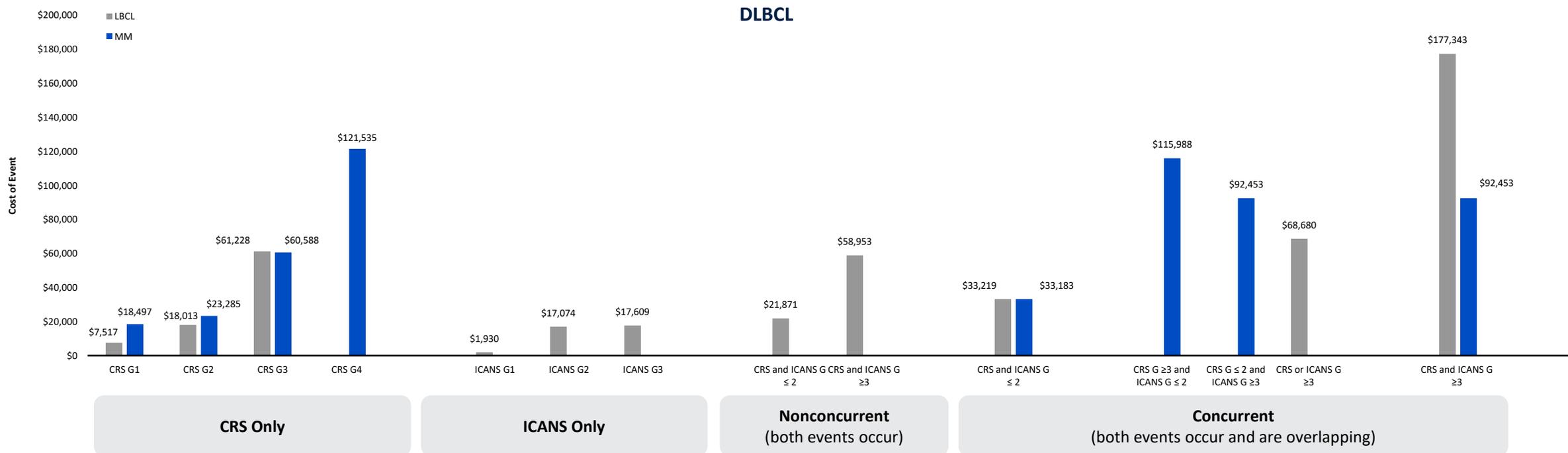
- 28% of treated patients in complete remission (CR) with a median duration of remission of 13.6 months

	brexucabtagene autoleucel	blinatumomab	inotuzumab ozogamicin	Salvage Chemotherapy
Drug acquisition	\$357,919	\$425,188	\$252,146	\$11,571
Administration	\$202,249	\$80,811	\$1,607	\$120,725
Monitoring: Progression Free	\$3,309	\$1,621	\$2,507	\$849
Monitoring: Progression	\$5,262	\$4,515	\$623	\$1,777
Subsequent Treatment Acquisition	\$55,182	\$62,907	\$20,457	\$60,890
Subsequent Treatment Administration	\$5,406	\$353	\$11,100	\$5,965
Allo-SCT	\$75,724	\$101,414	\$200,745	\$95,483
Adverse Events	\$49,172	\$23,900	\$9,909	\$20,009
End of Life	\$22,368	\$24,699	\$25,969	\$27,023
Total Costs	\$776,320	\$725,407	\$524,789	\$344,293
QALYs (years)	5.95	3.5	2.69	1.34
Incremental Cost-Effectiveness Ratio (ICER) of brexucabtagene autoleucel vs.		\$20,843	\$77,271	\$93,768

With a strong efficacy profile vs standard of care, new therapies like Tecartus™ produce ICERs well within acceptable willingness to pay thresholds (far below \$150,000)

