



## Autolus Therapeutics presents AUTO1 and AUTO3 data at the 2020 EHA25 Virtual Congress

June 12, 2020 at 2:30 AM EDT

### Pivotal AUTO1 study in adult ALL patients enrolling

- AUTO1 continued favorable safety profile and high level of clinical activity, pivotal Phase 1b/2 AUTO1-AL1 program in adult ALL initiated and enrolling patients
- AUTO3 profile potentially supports use in a broader outpatient setting

### Conference Call and Webcast to be held Friday, June 12, 2020 at 7:30 am EDT / 12:30 pm BST

LONDON, June 12, 2020 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced new data highlighting progress on its AUTO1 program, the company's CAR T cell therapy being investigated in the ongoing ALLCAR Phase 1 study of relapsed / refractory adult B-Acute Lymphocytic Leukemia (ALL), at the European Hematology Association EHA25 Virtual Congress beginning June 11.

#### AUTO1 in ALL

As of the data cut-off date of May 13, 2020, 19 patients had received AUTO1. AUTO1 was well tolerated, with no patients experiencing  $\geq$  Grade 3 CRS. Three patients (16%) with high leukemia burden ( $>50\%$  blasts) experienced Grade 3 neurotoxicity that resolved swiftly with the application of steroids. Of the 19 patients, 16 (84%) achieved MRD-negative CR. Two out of 16 patients received a transplant while in remission and CD19-negative relapse occurred in 3 (16%) patients. Durability of remissions is encouraging. Event Free Survival (EFS) and Overall Survival (OS) at 6 months are 62% and 72% respectively in all patients, and 76% and 92% respectively in the 13 patients treated with the closed (commercial) process. Median EFS and OS has not been reached, at a median follow up of 12.2 months (range up to 24.4 months).

"I am very encouraged by the tolerable safety profile and high level of sustained CRs we have observed with AUTO1 in the ALLCAR19 study that was achieved without subsequent stem cell transplant," said Dr. Claire Roddie, Consultant Hematologist, UCL Cancer Institute and University College London Hospital.

"Approximately 60% of adult ALL patients relapse or are refractory to first line therapy and there continues to exist a high unmet need," said Dr. Michael Bishop, MD, Professor of Medicine and Director of the Cellular Therapy Program at University of Chicago Medicine. "AUTO1 is a novel CD19 CAR T candidate with a compelling activity and safety profile and has the potential to change standard of care as a curative therapy for r/r ALL."

"The data update on AUTO1 presented at this year's EHA meeting show an encouraging durability of response without subsequent stem cell transplant and confirm the positive safety profile," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "We have started enrolment of patients with r/r aALL in our pivotal Phase 1b/2 AUTO1-AL1 study."

#### AUTO3 in DLBCL

Dr. Wendy Osborne presented ALEXANDER Phase 1/2 clinical trial data for AUTO3. This data is consistent with our update on May 29, 2020, with a data cut-off date of April 27, 2020.

"These data are very encouraging, in terms of safety and tolerability, with a high level of clinical activity," said Dr. Wendy Osborne, Consultant Hematologist, Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust. "We are looking forward to enrolling additional patients in the outpatient cohort."

Dr. Wendy Osborne of Newcastle upon Tyne Hospitals NHS Foundation Trust also discusses AUTO3 data during the American Society of Clinical Oncology (ASCO) Annual Meeting in [this video](#) – courtesy of the Lymphoma Hub.

#### Investor call on Friday June 12, 2020

Management will host a conference call and webcast at 7:30 am EDT/12:30 pm BST to discuss the EHA data. To listen to the webcast and view the accompanying slide presentation, please go to: <https://www.autolus.com/investor-relations/news-and-events/events>.

The call may also be accessed by dialing (866) 679-5407 for U.S. and Canada callers or (409) 217-8320 for international callers. Please reference conference ID 4838626. After the conference call, a replay will be available for one week. To access the replay, please dial (855) 859-2056 for U.S. and Canada callers or (404) 537-3406 for international callers. Please reference conference ID 4838626.

#### About Autolus Therapeutics plc

Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer. Using a broad suite of proprietary and modular T cell programming technologies, the company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize cancer cells, break down their defense mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of hematological malignancies and solid tumors. For more information please visit [www.autolus.com](http://www.autolus.com).

#### About AUTO1

AUTO1 is a CD19 CAR T cell investigational therapy designed to overcome the limitations in safety - while maintaining similar levels of efficacy - compared to current CD19 CAR T cell therapies. Designed to have a fast target binding off-rate to minimize excessive activation of the programmed T

cells, AUTO1 may reduce toxicity and be less prone to T cell exhaustion, which could enhance persistence and improve the ability of the programmed T cells to engage in serial killing of target cancer cells. AUTO1 is currently being evaluated in two Phase 1 studies, one in pediatric ALL and one in adult ALL. The company has also now progressed the program to a potential pivotal study, AUTO1-AL1.

#### **About AUTO1-AL1 pivotal study**

The AUTO1-AL1 study will enroll patients with relapsed / refractory ALL. The study will have a short Phase1b component prior to proceeding to a single arm Phase 2 study. The primary end point is overall response rate and the key secondary end points include duration of response MRD negative CR rate and safety. The study will enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the US, UK and Europe.

#### **About AUTO3**

AUTO3 is a programmed T cell therapy containing two independent chimeric antigen receptors targeting CD19 and CD22 that have each been independently optimized for single target activity. By simultaneously targeting two B cell antigens, AUTO3 is designed to minimize relapse due to single antigen loss in patients with B cell malignancies. AUTO3 is currently being tested in diffuse large B cell lymphoma in the ALEXANDER clinical trial, with a 20-patient cohort that was initiated in Q2 2020 to assess feasibility of treatment in an outpatient setting.

#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding Autolus' financial condition and results of operations, including its expected cash runway; the development of Autolus' product candidates, including statements regarding the timing of initiation, completion and the outcome of pre-clinical studies or clinical trials and related preparatory work, and the periods during which the results of the studies and trials will become available; Autolus' plans to research, develop, manufacture and commercialize its product candidates; the potential for Autolus' product candidates to be alternatives in the therapeutic areas investigated; and Autolus' manufacturing capabilities and strategy. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such 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 with the Securities and Exchange Commission on March 3, 2020 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 press release is as of the date of the release, 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.

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