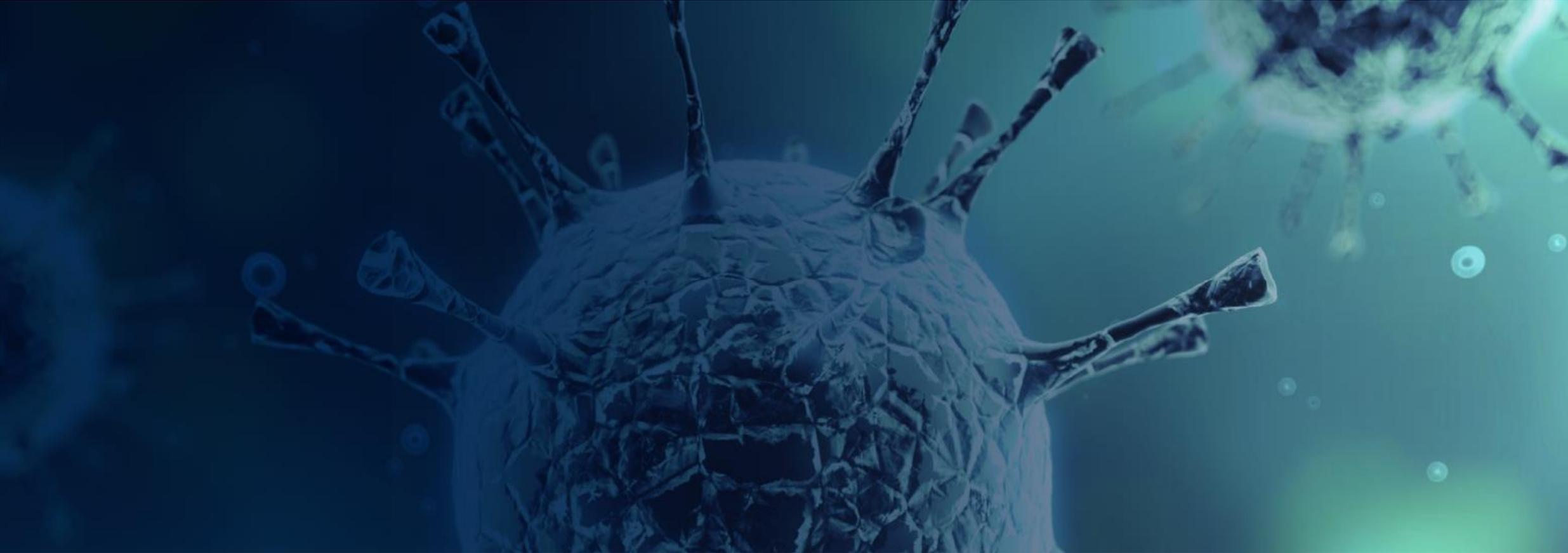


Autolus

Nasdaq: AUTL



Fourth Quarter and Full Year 2019 Financial Results and Operational Progress

March 3, 2020

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# Agenda

1. Welcome and Introduction: Dr. Christian Itin, Chairman and CEO
2. Operational Highlights: Dr. Christian Itin
3. Financial Results and Overview: Andrew J. Oakley, CFO
4. Upcoming Milestones and Conclusion: Dr. Christian Itin
5. Q&A: Dr. Christian Itin and Andrew J. Oakley

# Operational Highlights

*Dr. Christian Itin*

*Chairman and CEO*

# Corporate strategy

## Short term value steps with best in class programs for ALL and DLBCL

- Focus on potentially best in class Acute Lymphoblastic Leukemia (ALL) and Diffuse Large B Cell Lymphoma (DLBCL) therapies with major value steps expected in 2020 / 2021
  - First pivotal study of adult ALL to complete in H1 2021 with approval targeted in 2022
  - Drive DLBCL program to POC and prepare for pivotal study
- Additional value steps in T cell lymphoma and first solid tumor indication
- Broad preclinical pipeline of next generation programs transitioning to clinical stage in 2020
- Broad proprietary cell programming technology
- Scalable, fully enclosed manufacturing platform

# Corporate highlights - 2019

- Clinical progress with lead programs
  - AUTO1 in adult ALL
  - AUTO3 in DLBCL
  - AUTO6NG in Neuroblastoma; Melanoma; Osteosarcoma; SCLC
  - T-cell lymphomas (AUTO 4/5)
- Successful fundraisings
  - Net proceeds \$109.0 million in April 2019 and approx. \$75 million post year end in Jan 2020
- Manufacturing
  - Catapult site is fully operational and delivering clinical products for patients in Europe and the US
  - US facility progressing with expected capacity for 5,000 patients p.a.