CAR T associated CRS/ICANS events are costly

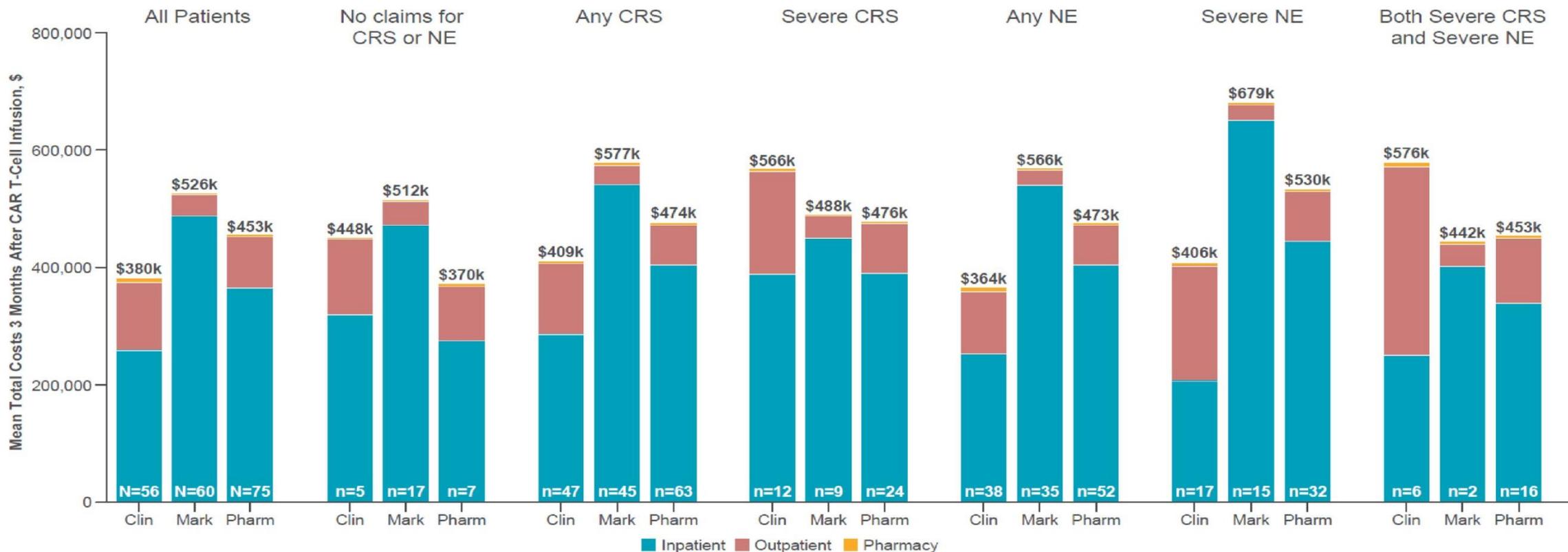
Data based on diffuse large B-cell Lymphoma (DLBCL) and Multiple Myeloma (MM) experience



The cost of CRS and ICANS increases significantly as the severity increases, but even lower grade CRS and ICANS events are associated with costs similar to other adverse events like cytopenias

CRS/ICANS may add ~\$30K to ~\$150K to the total cost of treatment

Data based on diffuse large B-cell lymphoma (DLBCL) and multiple myeloma (MM) experience



Among CAR T users, the mean total health care expenditures with CRS or ICANS (~\$406,000 to \$679,000) was generally higher than without (\$370,000 to \$512,000)

Among R/R adult ALL patients, CRS and ICANS remain an unmet need

A systematic literature review of prospective interventional studies found that current CAR Ts under development and recently approved continue to burden adult ALL patients

Toxicities (n = number of studies)	Rates (95% CI)
CRS	
All Grades (n = 13)	82% (61 to 95%)
Grade ≥3 (n = 16)	27% (18 to 36%)
ICANS	
All Grades (n = 11)	34% (24 to 47%)
Grade ≥3 (n = 16)	14% (1 to 25%)

The rate of CRS reported in the ZUMA-3 trial for Tecartus™ was 92% and 26% across all grades and grade ≥3, respectively.

Despite the clinical benefits CAR T therapies may offer the R/R aALL population, the clinical burden of CRS and ICANS is still persistent leading to economic implications that further burden the healthcare system

The incremental impact of CRS and ICANS is meaningful

In DLBCL	liso-cel	axi-cel	tisa-cel
CRS			
Grade 1-2	41.4%	80.6%	50.6%
Grade ≥3	4.1%	13.0%	23.0%
ICANS			
Grade 1-2	23.9%	56.0%	40.5%
Grade ≥3	11.6%	31.0%	18.0%
Total Cost per Patient	\$18,718	\$47,665	\$42,538
Current Acquisition Cost	\$447,227	\$424,000	\$427,047
% increase in spend due to CRS/ICANS	4.2%	11.2%	10.0%

Among DLBCL population, the cost of CRS/ICANS may add up 11% more cost to the mean total cost of care when considering clinical trial rates of CRS and ICANS

CAR T value drivers in the r/r ALL population

Durable and Robust Efficacy

- ✓ Complete remission rates relative to current SoC that result in the ability to demonstrate robust cost-effectiveness vs chemotherapy, allo-SCT and monoclonal antibodies
- ✓ Comparable remission rates to approved CAR T therapies that can be combined with an improved safety profile and demonstrate cost offsets and savings
- ✓ Long-term efficacy (duration of remission) that translates into real world effectiveness to address high relapse rates

Predictable Safety

- ✓ Lower rates and costs of all adverse events to reduce burden on inpatient site of care where chemotherapy, monoclonal antibodies, and CAR T are most often used
- ✓ Lower rates of CRS and ICANs of all grades that will result in a strong risk: benefit profile and lower overall total cost of care when differentiating with other CAR T therapies

