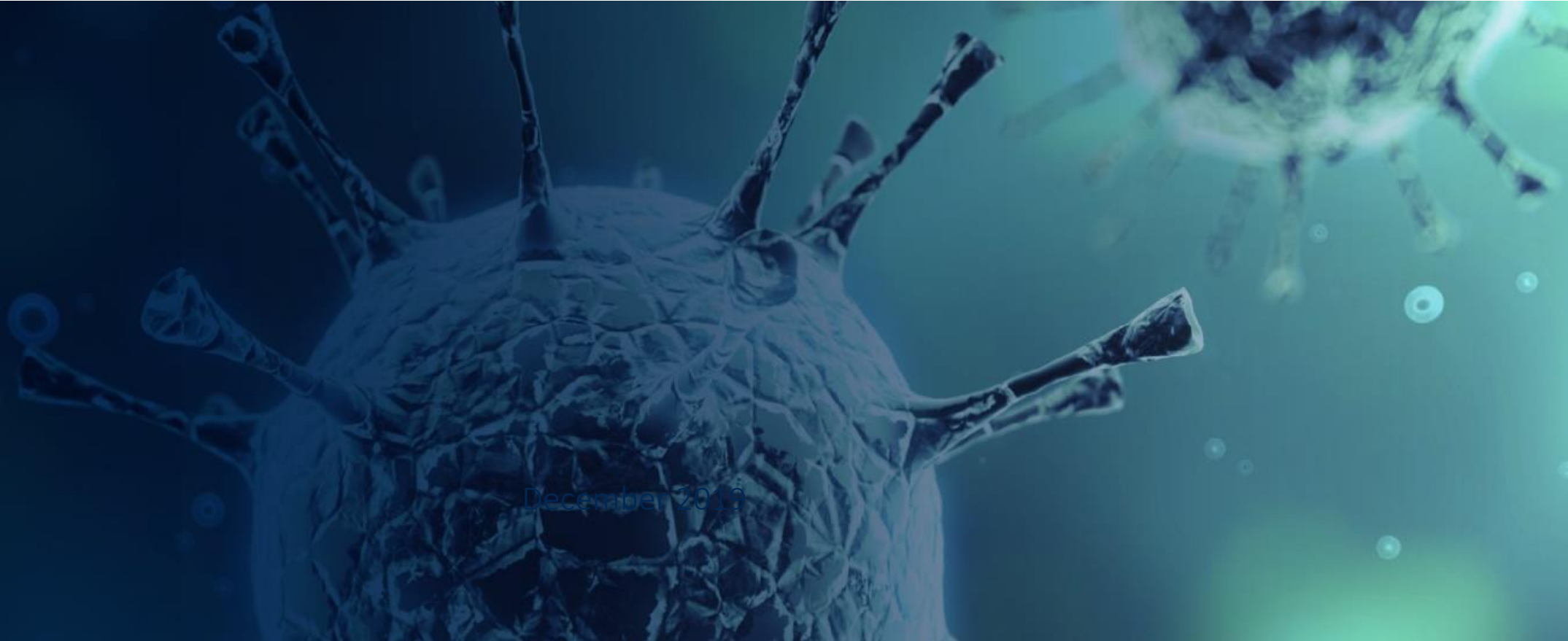




Nasdaq: AUTL



December 2019

AUTO3 Data Update - ASCO 2020

June 2020

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# Agenda

1. Welcome and Introduction: Dr. Christian Itin, Chairman and CEO
2. Data Review: Dr. Robert Chen, Executive Director, AUTO3 Program Lead
3. Commercial Opportunity: Brent Rice, Vice President, Chief Commercial Officer, US
4. Summary: Dr. Christian Itin, Chairman and CEO
5. Q&A: Dr. Christian Itin, Andrew Oakley (CFO), Dr. Vijay Reddy (CMO), Dr. Nushmia Khokhar (VP, Clinical Development), Dr. Robert Chen, Brent Rice

# Welcome and introduction

*Dr. Christian Itin*

*Chairman and CEO*

# Broad expertise in CAR T therapy development and market access



**Dr. Christian Itin**

*Chairman & CEO*

Previously CEO of Micromet; led development of Blincyto®, the first FDA-approved redirected T cell therapy



**Dr. Robert Chen**

*Executive Director, Clinical Development*

Previously Associate Professor at City of Hope Medical Center and Associate Director of the Toni Stephenson Lymphoma Center. Authored 100+ peer reviewed publications and abstracts



**Dr. Vijay Peddareddigari**

*SVP, CMO*

Experienced oncologist and drug developer; MD Anderson, GSK and most recently J&J



**Dr. Nushmia Khokhar**

*VP, Head of Clinical Development*

Board certified oncologist, lead several successful registration trials within industry including global daratumumab program at Janssen Oncology



**Andrew Oakley**

*CFO*

17+ years experience as public company CFO in bio-pharma sector; more than 10 years at Actelion