# No approved CAR T therapy for adult ALL patients

Severe toxicities of currently approved products have limited CAR T suitability in adult setting

- ALL is a significant opportunity
  - Up to 8,400\* new cases of adult ALL diagnosed yearly worldwide‡
  - Addressable patient population is projected at 3,000 patients US & EU
- High unmet medical need
  - Combination chemotherapy enables 90% of adult ALL patients to experience CR, but only 30% to 40% will achieve long-term remission
  - Median overall survival is < 1 year in r/r ALL
  - Only approved redirected T cell therapy approved for adults generally is blinatumomab
  - CAR T therapies are highly active, but no clear sense of durability without subsequent allograft
  - Patients are generally more fragile, more co-morbidities
  - Yet CAR T toxicities in this setting have been notable with high incidences of severe CRS and cases of fatal neurotoxicity

**FDA granted AUTO1 orphan drug designation for ALL**

# AUTO1: Key features

Designed for durability of responses without allo-transplant and reduced severe CRS

## Conventional CD19 CARs

- Approved and near approved CD19 CAR Ts use identical high affinity CD19 binder (FMC63)
- FMC63 has a fast on-rate and a very slow off rate
- Leads to over-activation, exhaustion and high-grade CRS and neurotoxicities

## AUTO1

- AUTO1 has an optimized CD19 CAR with a lower affinity and a fast off rate
- Engages efficiently, delivering a kill, disengages rapidly like a normal T cell
- Leads to enhanced activity and lower toxicities

# AUTO1 may be best-in-class redirected T cell therapy

## Relapsed/refractory Adult ALL clinical data

	<sup>1</sup> Blincyto	All patients	<sup>2</sup> AUTO1 Closed Process <sup>3</sup>
Patient Numbers	271	16	9
CR Rate	42%	87% <sup>◇</sup>	100%
EFS 6m	31%	68% <sup>◇</sup>	100%
CRS ≥ Grade 3	3%	0%	0%
Neurotox ≥ Grade 3	13%	19% <sup>‡</sup>	12% <sup>‡</sup>

<sup>◇</sup> 15 patients evaluable for efficacy with at least 4 weeks follow up or RIP prior to Month 1

<sup>‡</sup> All three patients had > 50% tumor burden

Data cutoff 25-Nov-2019

<sup>1</sup>Kantarjian et al., 2017

<sup>2</sup>Roddie et al., ASH 2019 presentation

<sup>3</sup>Commercial manufacturing process

- AUTO1 preliminary data suggest manageable safety profile and a high level of clinical activity
- KTE-X19 CR Rate 68-84%, Grade ≥3 cytokine release syndrome (CRS) events occurred in 22-29% and neurologic events 11-38% of patients\*

# First Autolus program to move to late stage development

Potential pivotal study in adult ALL:

- CTA filed in UK in November 2019 US IND to be filed in Q1 2020
- Single arm study
- 100 relapsed / refractory adult ALL patients
- Primary endpoint: overall complete response rate (CR/CRi)
- Secondary endpoints include MRD-negative CR EFS and DoR
- BLA filing targeted for Q4 2021

# DLBCL is a large commercial opportunity

## AUTO3 - addressable patient population 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 active CD19 CARs in r/r DLBCL. Safety profile limits use to centers of excellence, leaving about 80% of the eligible patients without access to CAR T therapy

# Current status of CAR T Cell therapies in DLBCL

Two approved products (Yescarta® and Kymriah®) and one near to approval (JCAR017)

## Efficacy

- Despite high ORR (70-80%) and high best CRR (40-55%), only 29-37% patients achieve durable CRR in DLBCL<sup>1,2</sup>
- Approximately a third of CRs are lost over time
- Loss of CRs are caused by PD-L1 upregulation<sup>3</sup> which contributes to CAR T exhaustion and CD19 antigen loss<sup>4</sup>

## Safety

- High rates of severe cytokine release syndrome (13-22%) and severe neurotoxicity (12-28%)<sup>2,4</sup>
- Early onset and severity of toxicities requires intensive inpatient management