Population decision makers continue to prioritize the key factors above when attempting to differentiate CAR T therapies against standard of care (chemotherapy, Allo-SCT and monoclonal antibodies) and CAR T therapies approved for use within the R/R adult ALL population



Commercial Roadmap

Christopher Vann, Chief Operating Officer
Autolus



COMMERCIAL OPPORTUNITY

Epidemiology

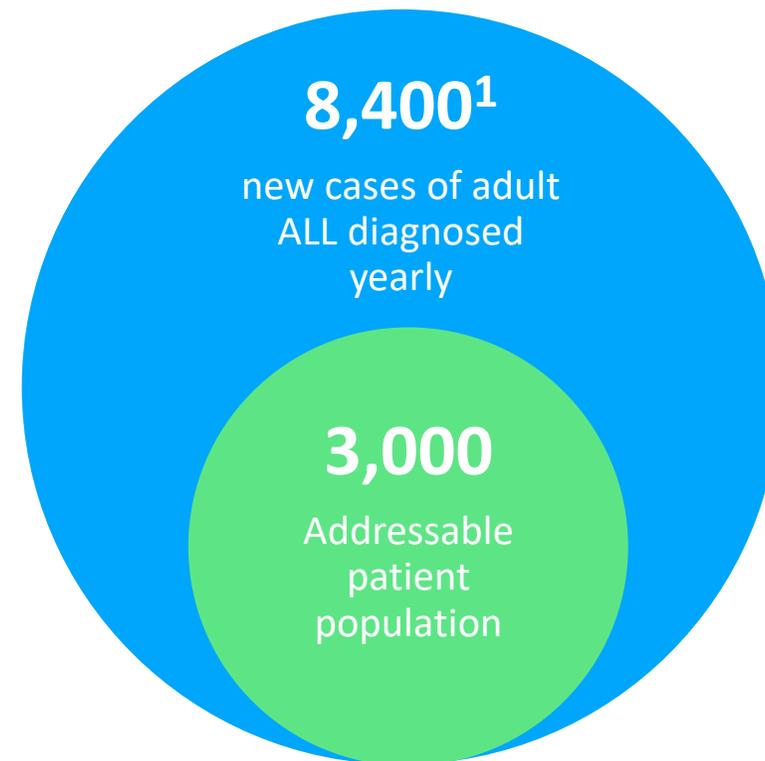
Sizing the aALL Market Opportunity

Pricing

Over 8,000 new cases of adult ALL annually worldwide

Successful therapy requires high level of activity and sustained persistence paired with good tolerability

- Median overall survival is < 1 year in r/r adult ALL
- Combination chemotherapy enables 90% of adult ALL patients to experience Complete Response (CR)
 - Only 30% to 40% achieve long-term remission
- Current T cell therapies for adult patients are Blincyto® and Tecartus™
 - Both therapies are highly active, but frequently followed by subsequent treatments (e.g. alloSCT)
 - Blincyto®: favourable 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 level of ICANS, and requires vasopressors for many patients
- Opportunity to expand the addressable patient population in earlier lines of therapy