**Brent Rice**

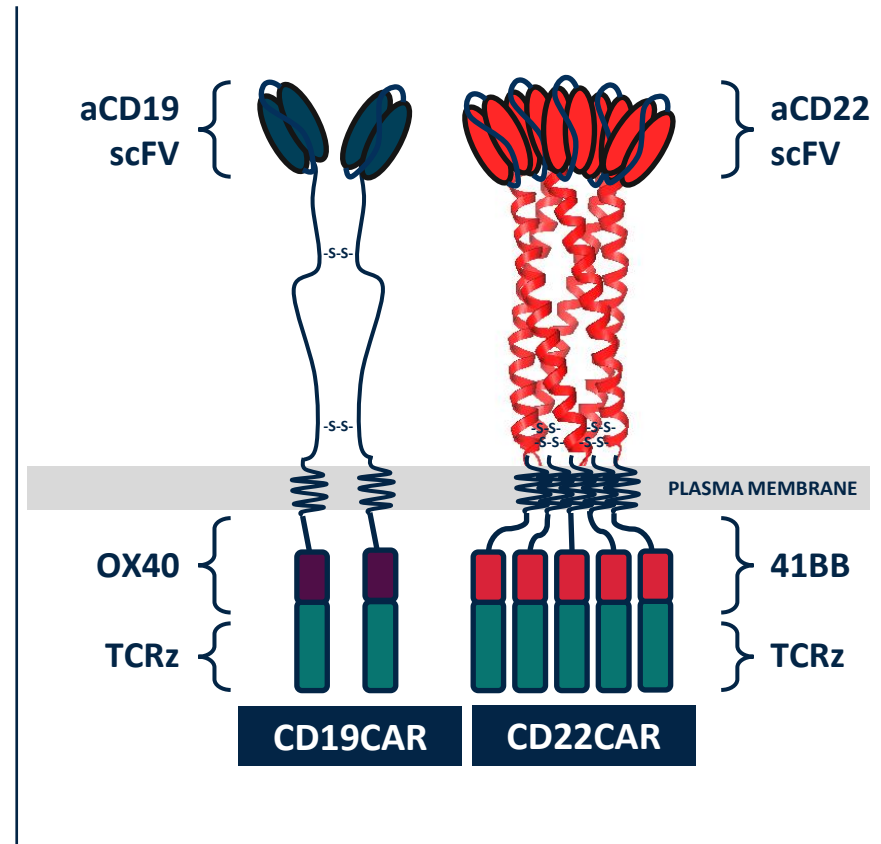
*VP, Chief Commercial Officer, US*

25 years biotech/pharma experience; previously at Juno Therapeutics; 18 years at Amgen

# Improving CAR T cell immunotherapy in DLBCL

## AUTO3 - Dual targeting CAR & prevention of early CAR T exhaustion

- CD19 CARs are active in r/r DLBCL
- However unmet need remains with CD19 CAR T cell therapy
  - 29-37% durable CRR in DLBCL<sup>1,2</sup>
  - The potential causes for relapse include:
    - PD-L1 upregulation<sup>3</sup> which contributes to CAR T exhaustion
    - CD19 antigen loss<sup>4</sup>
  - Rate of severe (grade  $\geq 3$ ) cytokine release syndrome (CRS 13-22%) and neurotoxicity (NT 12-28%)<sup>2,4</sup>
- Simultaneous targeting of CD19 and CD22 may reduce the probability of relapse due to antigen loss
- PD1/PDL1 mediated CAR T cell exhaustion may be prevented by adding pembrolizumab to the preconditioning regimen



<sup>1</sup> Locke F et al Lancet Oncol 2019

<sup>2</sup> Schuster S et al NEJM 2019

<sup>3</sup> Neelapu S et al ASCO 2018

<sup>4</sup> Neelapu S et al NEJM 2017

# DLBCL is a large commercial opportunity

## AUTO3 addressable patients in DLBCL

- Potential market size in DLBCL
  - Approx. 24,000\* patients diagnosed in the US every year
- Aggressive and rapidly advancing cancer, survival outcomes remain poor
  - Most common type of Non-Hodgkin Lymphoma
  - High dose chemotherapy + mAb leads to remission in about 50-60% of patients
  - DLBCL patients who fail salvage regimens median overall survival 4.4m
- Two approved CAR T products (Yescarta® and Kymriah®)
- Initial AUTO3 positioning in DLBCL
  - High unmet need remains, despite highly active CD19 CARs in r/r DLBCL, given the responses are not durable and toxicity limits broad application

## Data Review

*Dr. Robert Chen*

*Executive Director, AUTO3 Program Lead*



# Alexander, Phase 1/2 Study with AUTO3 in DLBCL

## Key eligibility criteria

### Inclusion criteria

- $\geq 18$  years
- Chemotherapy-refractory disease, or relapse after at least two lines of therapy, or after ASCT
- DLBCL not otherwise specified (NOS), and DLBCL with MYC and BCL2 and/or BCL6 rearrangements (double/triple hit)
- Transformed DLBCL from follicular lymphoma
- Transformed DLBCL from other indolent lymphomas (excluding Richter's transformation)
- High-grade B cell lymphoma with MYC expression (excluding Burkitt's lymphoma)
- Primary mediastinal large B cell lymphoma

