

Third Quarter Financial Results and Operational Progress November 5, 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



#### **Business update – third quarter 2020**

Impact from COVID-19 has been limited to date, but situation poses a risk to AUTO1

- AUTO1 pivotal program currently on track
  - AUTO1 pivotal program was initiated in Q2 as planned
  - Potential impact of infection surges on timelines continues to be closely monitored
  - Potential for disruption if infection rates continue to increase
- AUTO3 outpatient extension cohort continued to enrol patients in Q3
  - Infection surges continue to be closely monitored to ensure continued enrolment
- Impact on AUTO4 Ph1 clinical trial stabilized
  - Continue to expect Ph1 interim data 2021
- Preclinical programs still minimally impacted

#### **Corporate highlights – third quarter 2020**

#### Advancing our clinical programs to value inflection

- AUTO1 in adult ALL;
  - AUTO1 pivotal program initiated and enrolling
  - Targeting data by end 2021, assuming no COVID-19 disruptions to clinical trial conduct
- AUTO3 in DLBCL
  - AUTO3 data at ESMO continue to show encouraging clinical profile
- Additional clinical data expected at ASH in December 2020
  - AUTO1 in adult ALL, presenting longer term follow up
  - AUTO3 in DLBCL, presenting updated data and longer term follow up from ALEXANDER study
  - Analyst call planned post ASH

#### No approved CAR T therapy for adult ALL patients

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

ALL is a significant opportunity:

8,400\*

new cases of adult ALL diagnosed yearly worldwide

**3,000** addressable patient population in last line setting

#### 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</li>
- 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
- Opportunity to conduct further clinical study for second line treatment label increasing addressable patient population

FDA granted AUTO1 orphan drug designation for ALL

# AUTO1 potentially has a superior efficacy profile compared to standard of care

**Comparable and manageable safety profile** 

	¹AUTO1		Standard of Care		
	All patients	Closed Process	<sup>2</sup> Blinatumumab	<sup>3</sup> Inotuzumab	
Patient Numbers	19	13	271	218	
CR Rate	84%	92%	44%	80.7%	
EFS 6m	62%	76%	31%	mPFS 5m	
CRS ≥ Grade 3	0%	0%	3%	0%	
Neurotox ≥ Grade 3	16%*	15%*	13%	0%	
Other notable toxicities				14% Hepatic VoD	

- Approximately 50% of blinatumumab and inotuzumab patients received subsequent HSCT
- Veno-Occlusive Disease (VoD) during treatment and following subsequent HSCT, with the latter causing a higher post-HSCT non-relapse mortality rate, has limited inotuzumab uptake



#### **AUTO1** is the first Autolus program to move into a pivotal program

Preliminary Ph1 data supports development as a standalone therapy

Pivotal program, AUTO1-AL1, in adult ALL enrolling with data targeted by end 2021 CTA approved by the MHRA in January 2020 and US IND accepted by the FDA in April 2020

- Ph1b run-in component, prior to single arm Ph2 pivotal study
- 100 relapsed / refractory adult ALL patients
- Primary endpoint: Overall
   Complete Response Rate (CR/CRi)
- Secondary endpoints: include MRD-negative CR EFS and DoR

#### **Capitalizing on the unique profile of AUTO1**

AUTO1 in late phase development in adult ALL, with four related Ph1 trials enrolling by Q1 2021

<b>PRODUCT</b>	INDICATION	TARGET	<b>CTA Enabling</b>	Phase 1/2	Pivotal
AUTO1	Adult ALL	CD19		ALLCAR19	AUTO1-AL1
AUTO1	iNHL & CLL	CD19		ALLCAR19 ext. Stu	udy ongoing
AUTO1	Primary CNS Lymphoma*		CAROUSEL	Q4 2020 study start	
AUTO1/22	Paediatric ALL	CD19 & CD22	CARPALL ext.	Q4 2020 study start	

<sup>\*</sup>Primary CNS lymphoma annual incidence approx. 1400 cases in the US. Reference: Keva Green; Jeffery P. Hogg https://www.ncbi.nlm.nih.gov/books/NBK545145/.