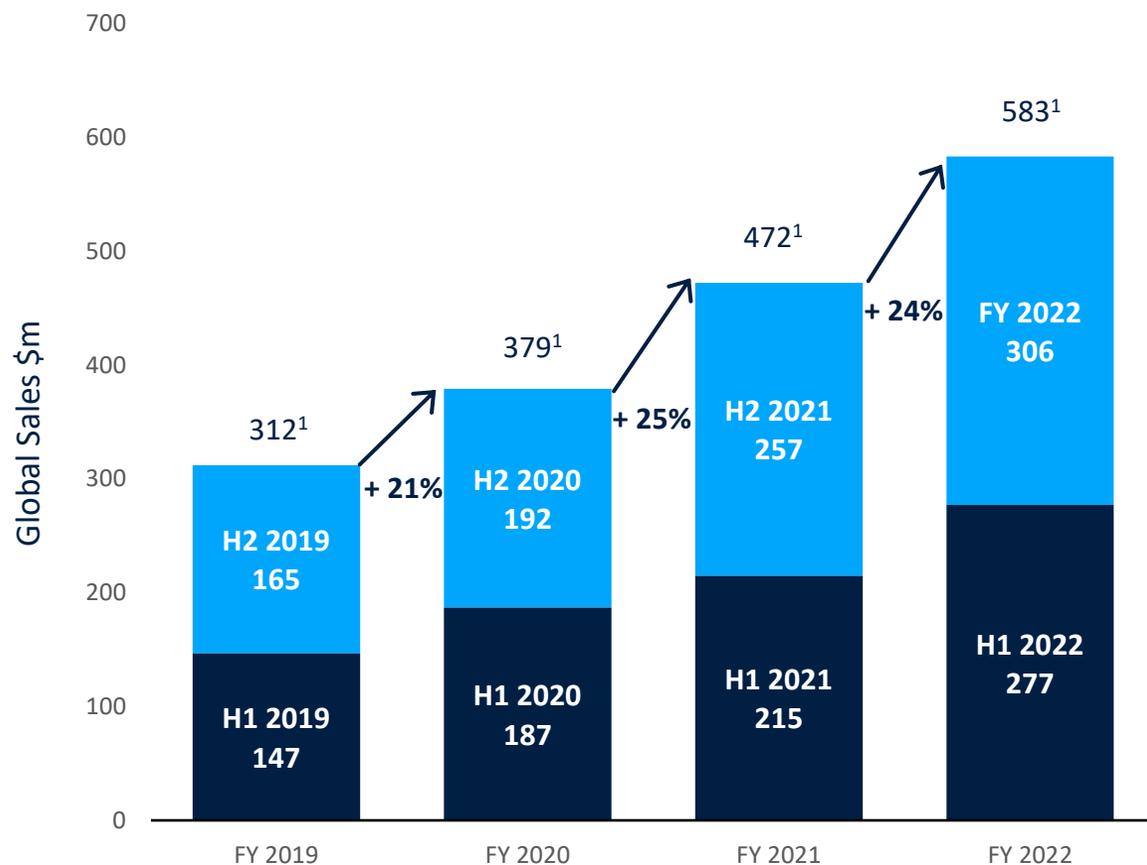
NOTES

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

Blincyto(r) is a good surrogate for sizing adult ALL opportunity

Blincyto® sales confirm opportunity to be >2,000 patients

Reported Blincyto® sales¹



- Blincyto® sales price estimated to be \$207k² (for 2 cycles) supporting approx. >2,000 commercial adult ALL patients, growing at a rate of 24%
- Kymriah® is priced at \$508k in pediatric ALL. Breyanzi® is priced at \$447k in DLBCL³. Tecartus™ is priced at \$424k⁴ 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

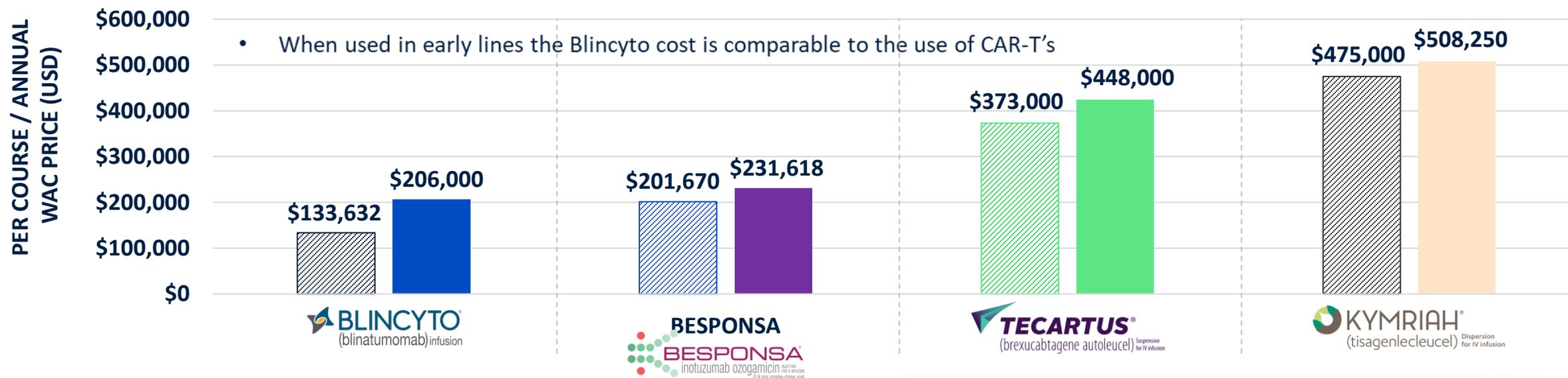
1. As per Amgen quarterly SEC filings
2. <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files>
3. Bristol Myers finally wins FDA approval for cancer cell therapy | BioPharma Dive – Komodo Health 2015 – 2020
4. Red Book pricing database <https://www.ibm.com/products/micromedex-red-book/pricing>

R/R adult ALL benchmark pricing comparison - USA

(Current – including price increases since launch)

▨ LAUNCH PRICE ■ CURRENT PRICE

USA R/R B-ALL current pricing landscape



- Currently available CAR Ts, **particularly TECARTUS[™]** (annual cost of \$448K), is likely to be viewed as a **relevant pricing anchor** in the USA, given that it is also available in **adult B-ALL**
- **KYMRIAH[®]** may be considered an inappropriate **pricing anchor** in the USA, despite its **B-ALL indication**, as KYMRIAH[®]'s **current price premium** is driven by its **first to market CAR T launch in B-ALL**, and targeted **pediatric vs. adult positioning**