### Exclusion criteria

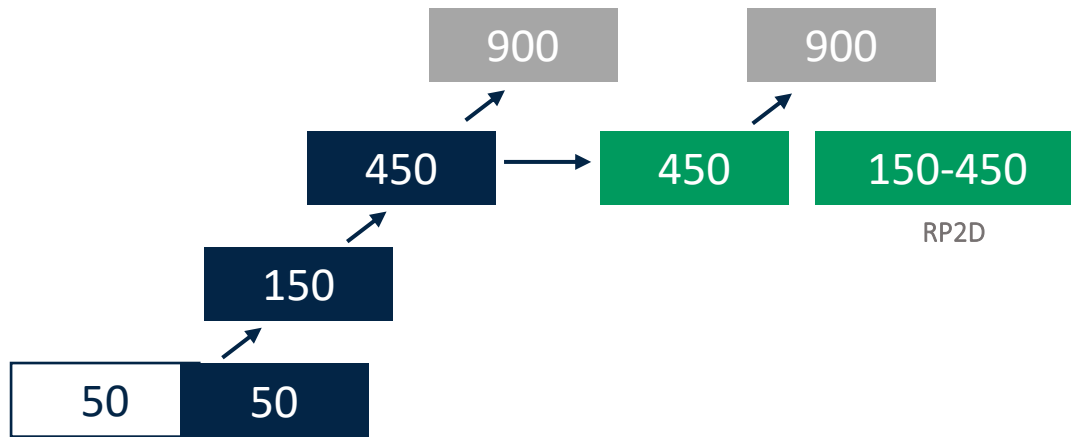
- Pre-existing significant neurological disorder
- Prior allogenic haematopoietic stem cell transplant
- Prior CD19 or CD22 targeted therapy
- Contraindication to receiving pembrolizumab (pembro)

# Alexander study design

AUTO3-DB1, single-arm, open-label, multi-center, Phase 1/2 Study

## Phase 1

### Dose Escalation Cohort



Dose in  $\times 10^6$  CD19/CD22 CAR T Cells

### Outpatient Cohort

@RP2D

## Phase 2

### (Efficacy Cohort)

#### Cohort 1

DLBCL NOS, high grade B cell lymphoma, tDLBCL from FL, > 2prior lines

#### Cohort 2

Primary mediastinal, tDLBCL from other iNHL, > 2prior lines

Preconditioning:  
Flu/Cy

Flu/Cy + Pembro  
day 14 x 3 doses

Flu/Cy + Pembro  
day -1 x 1 dose

# Patient characteristics

Baseline Patient Characteristics		N=23
Age, median (min-max)		57 (28-83)
Gender, N	Male, Female	14, 9
Current Histology, N	DLBCL	17 (74%)
	tDLBCL	6 (26%)
Disease Stage, N	II	2
	III	5
	IV	16
Relapsed/Refractory, N	Refractory	5
	Relapsed	3
	Relapsed and Refractory	15
IPI, N	0-1	4
	2	7
	3-4	12
No. Prior Therapies, median (min-max)		3 (2-10)
Prior ASCT, N		4
SPD, median (min-max)		22.3 cm (2.08 – 260.84)

# Cytokine Release Syndrome (CRS)

No grade 3 or higher CRS at  $\geq 150 \times 10^6$  cell dose

	50 x10 <sup>6</sup> AUTO3 no pembro (N=4)	50 x10 <sup>6</sup> AUTO3 D14 pembro (N=3)	150 x10 <sup>6</sup> AUTO3 D14 pembro (N=4)	450 x10 <sup>6</sup> AUTO3 D14 pembro (N=4)	450 x10 <sup>6</sup> AUTO3 D -1 pembro (N=4 <sup>#</sup> )	150-450 x 10 <sup>6</sup> AUTO3 D-1 pembro <u>RP2D</u> (N=4)	Total (N=23)
Grade 1 CRS	1	0	1	1	2	1	6 (26%)
Grade 2 CRS	0	0	1	1	0	1	3 (13%)
$\geq$ Grade 3 CRS	0	0*	0	0	0	0	0

\* 1 patient who had no CRS with primary infusion, developed G3 CRS (severe hypoxia) with re-treatment 1 year later without CAR T expansion and with significant disease burden in lung that had been treated with radiation

# Includes one patient that received only  $125 \times 10^6$

- No prophylactic measures of any kind
- No grade 3 or higher CRS\* with primary infusion
- Median time to CRS is 7 days (1-36), median duration of CRS is 5 days (1-19)
- 4 patients (17%) received tocilizumab for CRS