# Desired characteristics for broad use of a CAR T therapy for DLBCL

## Sustained CRs, low toxicity & toxicity management and broad healthcare utilization

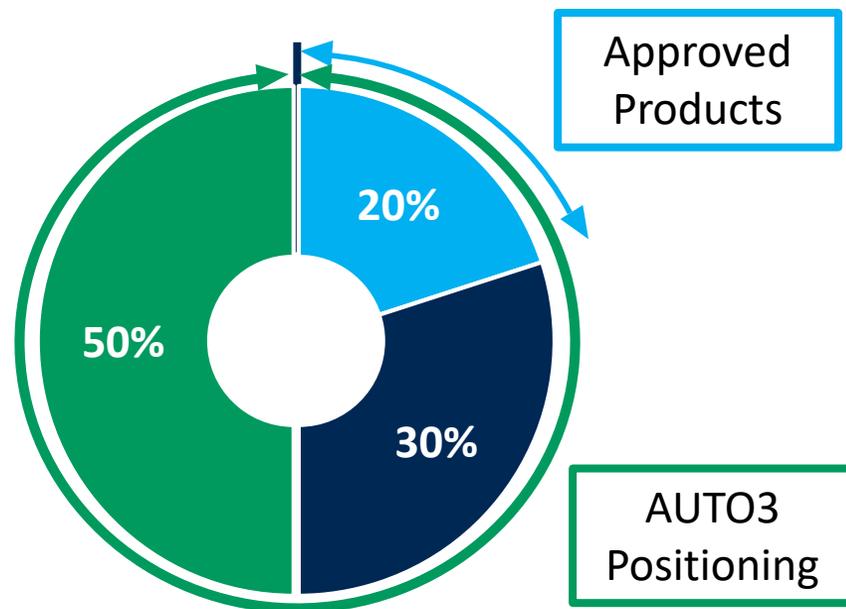
- High sustained complete response rate
  - Preventing target negative relapse
  - Preventing checkpoint mediated resistance / exhaustion
- Safety profile suitable for out patient therapy
  - Low severe CRS without intensive management
  - Low neurotoxicity rates

**AUTO3 has been designed to be highly active with a profile suitable for all settings of care including outpatient therapy and oncology clinics**

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

AUTO3 has the potential to be a true outpatient therapy

## US Site of Care Distribution 3L+ R/R DLBCL



- Academic Centers of Excellence
- Non-Academic Hospitals
- Oncology Clinics

Source: 2016 IMS & CMS patient claims data

## 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 Products

- Minimal tox management of AUTO3 should allow treatment across all settings of care
- Increased healthcare utilization of AUTO3 grows the addressable market and maximizes reimbursement options compared to approved products

# Preliminary efficacy\* indication of dose response

## AUTO3 - DLBCL

	50 x 10 <sup>6</sup> No Pem (n=4)	50 x 10 <sup>6</sup> D14 Pem (n=3)	150 x 10 <sup>6</sup> D14 Pem (n=4)	450 x 10 <sup>6</sup> D14 Pem (n=4)	450 x 10 <sup>6</sup> D-1 Pem (n=3)
CR	1	1	2	2	2
PR	1	1	0	1	NA
NE	0	1	0	0	0
CRR	25%	33%	50%	50%	66%

- 450 million: ORR 5/7 (71%) and CR 4/7 (57%)

