# Autelus



#### Financial Results and Operational Highlights for Q3 2019 November 7, 2019

### **Disclaimers**

These slides and the accompanying oral presentation contain forward-looking statements, including statements about the Company's plans to develop and commercialize its product candidates, the Company's ongoing and planned clinical trials, the anticipated benefits of the Company's product candidates, the timing and availability of data from clinical trials, the timing and ability to obtain and maintain regulatory approvals for the Company's product candidates and the size and growth potential of the markets for its product candidates. All statements other than statements of historical fact contained in this presentation, including statements regarding the Company's future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forwardlooking statements by terms such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These statements involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 20-F filed on November 23, 2018 as well as discussions of potential risks, uncertainties, and other important factors in Autolus' future filings with the Securities and Exchange Commission from time to time. All information in this presentation is as of the date hereof, and the company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Certain data in this presentation was obtained from various external sources. Such data speak only as of the date referenced in this presentation and neither the Company nor its affiliates, advisors or representatives make any representation as to the accuracy or completeness of that data or undertake to update such data after the date of this presentation. Such data involve risks and uncertainties and are subject to change based on various factors.

## Agenda for today

- 1. Welcome and Introduction: Dr. Christian Itin, Chairman and CEO
- 2. Operational Highlights: Dr. Christian Itin
- 3. Financial Results and Overview: Andrew J. Oakley, Chief Financial Officer
- 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



## **Upcoming ASH Meeting Presentations**

Data highlights progress of foundational AUTO1 program

- > Adult ALL (AUTO1) Saturday December 7, oral presentation
- > **Pediatric ALL (AUTO1)** Saturday December 7, oral presentation
- > Integration Site Analysis (AUTO1) Saturday December 7, oral presentation
- > **DLBCL (AUTO3)** Saturday December 7, oral presentation
- > Pediatric ALL (AUTO3) Sunday December 8, poster presentation
- > Multiple Myeloma (AUTO2) Sunday December 8, poster presentation

#### Adult Acute Lymphoblastic Leukemia Adult ALL is a significant commercial opportunity

- > Potential market size in adult ALL
  - Up to 8,400 new cases of adult ALL diagnosed yearly worldwide
  - Addressable patient population is projected at 3,000 patients US & EU5
- > High unmet medical need

Autolus

- 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
- > No CAR T therapy approved in adult ALL
- > Only approved redirected T cell therapy is blinatumomab
- > AUTO1 granted FDA orphan drug designation for ALL

Sources: Prevalence calculated using SEER and EUCAN and extrapolated using IMS; American Cancer Society

#### AUTO1 in Adult ALL: Durable remissions observed AUTO1 may be best-in-class for Adult ALL

> As of July 24, 2019:

Aut

- 10 of 12 (83%) evaluable patients achieved MRD negative CR at 1 month
- 7 of 12 (58%) evaluable patients remain on study in flow/molecular MRD negative remission with a median follow-up of 9 months
- > 6 patients had ≥ 50% BM blasts prior to lympho-depletion (CRS 'high risk')
- No high-grade CRS, 1 of 13 patients had Grade 3 neurotoxicity (dysphasia), resolved swiftly with steroids
- Oral presentation at ASH: Additional follow-up data, including additional safety and efficacy will be presented

Data as of July 24, 2019 Roddie, C. et al. A novel fast off CD19CAR delivers durable remissions and prolonged CAR T cell persistence with low CRS or neurotoxicity in adult ALL [abstract]. In: 61st American Society of Hematology (ASH) Annual Meeting and Exposition; 2019 December 7-10; Orlando, FL; Abstract nr 131086.

#### **Comparison of AUTO1 vs. Kymriah® and Blincyto®** AUTO1 may be best-in-class, redirected T cell therapy in ALL

|                       | Pediatric ALL                  |                           | Adult ALL               |                           |
|-----------------------|--------------------------------|---------------------------|-------------------------|---------------------------|
|                       | <sup>1</sup> Kymriah®-<br>pALL | <sup>2</sup> AUTO1 - pALL | <sup>3</sup> AUTO1 aALL | <sup>4</sup> Blinatumomab |
| Patient Numbers       | 75                             | 14                        | 13                      | 271                       |
| CR Rate               | 81%                            | 86%                       | 83%*                    | 42%                       |
| EFS                   | EFS 12m: 50%                   | EFS 12m: 52%              | TBD                     | EFS 6m: 31%               |
|                       | (95% CI, 35 to 64)             | (95% CI, 16 to 72)        |                         |                           |
| CRS ≥ Grade 3         | 47%                            | 0%                        | 0%                      | 3%                        |
| Neurotox ≥<br>Grade 3 | 13%                            | 7%                        | 8%                      | 13%                       |

\* In 10 of 12 evaluable patients at 1 month.