# Neurotoxicity

No neurotoxicity (NT) of any grade at  $\geq 150 \times 10^6$  cell dose

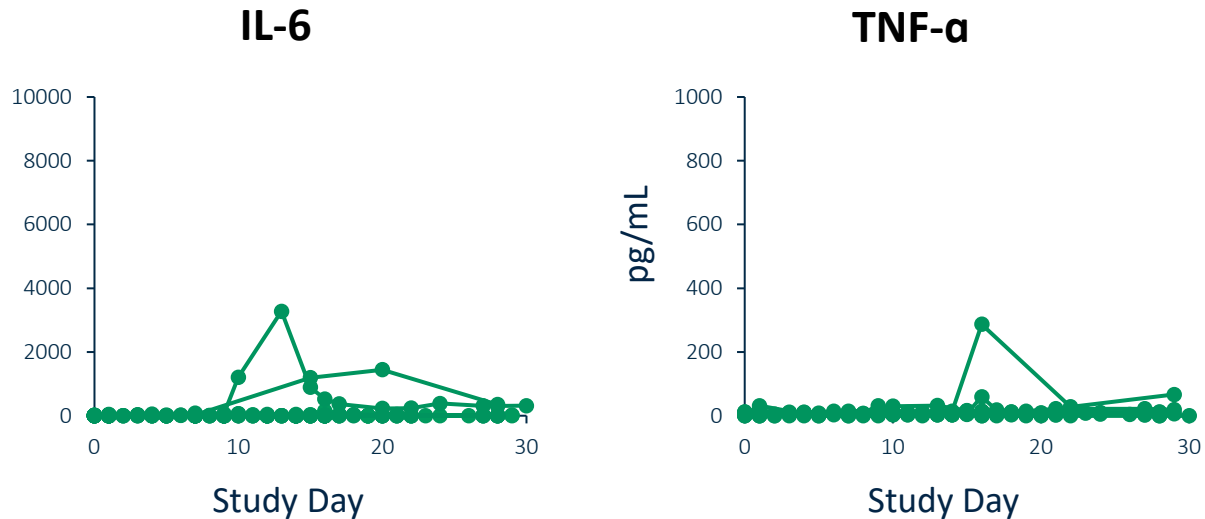
	50 x10 <sup>6</sup> AUTO3 no pembro (N=4)	50 x10 <sup>6</sup> AUTO3 D14 pembro (N=3)	150 x10 <sup>6</sup> AUTO3 D14 pembro (N=4)	450 x10 <sup>6</sup> AUTO3 D14 pembro (N=4)	450 x10 <sup>6</sup> AUTO3 D -1 pembro (N=4 <sup>#</sup> )	150-450 x 10 <sup>6</sup> AUTO3 D-1 pembro <u>RP2D</u> (N=4)	Total (N=23)
All grades NT	1	0	0	0	0	0	1 (4%)
$\geq$ Grade 3 NT	1	0	0	0	0	0	1 (4%)

# Includes one patient that received only  $125 \times 10^6$

- No prophylactic measures of any kind
- No neurotoxicity of any grade in AUTO3 + pembro
- Only 1 case of neurotoxicity (Grade 3) at lowest dose level which resolved quickly with steroids
  - No CAR T expansion was seen at any time. Grade 3 NT occurred on day 53. Symptoms improved in 3 days. The same symptoms of facial/muscle weakness occurred > 10 years ago without specific diagnosis.

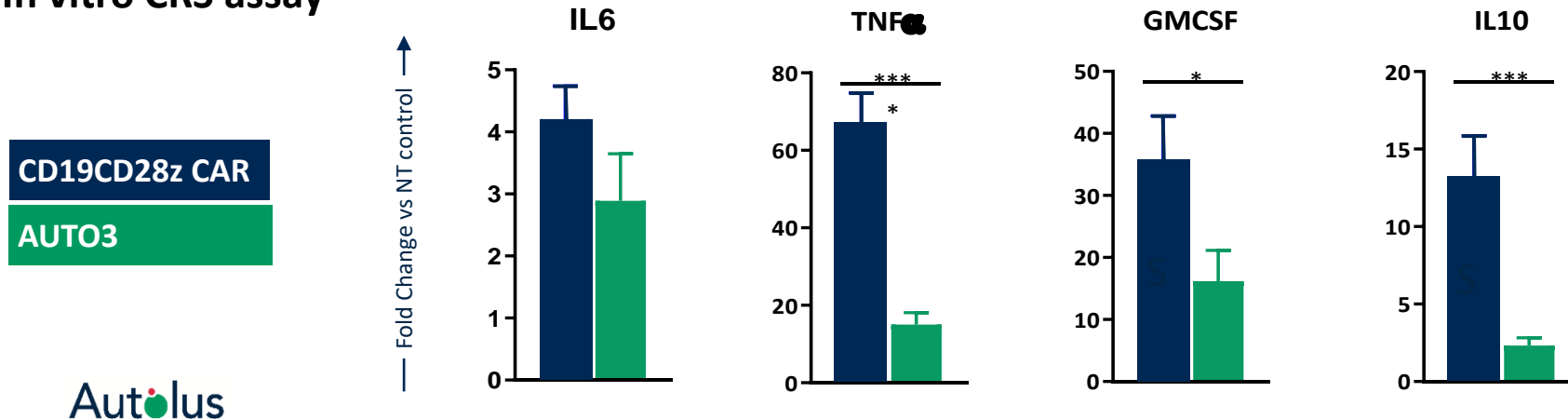
# Low *in-vitro* and *in-vivo* cytokines consistent with low grade CRS