Pre-CAR T-cells



Post-CAR T-cells



**Dose:** 50 x 10<sup>6</sup>

**DLBCL:** ABC, Primary refractory & refractory to RCHOP/RICE/RESHAP

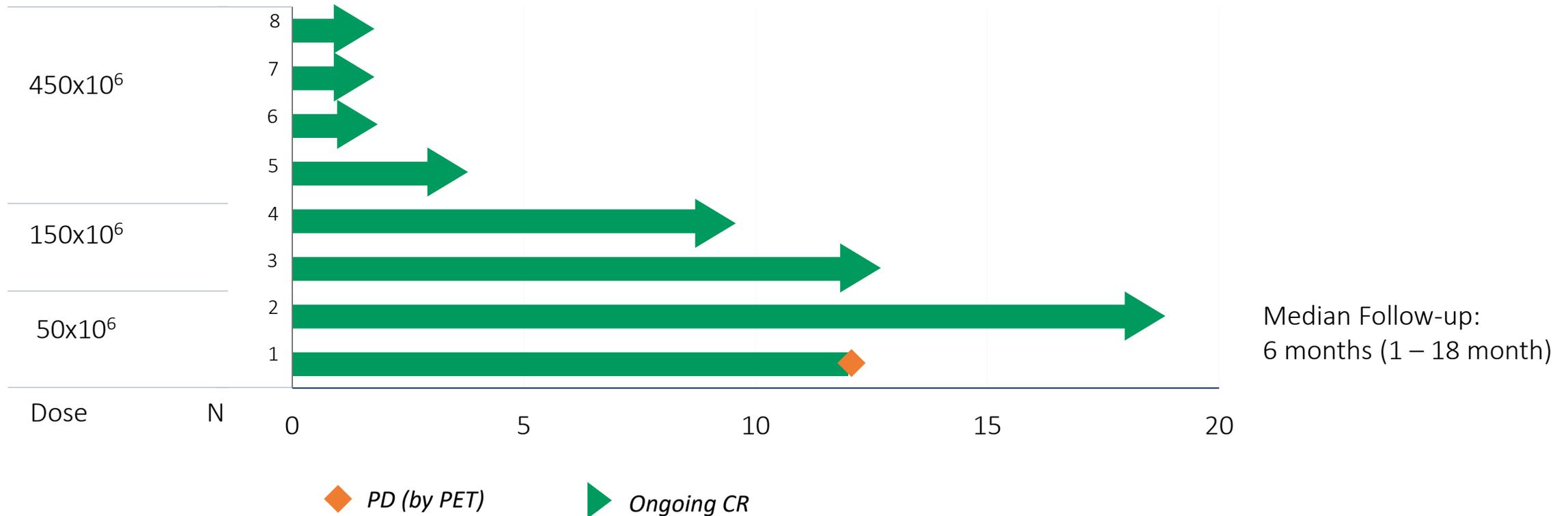
**No CRS or NT**

**CR duration 18 months+**

21 January 2020 data cut-off

# Early encouraging signs of durable complete responses

## AUTO3 in DLBCL



18 patients treated, 7 out of 8 (87%) CRs ongoing, 3 PRs not durable

7 of 7 (100%) CRs\* are ongoing in AUTO3+ Pembro cohorts at a median f/u of 3 months (1-18m)

21 January 2020 data cut-off

# AUTO3 has a safety profile which may allow outpatient use

	<sup>1</sup> AUTO3 + Pembro ≥ 150 x10 <sup>6</sup> Dose	<sup>2</sup> Yescarta <sup>®</sup>	<sup>3</sup> Kymriah <sup>®</sup>	<sup>4</sup> JCAR017
Best CR	55%*	54%	40%	53%
CRS ≥ grade 3	0%	11% #	23%	2% #
Neurotox any grade	0%	64%	21%	30%
Neurotox ≥ Grade 3	0%	28%	12%	10%

\* All CRs ongoing at a median f/u of 2 months (1-12 month)

# CRS rate achieved with intensive management

# Early data encouraging – full read-out expected in mid-2020

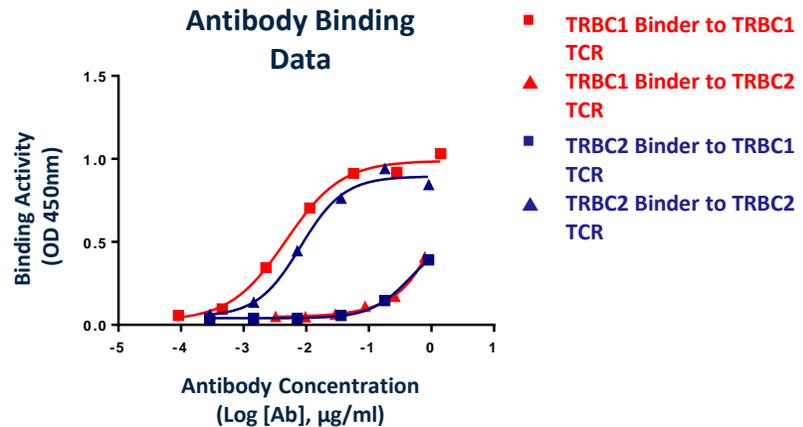
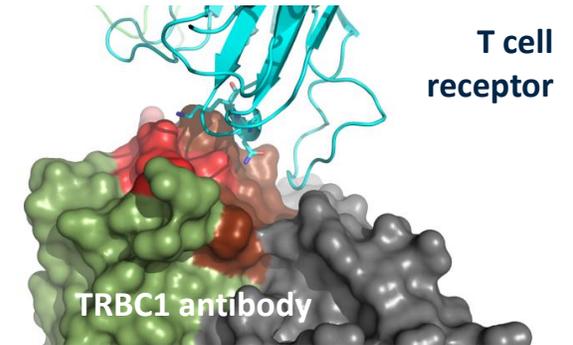
## AUTO3 in DLBCL