1. Maude et al., NEJM 2018

2. Ghorasian et al., ASH 2019 (abstract)

3. Roddie et al., ASH 2019 (abstract)

4. Kantarjian et al., 2017

## AUTO1 in aALL - Summary and next steps

First Autolus program to move to a registration trial

- > Potential to have best-in-class profile
- > Favorable safety profile and high level of clinical activity
  - Data suggest AUTO1 may be twice as active as current standard of care, blinatumomab, with comparable safety profile
- > Pivotal study:
  - Feedback from FDA and EMA
  - CTA to be filed in UK in Nov, US IND to be filed in Q1
  - Single arm study with approx. 100 patients
- > Primary endpoint is overall complete response rate (CR/CRi)
- > Secondary endpoints include:
  - MRD-negative CR and EFS
- > BLA filing targeted for H2 2021

#### **Pediatric ALL – Focus on AUTO1/AUTO1NG** AUTO3 data support dual antigen targeting hypothesis

- > Development in pediatric ALL will focus on AUTO1 and AUTO1NG
- > Pediatric program (PIP) with AUTO1
- > Dual-targeting AUTO1NG with CD19 CAR of AUTO1 and a novel CD22 CAR expected to enter first clinical trial in H1 2020



#### **Diffuse Large B Cell Lymphoma (DLBCL)** DLBCL is a large commercial opportunity

- > Potential market size in DLBCL
  - Approx. 24,000 patients diagnosed in the US every year\*
  - Addressable patient population projected at 10,000 patients for US & EU5 combined
- > Aggressive and rapidly advancing cancer
  - Most common type of Non-Hodgkin Lymphoma
  - High dose chemotherapy + MAB leads to remission in about 50-60% of patients
- > Two Approved CAR T products (Yescarta and Kymriah)



\*Source: American Cancer Society

### DLBCL – AUTO3

Program on track for a mid 2020 decision point

- > Interim Phase 1 data planned to be presented at ASH 2019 in December, including patients at the 450 mm dose level
- > First US patient consented and currently being manufactured at Cell and Gene Therapy Catapult at Stevenage in the UK
- > Decision for triggering Phase 2 initiation planned for mid 2020
- > AUTO3NG next generation product for life cycle management

### Multiple Myeloma

#### **Transitioning to next generation CAR in 2020**

- > AUTO2 is not differentiated from more advanced competitor programs
- > Phase 1 data will be presented at ASH
- > Next generation program to enter into the clinic in H2 2020
  - Addresses need for increased persistence and tumor defense mechanisms
  - Incorporates additional programming modules
  - Study to be conducted in collaboration with University College London
- > Phase 1 data expected in H2 2021



#### T Cell Lymphoma Positioned for value inflection in 2020

- > Patient enrolment in AUTO 4 Phase 1 study will resume in Q1 2020
- > Expect to present initial AUTO4 Phase 1 data H2 2020
- > AUTO5 Phase 1 decision based on AUTO4 data
- > Companion diagnostic development on track



#### Solid tumor programs—AUTO6NG (GD2+ solid tumors) Positioned for additional value inflection in 2020

- > Plan to commence Phase 1 H2 2020
- > Encouraging pre-clinical data on three T cell programming modules to be presented at SITC 2019
  - Constitutively signaling IL7 cytokine receptor (IL7R\_CCR module) is shown to enhance persistence
  - Dominant negative TGFbRII (dnTGFbRII module) is shown to block TGFβ signaling
  - Truncated SHP2 (dSHP2 module) is shown to confer resistance to inhibitory signals such as those from PD1
  - I.V. delivery exhibited potent anti-tumor activity and extended survival in-vivo