## Clinical



CAR T Product	CRS Grade 0-2 Median IL-6 level pg/ml	CRS Grade ≥3 Median IL-6 level pg/ml
AUTO3	16.55 (0 – 3275)	NA
Yescarta®	49.4 (3.5, 12109.7)	713.9 (152.5- 50705)

## In vitro CRS assay



CRS-associated cytokines were produced at multi-fold higher levels by CD19CD28z CAR\* versus AUTO3 in a transwell/ macrophages in vitro CRS model (Norelli et al 2018)

\* CD19CD28z CAR is an FMC63 based CAR similar to Yescarta®

# Preliminary efficacy indicative of high level of activity

Dose level  $\geq 150 \times 10^6$  cells with day -1 pembro selected as Phase 2 dosing regimen (RP2D)

	50 x 10 <sup>6</sup> No pembro (N=4)	50 x 10 <sup>6</sup> D14 pembro (N=3)	150 x 10 <sup>6</sup> D14 pembro (N=4)	450 x 10 <sup>6</sup> D14 pembro (N=4)	450 x 10 <sup>6</sup> D-1 pembro (N=4)	150-450 x 10 <sup>6</sup> D-1 pembro <u>RP2D</u> (N=4)
CR	1	1	2	2	2	3
PR	1	1	0	1	0	1
PD	2	0	2	1	2**	0
NE	0	1*	0	0	0	0

- All Dose Levels (N=23): ORR 65%, CRR 48%
  - $\geq 150 \times 10^6$  (N=16): ORR 69%, CRR 56%
  - $\geq 150 \times 10^6$ , Day -1 pembro (N=8): ORR 75%, CRR 63%

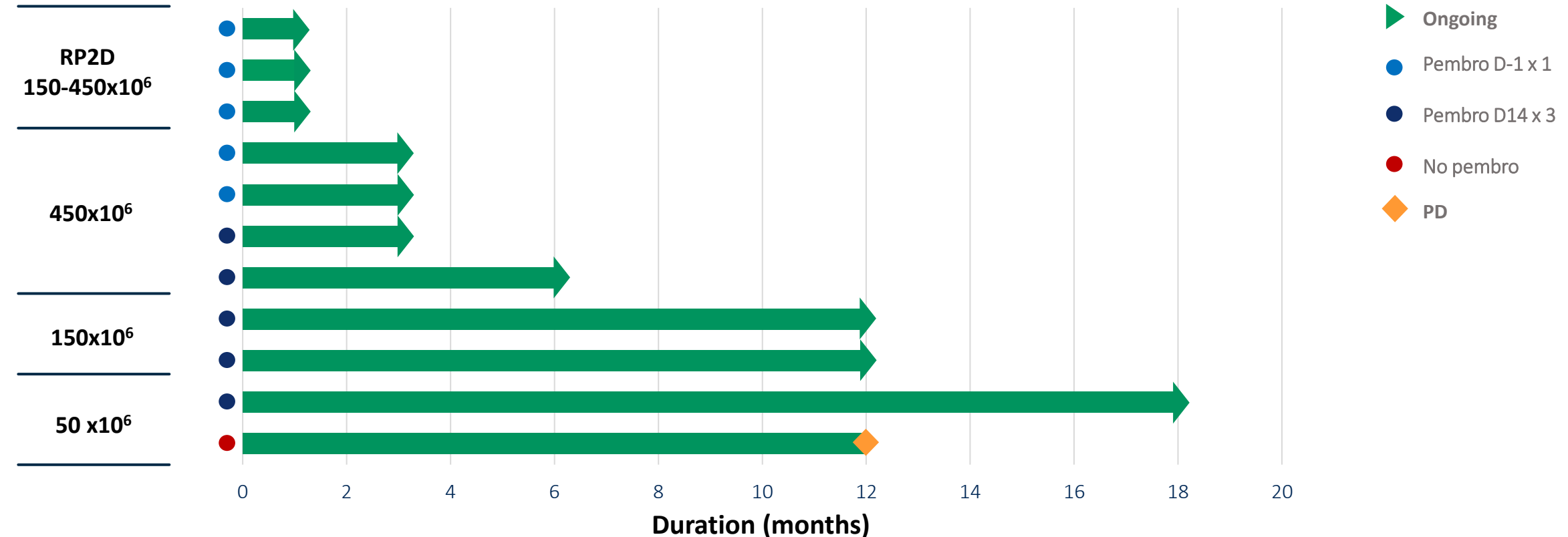
\* NE because baseline PET negative disease,

\*\* Includes one patient that received only  $125 \times 10^6$  and NE per protocol

# Encouraging signs of durable complete responses

10 of 11 complete responses ongoing

Dose



At  $\geq 150 \times 10^6$  dose, all complete responses are ongoing with a median follow up 3 months (range 1-12m)