- AUTO3 product was successfully manufactured for all patients
  - Products manufactured at Catapult in the UK, for US and EU use
- No neurotoxicity or severe CRS\* in patients treated with AUTO3 at active dose levels
- Complete responses achieved without intensive management or ICU care
- 7/8 CRs ongoing with a median follow up of 6 months (1-18 months)
- Pembrolizumab on D-1 x single dose is being evaluated further
- Decision for triggering Phase 2 initiation planned for mid-2020

# Unique targeting of TRBC1 and TRBC2 opens new therapeutic approach AUTO4/5 in Peripheral T Cell Lymphoma

## Differences between TRBC1 and TRBC2 are small

		NK-KN 4/5		F-Y 36
TRBC1	1	EDLNKVFPPPEVAVFEPSEAEISHTQKATLVCLATGFF		PDHVLSWWVNGK
TRBC2	1	EDLNKVFPPPEVAVFEPSEAEISHTQKATLVCLATGFF		PDHVLSWWVNGK
TRBC1	51	EVHSGVSTDPQPLKEQPALNDSRYCLSSRLRVSATFWQNP		NHFRCQVQF
TRBC2	51	EVHSGVSTDPQPLKEQPALNDSRYCLSSRLRVSATFWQNP		NHFRCQVQF
TRBC1	101	YGLSENDEWTODRAKPVTQIVSAEAWGRADCGFTS		VSYYQOGVLSAT
TRBC2	101	YGLSENDEWTODRAKPVTQIVSAEAWGRADCGFTS		ESYYQOGVLSAT
				V-E 135



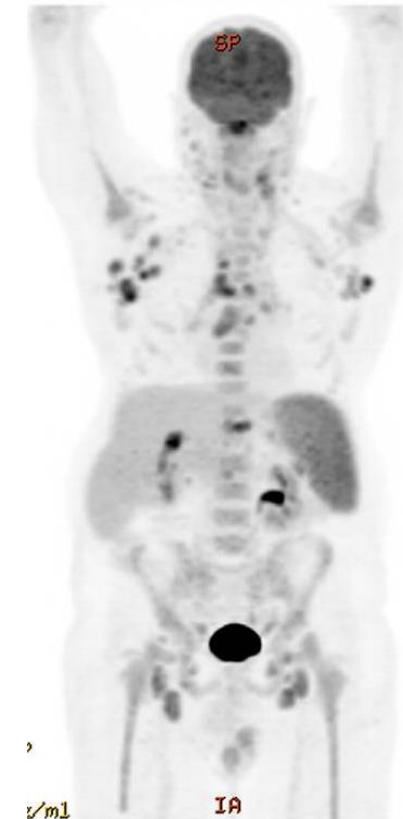
- Patient enrolment on AUTO4 Phase 1 study ongoing
- Expect to present initial AUTO4 Phase 1 data H2 2020
- AUTO5 Phase 1 to commence H2 2020
- Companion diagnostic development on-track