Elements Driving Market Adoption and Leadership

Efficacy/Tolerability

FELIX Study Data Releases

Robust & Reliable Supply

Obe-cel showed consistent clinical profile across three clinical studies

Data from 3 studies - range of ages and patient conditions

Obe-cel demonstrated a favourable tolerability profile: no high-grade CRS and limited ICANS

	CARPALL #1 Peds ALL	ALLCAR19 #2 Adult ALL	FELIX P1b #3 Adult ALL	FELIX P2 Adult ALL
n	14	20	16	50 (92)*
ORR (CR & CRi) (95% CI)	86% (57%, 98%)	85% (62%, 97%)	75% (48%, 93%)	70%
CRS ¹ ≥ Grade 3	0%	0%	0%	3%
CRS ¹ any Grade	93%	55%	56%	ND
Neurotox ² ≥ Grade 3	7%	15%	6%	8%
Neurotox ² any Grade	50%	20%	13%	23%
Median Age	9	42	42	ND
Bone marrow blast >20% at LD	21%	60%	75%	ND
Bone marrow blast <5% at LD	71%	35%	25%	ND
Prior blinatumomab	7%	25%	56%	ND

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

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

* Efficacy analysis for FELIX 2 trial conducted in 50 patients whereas safety analysis conducted in 92 patients

#1 Ghorashian et al. Nature Medicine 2019

#2 Roddie et al. J Clin Oncol, 2021

#3 Culshaw et al, ASH 2021, abstract #477

Significance of improved tolerability

Lower levels of ICANS and CRS, particularly \geq grade 3, has several potential benefits:

- Important factor in Physician treatment choice
- Improvement in patient treatment experience
- Reduces costs associated with managing severe adverse events
- A more manageable product facilitates use in a broader range of hospital settings
- In some healthcare systems, allows hospitals opportunity to optimize their revenue