# Complete responses seen in bulky tumors without sCRS or NT

Pre AUTO3

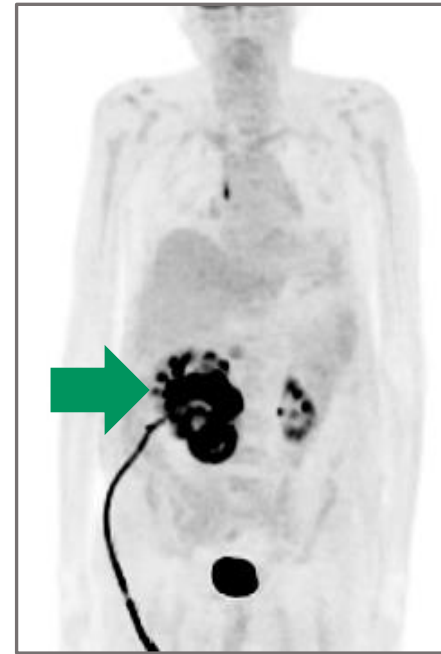


Post AUTO3 Day 28



60 yo male, Refractory DLBCL NOS, Bulky  
Refractory to RCHOP/RICE/RESHAP  
Dose:  $50 \times 10^6$  D14 pembro  
No CRS or NT  
CR duration 18 months+

Pre AUTO3



Post AUTO3 Day 28



83 yo male, Refractory DLBCL NOS, Bulky: SPD 125 cm<sup>2</sup>  
Refractory to RCHOP, RDHAX, Polatuzumab + R  
Bendamustine  
Dose  $450 \times 10^6$  D-1 pembro  
Grade 2 CRS, no NT

# Updated Alexander data suggests unique clinical profile

- AUTO3 product was successfully manufactured for all patients
- Tolerable safety profile, 0%  $\geq$  Grade 3 CRS and 4% (1/23) Grade 3 neurotox with primary infusion
  - No neurotoxicity of any grade in patients treated  $\geq 150 \times 10^6$  cells
- RP2D range of 150 - 450  $\times 10^6$  cell dose with pembro D-1 selected
  - CRR  $\geq 150 \times 10^6$  with D-1 pembro is 63% (N=8)
- Complete responses achieved with minimal management of patients
- Complete responses are durable, 10/11 ongoing (median f/u 3 months)
- Outpatient expansion cohort is enrolling

# Commercial Opportunity

*Brent Rice*

*Vice President, Chief Commercial Officer, US*

# Full outpatient opportunity unlikely to be realized with current CAR Ts

- Real-world Medicare claims data for adults with lymphoma who received CAR T-cell therapy from 2017 to 2018 suggests median length of hospital stay is 17 days. Median time in the intensive care unit (ICU) is 13 days, nearly 50% of patients require an ICU stay<sup>\*</sup>
- Outpatient treatment with liso-cel in r/r DLBCL resulted in 57% of patients requiring hospitalisation post-treatment with a median time to hospitalization of 5.5 days<sup>\*\*</sup>
- Aggressive steroid management to reduce toxicity may have a negative impact on efficacy<sup>\*\*\*</sup>

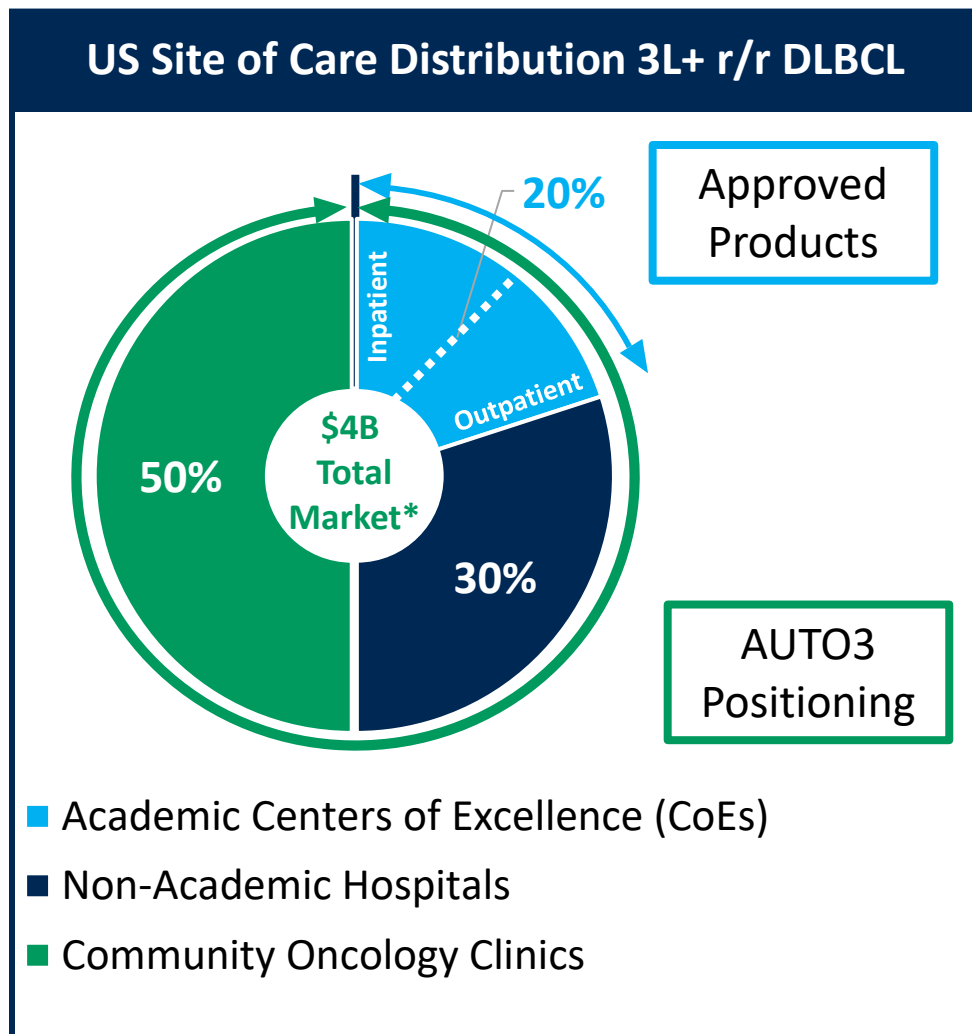
# AUTO3 is designed for potential best-in-class efficacy and safety