# Encouraging signal of anti tumor effect from AUTO4 treated patient

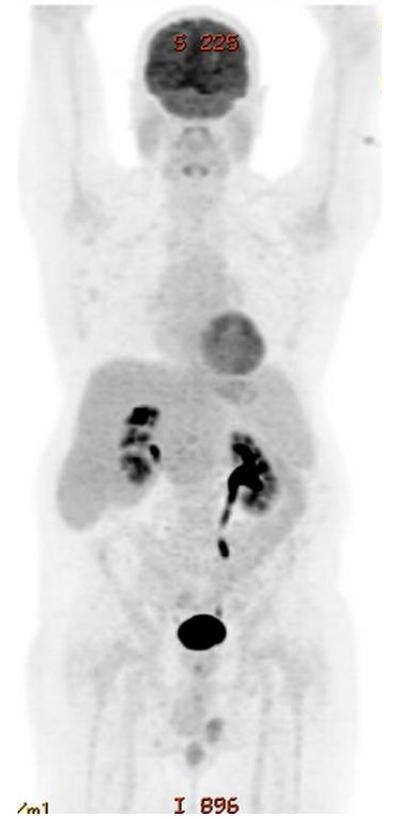
## Clinical outcome of patient 1

- 57 yr old with Angioimmunoblastic T cell lymphoma
- Past treatments include CHOP (CR) & IVE (refractory)
- AUTO4 Treatment
  - Treated with  $25 \times 10^6$  anti-TRBC1 CAR T cells
  - No expansion of CAR T cells was noted
  - No CRS or neurotoxicity or T-cell aplasia was noted
  - Initial PET/CT at one month showed Complete Metabolic Response but subsequently had progression on day 71

Baseline PET/CT scan  
Pre-AUTO4 treatment



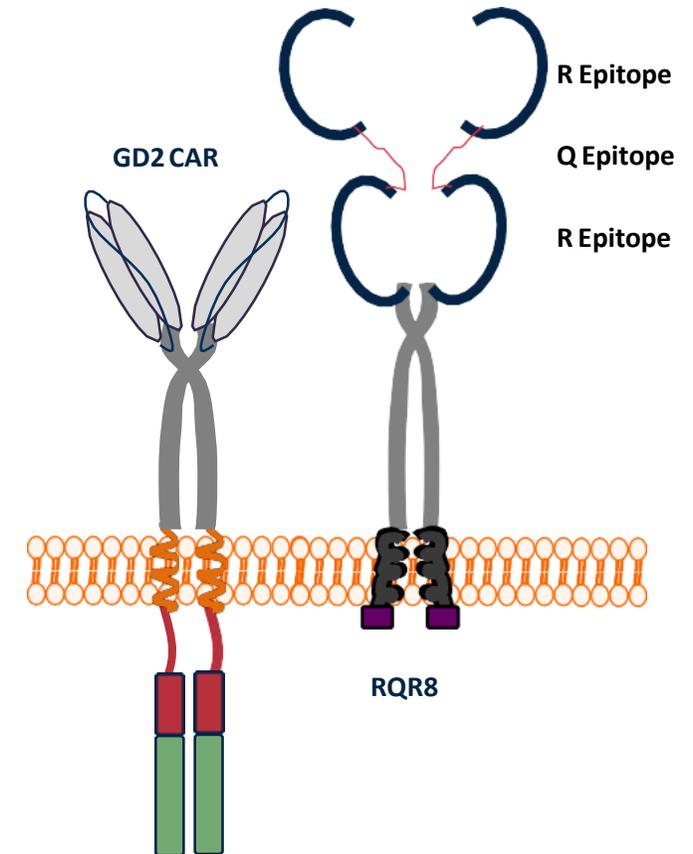
Month 1 PET/CT scan



# Designed to drive anti-tumor activity without inducing neurotoxicity

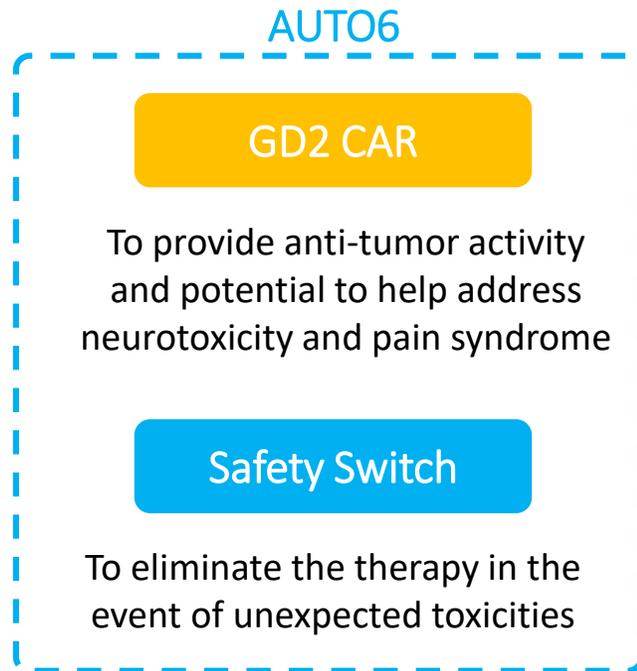
## AUTO6: GD2-targeted programmed T cell therapy