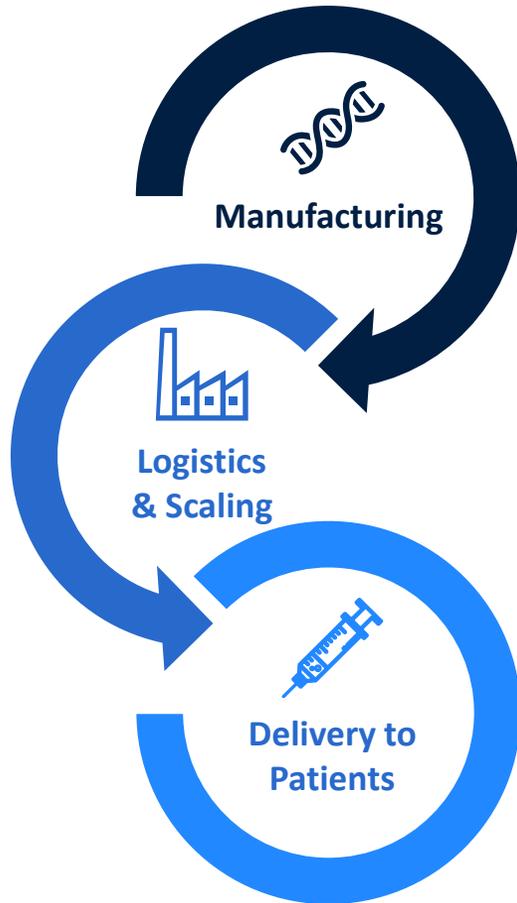
Planned upcoming FELIX data releases

Data will continue to mature over the next 18 months



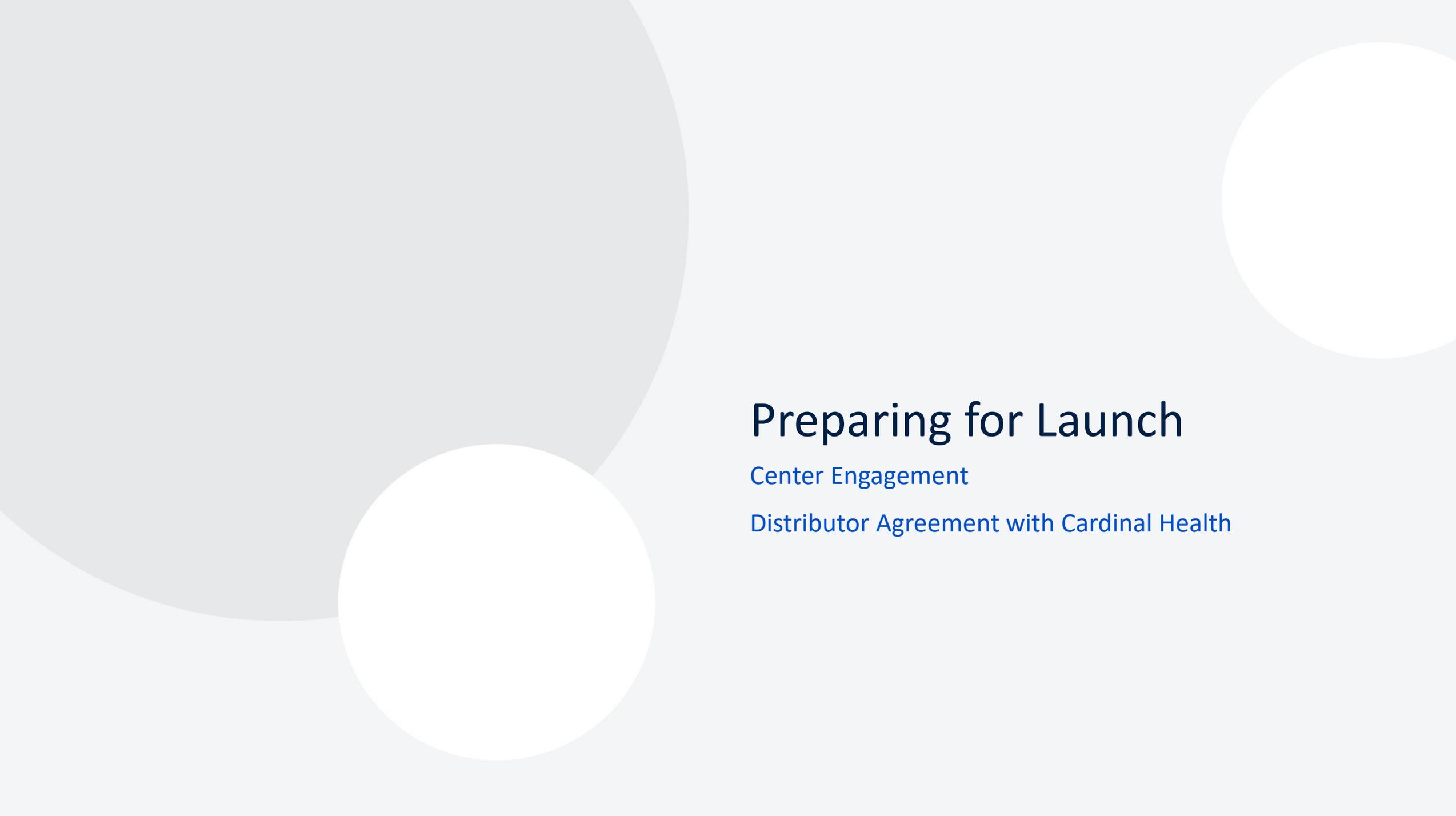
Fully integrated manufacturing and logistics platform

Scaling up with new Commercial Manufacturing Facility (“The Nucleus”)



- Established UK supply and logistics network for FELIX study
- Manufacturing facility on-track: Phase 1 of build project completed in Q4 2022 – handover of first clean rooms to Autolus on Nov 25, 2022
- Equipment installations and qualification by Autolus on track for Good Manufacturing Practice (GMP) operations by H2 2023
- Tried and tested manufacturing process within an established regulatory framework
- Planned annual capacity of at least 2,000 batches per year to service global demand in ALL
- CMC package for submission to FDA progressing per plan





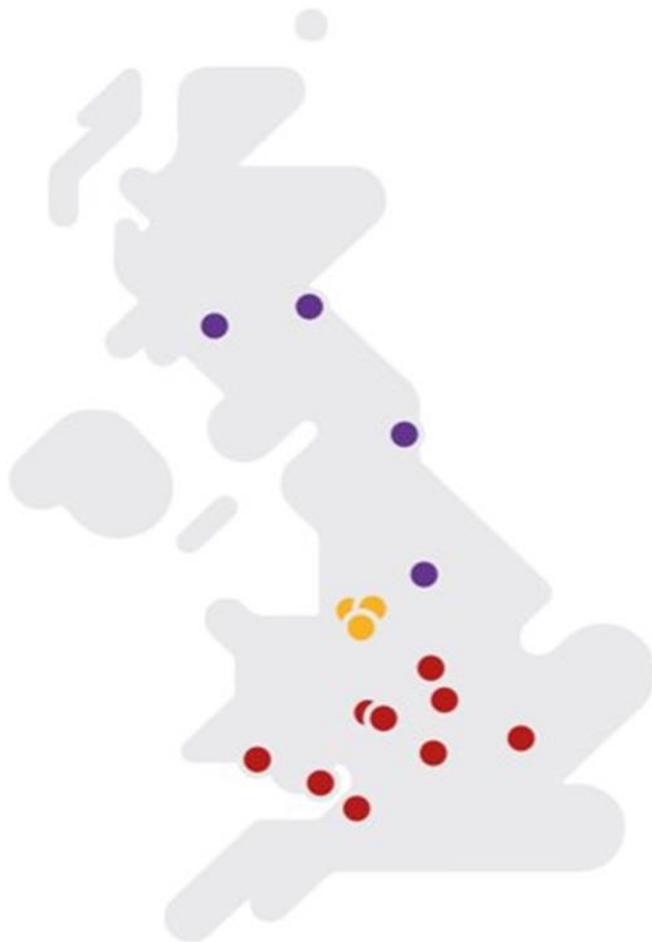
Preparing for Launch

Center Engagement

Distributor Agreement with Cardinal Health

Autolus has a history of engagement with treatment centers

We have supported establishment of NHS Advanced Treatment Therapy Centres since 2018