## Differentiated product profile expected to open access to full market opportunity

- First-in-class CD19 & CD22 CAR with novel signaling domains, design & manufacturing process
- Designed to provide best-in-class efficacy with high rates of durable complete responses
- Potential for best-in-class safety with no need for intensive patient management
- Highly differentiated clinical profile with potential for true outpatient treatment across all settings of care
- Outpatient cohort initiated with potential to move to a pivotal study early 2021
- AUTO3 has the potential to reach patients without the need for referrals to academic centers

# AUTO3 is designed to reach total addressable r/r DLBCL population

AUTO3 has the potential to be a true outpatient therapy



Source: US Retrospective Claims Analysis by Site of Distribution  
\*Autolus approximate estimates

## Approved CD19 CAR T Products

- Patients receive approved products as inpatients in CoEs because of the high rate & severity of toxicities plus intensity of patient management
- Market opportunity limited to ~20% of patients

## AUTO3

- Minimal toxicity management of AUTO3 should allow treatment across all settings of care
- AUTO3 potentially grows the addressable market and maximizes reimbursement options compared to approved products
- >80% of 3L+ and 2L DLBCL patients treated outside of Academic CoEs

# Widespread adoption of CAR T products has been limited by toxicities

High rates and severity of toxicities require intensive management and inpatient care

	Yescarta®	Kymriah®/ liso-cel	AUTO3*
Best CRR	54%	40-53%	63%
Ongoing CR rate	36% at 6m	29-35% at 6m	tbd
CRS ≥ grade 3	11%	2-23%	0%
NTX any grade	64%	21-30%	0%
NTX ≥ grade 3	28%	10-12%	0%
Toxicity management	Intensive		Minimal
Healthcare utilization	Inpatient Treatment		Outpatient Positioning

AUTO3 has been designed to minimise loss of CRs with a safety profile suitable for all settings of care including outpatient therapy

\*AUTO3: 27 April 2020 Data cut (AUTO3 + Day – 1 Pembro ≥ 150 x10<sup>6</sup>)  
Nellapu et al, 2017  
Schuster et al., 2019  
Abramson et al., 2019 (ASH)

# Yescarta® & Kymriah® utilization capped in Academic COEs

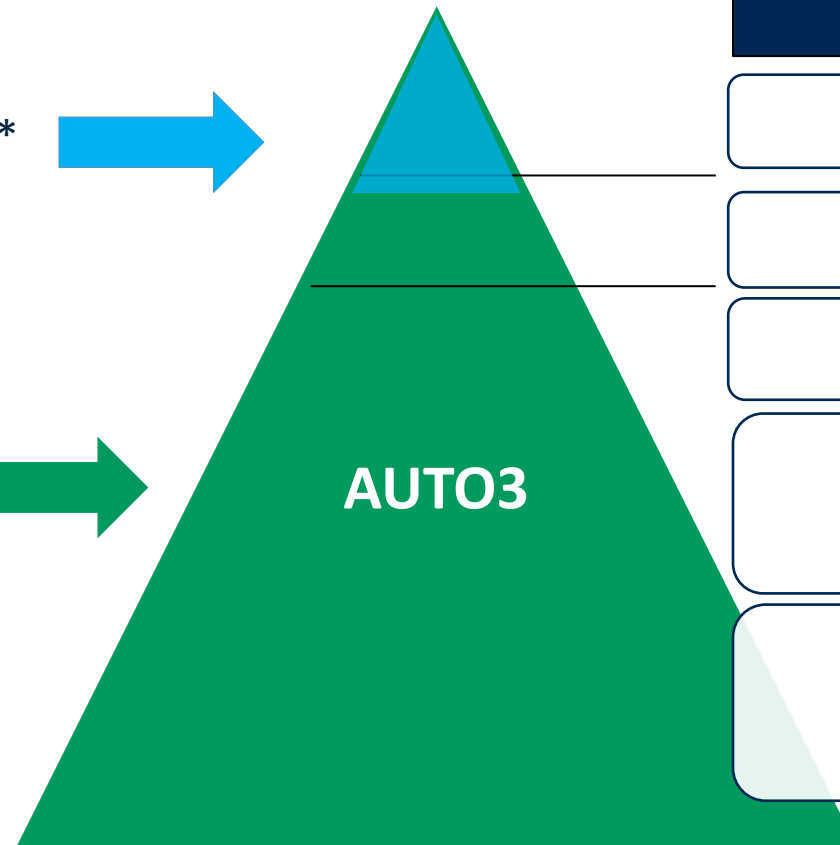
**AUTO3 democratizes use across all settings of care**