#### **Current status of CAR T Cell therapies in DLBCL**

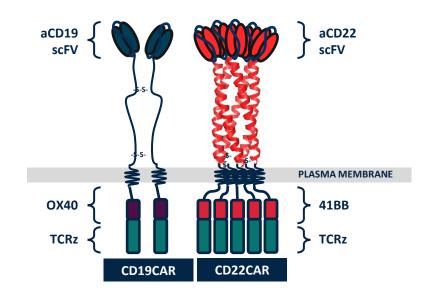
Two approved products (Yescarta® and Kymriah®) and one near to approval (liso-cel)

#### **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





- Locke F et al Lancet Oncol 2019
- 2. Schuster S et al NEJM 2019
- 8. Neelapu S et al ASCO 2018
- I. Neelapu S et al NEJM 2017





### **Complete Response Rate (CRR) - Completed Cohorts Only**

Dose level  $\geq$  150 x 10<sup>6</sup> cells with day -1 pembro selected as Phase 2 dosing regimen (RP2D)

	50 x10 <sup>6</sup> AUTO3 no pem (N=4)	50 x10 <sup>6</sup> AUTO3 D14 pem (N=3)	150-450 x10 <sup>6</sup> AUTO3 D14 pem (N=8)	150-450 x 10 <sup>6</sup> AUTO3 D-1 pem <u>RP2D</u> (N=15)	Total (N=30)
N evaluable*	4	2	8	14	28
ORR (CR + PR)	2	2	5	10	19
CR	1	1	4	9	15
PR	1	1	1	1	4
PD	2	0	3	4	9

<sup>\*</sup> Evaluable = PET positive disease prior to start of pre-conditioning

- Overall: ORR 68%, CRR 54%
- $\geq$  150 x 10<sup>6</sup> CD19/CD22 CAR T cells, Day -1 pem (N=14 evaluable): ORR 71%, CRR 64%







### **Cytokine Release Syndrome and Neurotoxicity – All Patients**

#### No severe CRS and low rates of NT

	50 x10 <sup>6</sup> AUTO3 no pem (N=4)	50 x10 <sup>6</sup> AUTO3 D14 pem (N=3)	150-450 x10 <sup>6</sup> AUTO3 D14 pem (N=8)	150-450 x 10 <sup>6</sup> AUTO3 D-1 pem <u>RP2D</u> (N=20)	Total (N=35)
Grade 1 CRS	1	0	2	5	8 (22.9%)
Grade 2 CRS	0	0	2	2	4 (11.4%)
≥ Grade 3 CRS	0	0*	0	0	0 ( 0%)
≥ Grade 3 NT	1	0	0	1	2 (5.7%)
Total NT	1	0	0	2	3 (8.6%)

1 patient who had no CRS with primary infusion, developed G3 CRS (severe hypoxia) with re-treatment 1 year later which happened in a setting of no CAR T expansion and significant disease burden in lung that had been treated with radiation

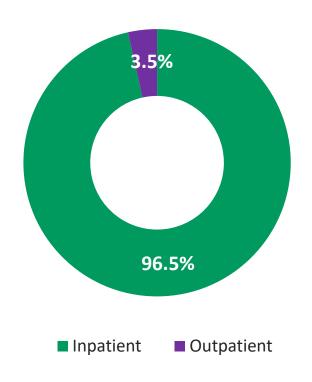
- No prophylactic measures of any kind
- Median time to CRS 6 days (1-36), median duration of CRS 3 days (1-19), no Grade 3 or higher CRS\* with primary infusion, 5 patients (14%) received tocilizumab for CRS
- No NT of any grade in patients that achieved CR (these patients had robust CAR T expansion), all NT atypical in context of tumour progression with zero to minimal CAR T expansion in peripheral blood



### Approved CAR T's have not penetrated outpatient setting

Creates significant upside for AUTO3 with potential to go where patients reside

# Percentage of patients who currently receive a CAR T in outpatient or inpatient setting



- 97% of patients receive approved CAR Ts as inpatients in CoEs because of the high rate and severity of toxicities and the need for intensive patient management
- 54% of patients required hospitalisation post —
  treatment when treated with liso-cel\*. Reason for
  hospitalisation was mainly CRS and/or NEs (29%) or
  other AEs (25%)
- AUTO3 is designed to have best-in-class clinical profile potentially best suited for outpatient use
- AUTO3 stands to democratize use across all settings of care