### **Corporate Update**

#### UK clinical manufacturing site full operational

- > Manufacturing update
  - Catapult fully operational for European and US patients
  - First US patient enrolled, manufacturing ongoing
- > Significant change in shareholder base
  - In September, PPF Group announced that they had acquired, mainly from Woodford Investment Management, an approximate 19% holding of Autolus
  - Control of all the remaining shares of Autolus held by Woodford Investment Management are in the process of being transferred to Schroder UK Public Private Trust plc
- > Changes in operational management reflect evolving organisational need
  - David Brochu appointed as head of Product Delivery as we transition from Phase 1 to registration stage
  - Vishal Mehta appointed as head of Clinical Operations as we transition from UK academic setting to managing global registrational studies

**Financial Results** 

Andrew J. Oakley Chief Financial Officer



## Third quarter 2019 financial summary

| USD m                             | 3Q19          | 3Q18          | Variance |
|-----------------------------------|---------------|---------------|----------|
| Grant Income                      | 0.3           | 0.3           | (0.0)    |
| R&D                               | (27.3)        | (10.1)        | (17.2)   |
| G&A                               | (8.6)         | (7.3)         | (1.3)    |
| Total Operating<br>Expenses, net. | (35.6)        | (17.1)        | (18.5)   |
| Other Income                      | 3.8           | 2.0           | 1.8      |
| Tax Benefit                       | 4.6           | 2.2           | 2.4      |
| Net Loss                          | (27.2)        | (12.9)        | (14.3)   |
| USD m                             | Sept. 30 2019 | Sept. 30 2018 | Variance |
| Cash Balance                      | 229.4         | 247.1         | (17.7)   |

Autelus

> Cash runway expected into second half of 2021

### **Upcoming Milestones and Conclusion**

Dr. Christian Itin CEO and Chairman



### **Newsflow expected through 2020**

| Product             | Indication  | Target      | Event   |
|---------------------|---|-------------|---|
| B Cell Malignancies |   |             |   |
| AUTO1               | Pediatric ALL                                     | CD19        | <ul> <li>Ph 1 data 4Q 2019</li> </ul>   |
| AUTO1               | Adult ALL   | CD19        | <ul> <li>Ph 1 (ALLCAR19) data 4Q 2019</li> <li>Start pivotal program H1 2020</li> </ul>     |
| AUTO1NG             | Pediatric ALL                                     | CD19 & 22   | • Start Ph 1 H1 2020  |
| AUTO3               | DLBCL   | CD19 & 22   | <ul> <li>Ph 1 interim data 4Q 2019</li> <li>Decision on Ph 2 transition mid 2020</li> </ul> |
| AUTO3NG             | DLBCL   | CD19 & 22   | • Start Ph 1 H2 2020  |
| Multiple Myeloma    |   |             |   |
| NG program          | Multiple Myeloma                                  | Undisclosed | Start Ph 1 study H2 2020  |
| T Cell Lymphoma     |   |             |   |
| AUTO4               | TRBC1+ Peripheral TCL                             | TRBC1       | Ph 1 interim data H2 2020   |
| GD2+ Tumors         |   |             |   |
| AUTO6NG             | Neuroblastoma;<br>Melanoma;<br>Osteosarcoma; SCLC | GD2         | <ul><li>Non-clinical data 4Q 2019</li><li>Start Ph 1 H2 2020</li></ul>                      |



## Key Q3 Messages

- > AUTO1:
  - First Autolus program to move into a pivotal program Adult ALL
  - FDA granted orphan drug designation for treatment of ALL
  - Opportunity for best in class CD19 CAR T
  - Pediatric ALL: moving forward with AUTO1/AUTO1NG
- > AUTO3:
  - Focus on DLBCL, Phase 2 decision point mid-2020
  - AUTO3NG opportunity as next generation product
- Opportunity for additional value steps in 2020 from multiple myeloma, T cell lymphoma and GD2+ tumor programs
- > Management changes strengthen operational capability
- > Company has a strong balance sheet with \$229M in cash
- > Key data releases this year at SITC and ASH

#### Q&A

### Dr Christian Itin (Chairman and CEO) Andrew Oakley (CFO)



# Thank you.