- Programmed T cell product candidate:
  - New binder to minimize on-target, off-tumor toxicity
  - Humanized binder to reduce immunogenicity
  - RQR8 safety switch
- Phase 1 clinical trial in r/r neuroblastoma conducted by CRUK\* in collaboration with UCL
- Autolus has exclusive worldwide rights to clinical data and patents
- Preliminary data has shown initial anti-tumor activity in this solid tumor indication



# Modular approach enhances AUTO6NG for solid tumor environment

Next generation programs powered by a technology tool box



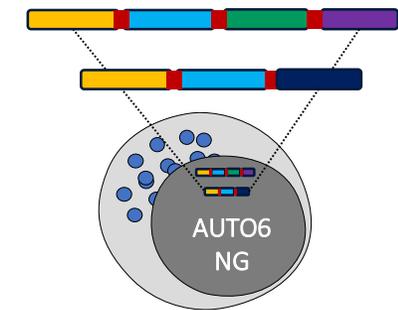
To overcome multiple checkpoint pathways



IL7R chimeric protein designed to improve CAR T cell persistence



To overcome inhibitory effect of TGFβ in microenvironment



## AUTO6NG:

- Utilizes GD2 CAR from AUTO6, but further enhanced to address persistence, control and tumor defences
- Targeting neuroblastoma, osteosarcoma, melanoma and small cell lung cancer amongst others
- Plan to commence Phase 1 H2 2020

# Positioned for additional value inflection in 2020

## AUTO6NG

- Plan to commence Phase 1 H2 2020
- Encouraging preclinical data on three T cell programming modules presented at SITC 2019
  - Constitutively signaling IL7 cytokine receptor (IL7R\_CCR) is shown to enhance persistence
  - Dominant negative TGFbRII (dnTGFbRII) observed to block TGFβ signaling
  - Truncated SHP2 (dSHP2) observed to confer resistance to inhibitory signals such as those from PD1
  - In established tumor model AUTO6NG eliminated the tumor, whereas AUTO6 did not

# Financial Results

*Andrew J. Oakley*

*CFO*

# Financial summary

USD m	Year ended 31 Dec 2018	Year ended 31 Dec 2019	Variance
Grant Income	1.5	2.9	1.4
R&D	(48.3)	(105.4)	( 57.1)
G&A	(27.3)	(39.5)	(12.2)
Loss on impairment of leasehold improvements	-	(4.1)	(4.1)
<b>Total Op Expenses, net.</b>	<b>(74.1)</b>	<b>(146.1)</b>	<b>(72.0)</b>
Interest Income	2.0	2.5	0.5
Other Income	5.8	4.5	(1.3)
Tax Benefit	8.5	15.2	6.7
<b>Net Loss</b>	<b>(57.9)</b>	<b>(123.8)</b>	<b>(65.9)</b>

USD m	Dec 31 2018	Dec 31 2019	Variance
Cash Balance*	217.5	210.6	(6.9)

- Follow on offering in Jan 2020 raised \$75m in net proceeds
- Cash runway increased to into 2022

# Upcoming Milestones and Conclusions

*Dr. Christian Itin*

*Chairman and CEO*

# Multiple clinical data points expected through 2020

Product	Indication	Target	Event
<b>B Cell Malignancies</b>			
AUTO1	Adult ALL	CD19	<ul style="list-style-type: none"> <li>• Ph 1 long-term follow up Q2 &amp; Q4 2020</li> <li>• Start pivotal program H1 2020</li> </ul>
AUTO1NG	Pediatric ALL	CD19 & 22	<ul style="list-style-type: none"> <li>• Start Ph 1 H1 2020</li> </ul>
AUTO3	DLBCL	CD19 & 22	<ul style="list-style-type: none"> <li>• Ph 1 data Q2 &amp; Q4 2020</li> <li>• Decision on Ph 2 transition mid 2020</li> </ul>
AUTO3NG	DLBCL	CD19 & 22	<ul style="list-style-type: none"> <li>• Ready to start Ph 1 H2 2020</li> </ul>
<b>Multiple Myeloma</b>			
AUTO8	Multiple Myeloma	BCMA & CAR X	<ul style="list-style-type: none"> <li>• Start Ph 1 study H2 2020</li> </ul>
<b>T Cell Lymphoma</b>			
AUTO4	TRBC1+ Peripheral TCL	TRBC1	<ul style="list-style-type: none"> <li>• Ph 1 interim data Q4 2020</li> </ul>
<b>GD2+ Tumors</b>			
AUTO6NG	Neuroblastoma; Melanoma; Osteosarcoma; SCLC	GD2	<ul style="list-style-type: none"> <li>• Start Ph 1 H2 2020</li> </ul>
<b>Allogeneic Approach</b>			
NA	NA	NA	<ul style="list-style-type: none"> <li>• Start Ph 1 Q4 2020</li> </ul>