#### **Expansion cohort is assessing feasibility in outpatient setting**

- Purpose of the ALEXANDER expansion cohort is to assess the feasibility of using AUTO3 in an outpatient setting
  - Opportunity to evaluate additional safety and efficacy data with more patients' data
  - Enables centers to broaden their experience with AUTO3 and gain confidence in use as an outpatient therapy
  - Drive early adopters in a potential pivotal study, planned to start H1 2021
  - Allows us to build an understanding of healthcare resource utilization, facilitating the design of a pivotal study
  - Enables early exploratory metrics to be considered (e.g. readmission rates), which may be relevant to supporting an outpatient profile

#### **AUTO3** is designed for potential best-in-class clinical profile

Differentiated product profile should open access to full market opportunity

Outpatient cohort initiated with data planned for ASH 2020

Potential to move to a pivotal study H1 2021

First-in-class CD19 & CD22 CAR with novel signaling domains

- AUTO3 is designed to provide best-in-class clinical profile, which negates the need for intensive patient management
- Potential for true outpatient treatment across all settings of care
- AUTO3 has the potential to reach patients without the need for referrals to academic centers

#### **Broad pipeline of next generation programs**

#### Designed to address limitations of current T cell therapies

PRODUCT	INDICATION	TARGET	PRECLINICAL	PHASE 1
•	Pediatric ALL	CD19 & CD22		Q4 2020
AUTO3NG	DLBCL	CD19 & CD22		Life cycle mgmt
AUTO5	TRBC2+ Peripheral TCL	TRBC2		2021
AUTO6NG	Neuroblastoma; Melanoma; Osteosarcoma; SCLC	GD2		2021
AUTO7	Prostate Cancer	PSMA		2021
AUTO8	Multiple Myeloma	BCMA & CAR X		H1 2021



B Cell Malignancies T Cell Lymphoma DD2+ Tumors Prostate Cancer Multiple Myeloma









### **Financial Results**

Andrew J. Oakley CFO



# **Financial summary**

USD m	3Q 2020	3Q 2019	Variance
Grant Income	0.4	0.3	0.1
License Revenue	0.2	-	0.2
R&D	(33.5)	(27.3)	(6.2)
G&A	(9.8)	(8.6)	(1.2)
Total Op Expenses, net.	(42.7)	(35.6)	(7.1)
Interest Income	0.0	0.5	(0.5)
Other Income	(2.5)	3.3	(5.8)
Tax Benefit	7.9	4.6	3.3
Net Loss	(37.3)	(27.2)	(10.1)
USD m	September 30, 2020	June 30, 2020	Variance
Cash Balance	177.7	212.0	(34.3)

Autilus

Cash runway into 2022

### **Upcoming Milestones and Conclusions**

Dr. Christian Itin Chairman and CEO



### Multiple clinical milestones expected through Q4 2020 / 2021

T Cell Lymphoma

PRODUCT	INDICATION	TARGET	EVENT
AUTO1	Adult ALL	CD19	Ph1 long-term follow up at ASH
AUTO1/22	Pediatric ALL	CD19 & CD22	Start Ph1 Q4 2020
AUTO3	DLBCL	CD19 & CD22	Ph1 data update at ASH
AUTO4	TRBC1+ Peripheral TCL	TRBC1	Ph1 interim data 2021
AUTO6NG	Neuroblastoma; Melanoma; Osteosarcoma; SCLC	GD2	Start Ph1 2021
AUTO7	Prostate Cancer	PSMA	Start Ph1 2021
AUTO8	Multiple Myeloma	BCMA & CAR X	Start Ph1 study H1 2021
Allo Product	Undisclosed	Undisclosed	Start Ph1 Q1 2021

Solid Tumors

Autelus

**B Cell Malignancies** 

Allogeneic Approach

Multiple Myeloma

#### Autolus poised for value inflection

- AUTO1 and AUTO1/22
  - Currently enrolling Autolus' first Ph1b / 2 pivotal program in adult ALL
  - Granted orphan drug designation by the FDA for treatment of ALL
  - Pediatric ALL moving forward with AUTO1/22
  - ALLCAR study extension in iNHL and CLL ongoing
  - Opportunity to develop AUTO1 in Primary CNS Lymphoma, potential study start in Q4 2020
- AUTO3
  - Pivotal study could start H1 2021
- Key data updates next planned for ASH
  - AUTO3 ALEXANDER study update
  - AUTO1 Update from ALLCAR with adult ALL patients
- Multiple Next Generation development candidates entering clinical development in 2021

Q&A

Dr. Christian Itin and Andrew Oakley