The ATTC network was founded as a public-private sector partnership to find innovative solutions to the challenges of delivering Advanced Medicinal Therapeutic Products (ATMPs) to UK patients

Autolus supported the establishment of NHS treatment centres, processes and resources in areas such as apheresis standards, samples (product) handling, logistics, centre readiness tools, nurse training, patient education etc.

theattcnetwork.co.uk

Global market engagement

Support ASTCT 80/20 Harmonisation Project, active members of Alliance for Regenerative Medicine etc.



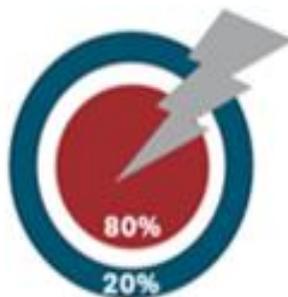
Mission

Advocate for standardization

Identify 80% common workflows
(contrasting **20% product-specific**)

Streamline auditing and education

Leverage existing entities



- "The voice of the cell and gene therapy sector"
- 480-member organisation
- Active, members particularly in areas of market access and regulatory guidelines

Autolus will initiate US Center on-boarding process in H2 2023

Center on-boarding process takes c. 10-12 months

CAR T Center Certification

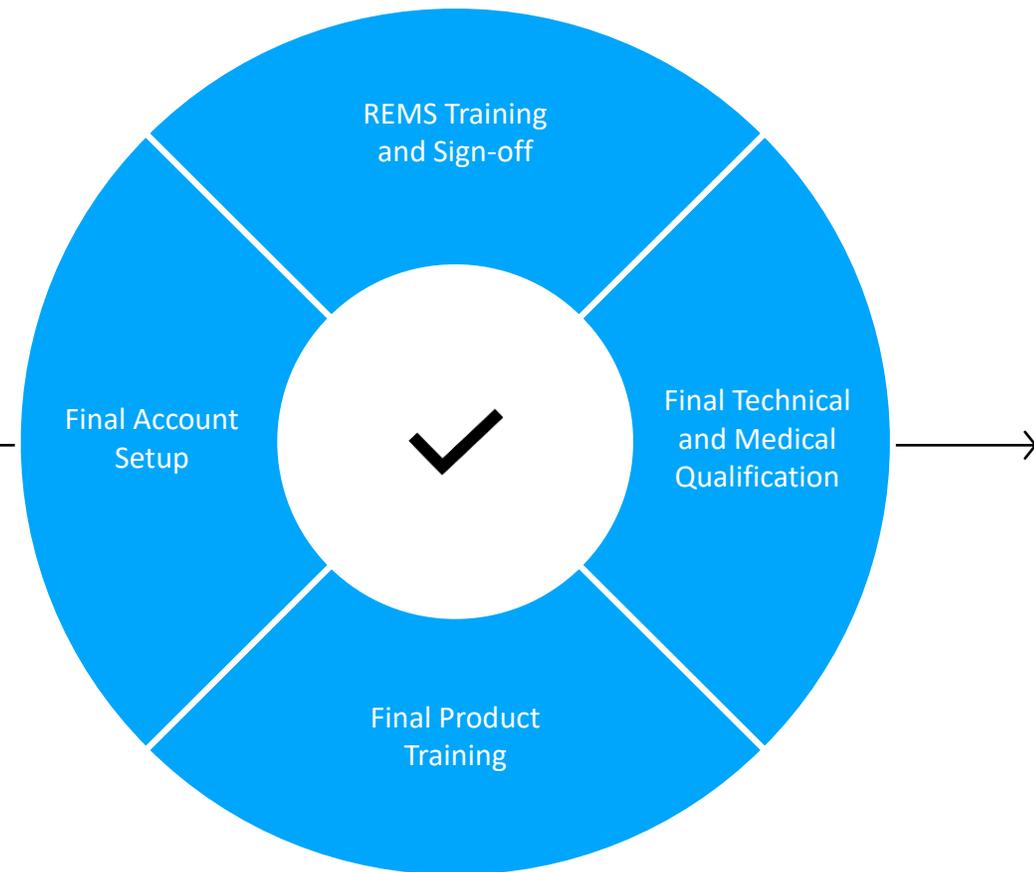


Center Launch



FDA
Approval

CAR T Center Activation



Product Launch

Basis for selection of Cardinal Health

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

Distribution

Standard suit of services including:

- “Flash ordering”
- Center checks
- Government reporting of prices

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

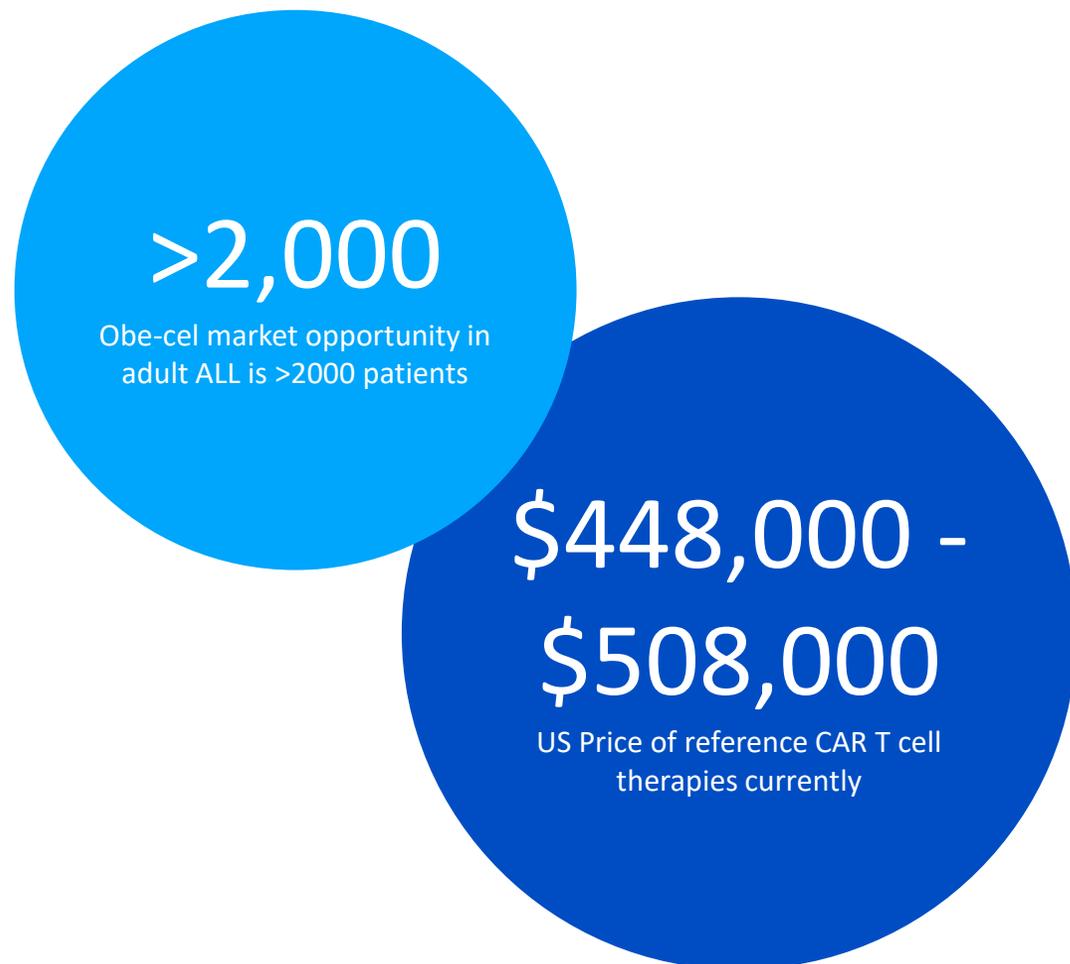
Facilitates reduction in vein to delivery time



Summary

Summary

Autolus will initiate US pre-launch activities in H2 2023



- Obe-cel offers consistently high levels of initial ORR in adult ALL (70-85%), with the potential for durable responses as a stand-alone product in some patients
- Improved tolerability is not only important for physician and patient preference, but also reduces total treatment costs and potentially allows the product to be administered in a wider array of hospital settings
- Foundation for robust and reliable supply established during the FELIX study
- The Nucleus is on-track to be GMP-certified by year-end
- Other key elements needed for competitive commercial distribution, like the Cardinal Health distributor arrangement, are being put in place



Final remarks and Q&A

Dr Christian Itin

The Autolus opportunity

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

- Obe-cel, a potentially best in class product candidate, met primary endpoint of ORR in adult patients with r/r ALL
- Planned BLA filing end of 2023
- Additional opportunity for obe-cel in B-NHL indications
- Highly valuable pipeline with potential broad applicability in cancers with limited treatment options
- Purpose-built commercial manufacturing facility ready for qualification and validation activities in H1 2023 with an initial capacity of up to 2,000 batches per year, sufficient to serve global demand in ALL
- Strong technology foundation, validating collaborations with leading pharma and biotech companies – BMS, Moderna and Cabaletta Bio
- Strong cash position with \$382.8 million (December 31, 2022)

Thank you