**Pre-clinical data presentations at AACR (April 2020)**

# Autolus poised for value inflection in 2020

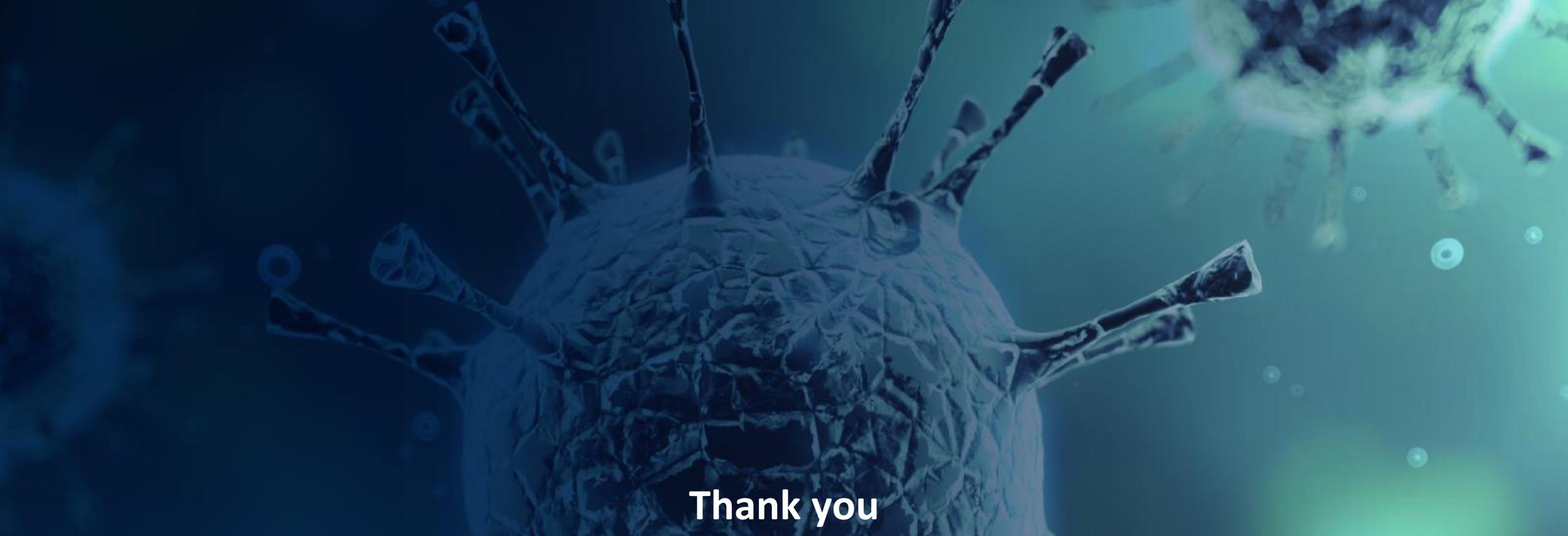
- AUTO1
  - Encouraging data at ASH Dec 2019
  - First Autolus program to move into a pivotal program – Adult ALL
  - Opportunity for best in class CD19 CAR T with FDA Orphan drug designation
  - Pediatric ALL – moving forward with AUTO1/AUTO1NG
- AUTO3
  - Encouraging data at EHA-EBMT 2nd European CAR T Cell conference Jan 2020
  - Initial focus on DLBCL, Phase 2 decision point mid-2020
  - AUTO3NG opportunity as next generation product
- Opportunity for additional value in 2020 from AUTO1NG, AUTO4, AUTO6NG and AUTO8
- Strong balance sheet with approx. \$210.6m in cash as of 31 December 2019\*
- Key data releases expected at upcoming medical conferences

\*Before adjusting for \$75m in net proceeds from Jan 2020 public offering

## Q&A

*Dr. Christian Itin (Chairman and CEO)*

*Andrew J. Oakley (CFO)*



**Thank you**