## Yescarta® and Kymriah® Medicare utilization:

- 42% in 7 PPS Exempt COEs\*
- 58% in 52 PPS Hospitals\*

**Greatest and untapped  
market opportunity**

**Market  
Penetration**



## Total Addressable Market

Inpatient Academic &  
11 PPS Exempt

- AUTO3

Outpatient Academic &  
11 PPS Exempt

- AUTO3

Inpatient Non-Academic  
Community Hospitals

- AUTO3

Outpatient Non-Academic  
Community Hospitals

- AUTO3

Community Clinic

- AUTO3

\*Medicare SAF Oct 2018 – June 30, 2019



# AUTO3 positioned to potentially leapfrog competition

## Alexander trial to include Academic, Non-Academic and Community Oncology Clinics

- Across all lines of DLBCL the vast majority of patients are treated outside of COEs
- Community Clinics generally choose not to refer 2L patients to COEs
- AUTO3 mitigates referral networks by going where patients are treated
- AUTO3 has potential to reach full addressable 2L and 3L+ patient opportunity
- AUTO3 product attributes and flexible reimbursement poised to be best-in-class

## Summary and Next Steps

*Dr. Christian Itin*

*Chairman and CEO*

# Autolus poised for value inflection in 2020

- AUTO1
  - Initiating recruitment for UK & US in Autolus' first pivotal program in Adult ALL in Q2 2020
  - Granted orphan drug designation by the FDA for treatment of ALL
  - Pediatric ALL – moving forward with AUTO1/AUTO1NG
- AUTO3
  - Outpatient treatment cohort started in Q2 2020
  - Confirmation of transition to pivotal stage in Q3 2020
  - Pivotal study could start early 2021
- Additional value inflection in 2020 from our preclinical solid tumor and hem-onc programs
- Key data releases expected at upcoming medical conferences
- Strong balance sheet with \$243.3m in cash as of March 31, 2020

# Multiple clinical data points expected through 2020

Product	Indication	Target	Event
B Cell Malignancies			
AUTO1	Adult ALL	CD19	<ul style="list-style-type: none"> <li>• Ph1 long-term follow up Q2 &amp; Q4 2020</li> <li>• Ongoing recruitment and dose last patient H1 2021</li> </ul>
AUTO1NG	Pediatric ALL	CD19 & 22	<ul style="list-style-type: none"> <li>• Start Ph1 H2 2020</li> </ul>
AUTO3	DLBCL	CD19 & 22	<ul style="list-style-type: none"> <li>• Decision on Ph2 Q3 2020</li> <li>• Full Ph1 data H2 2020</li> </ul>
AUTO3NG	DLBCL	CD19 & 22	<ul style="list-style-type: none"> <li>• Ready to start Ph1 H2 2020, life cycle mgmt</li> </ul>
Multiple Myeloma			
AUTO8	Multiple Myeloma	BCMA & CAR X	<ul style="list-style-type: none"> <li>• Start Ph1 study H2 2020</li> </ul>
T Cell Lymphoma			
AUTO4	TRBC1+ Peripheral TCL	TRBC1	<ul style="list-style-type: none"> <li>• Ph1 interim data H1 2021</li> </ul>
GD2+ Tumors			
AUTO6NG	Neuroblastoma; Melanoma; Osteosarcoma; SCLC	GD2	<ul style="list-style-type: none"> <li>• Start Ph1 H1 2021</li> </ul>
Allogeneic Approach			
Undisclosed	Undisclosed	Undisclosed	<ul style="list-style-type: none"> <li>• Start Ph1 Q4 2020</li> </ul>

## Q&A

*Dr. Christian Itin (Chairman and CEO)*

*Andrew Oakley (CFO)*

*Dr. Vijay Reddy (CMO)*

*Dr. Nushmia Khokhar (VP, Clinical Development)*

*Dr. Robert Chen (Executive Director, AUTO3 Program)*

*Brent Rice (VP, Chief Commercial Officer, US)*



**Thank you**