



Autolus Therapeutics presents compelling AUTO1 data from ALLCAR Phase 1 study in Adult Acute Lymphoblastic Leukemia (ALL) during the 62nd ASH Annual Meeting

December 5, 2020

Updated data from the ALLCAR study suggests AUTO1's potential for transformational activity in adult patients with r/r ALL

Conference call and webcast to be held Monday, December 7, 2020 at 4:00 pm ET / 9:00 pm GMT

LONDON, Dec. 05, 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 in relapsed / refractory adult B-Acute Lymphocytic Leukemia (ALL), during the American Society of Hematology (ASH) All-Virtual Annual Meeting, held between December 5-8, 2020.

As of the November 12, 2020 data cut-off date, 20 patients with r/r ALL had received AUTO1. AUTO1 was well tolerated, with no patients experiencing \geq Grade 3 cytokine release syndrome (CRS). Three patients (15%), all of whom had high leukemia burden ($>50\%$ blasts), experienced Grade 3 neurotoxicity (NT) that resolved swiftly with steroids.

Of the 19 patients evaluable for efficacy, 16 (84%) patients achieved minimum residual disease (MRD)-negative complete response (CR) at one month. Most notably, the durability of remissions is highly encouraging. Across all treated patients, event free survival (EFS) at six and 12 months is 69% and 52% respectively. Median EFS and overall survival (OS) has not been reached at a median follow up of 16.9 months (range up to 30.5 months).

"The high level of sustained CRs observed with AUTO1 in adult ALL, achieved without subsequent stem cell transplant, point to a potentially transformational treatment for adult ALL," said Dr. Claire Roddie, Consultant Hematologist, UCL Cancer Institute and University College London Hospital. "Despite high disease burden and despite this being a heavily pre-treated patient population on study, AUTO1 remains well tolerated. It's encouraging to also observe promising early activity and safety in indolent NHL."

"Adult ALL is a disease with high unmet need, whereby approximately 60% of patients relapse or are refractory to first line therapy," said Dr. Elias Jabbour, Professor of Leukemia at The University of Texas MD Anderson Cancer Center. "AUTO1 is a novel CD19 CAR T candidate with an impressive clinical profile. This profile has the potential to change standard of care as a curative therapy for r/r ALL."

Dr. Christian Itin, chairman and chief executive officer of Autolus, added "We are excited about the long-term remissions observed without a need for an additional stem cell transplant. Remarkably, this outstanding result was achieved with a well-tolerated safety profile in this fragile adult ALL population. We believe the unique characteristics of AUTO1, seen in the ALLCAR study, point to the potential for AUTO1 as a standalone and transformational therapy in r/r ALL. Our Phase 1b/2 pivotal study is under way, however, with the escalating COVID-19 pandemic, enrolment projections have had to be adjusted. We now expect to enroll patients throughout 2021 with a full data set in 2022."

In addition to adult ALL, the ALLCAR study was extended to patients with indolent B cell Non-Hodgkin Lymphoma (NHL) (Cohort 1), high grade B-NHL (Cohort 2) and chronic lymphocytic leukemia (CLL) (Cohort 3). As of the data cut-off date of November 12, 2020, four patients in Cohort 1 had been infused with AUTO1. AUTO1 was well tolerated, with no patients experiencing \geq Grade 2 CRS and no patients experiencing NT of any grade. All four patients achieved a Complete Metabolic Response (CMR).

Investor call on Monday December 7, 2020

Management will host a conference call and webcast on Monday, December 7, 2020 at 4:00 pm ET/9:00 pm GMT to discuss the ASH 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 9188389. 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 9188389.

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.

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.

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 the efficacy, safety and therapeutic potential of AUTO3 and the future clinical development of AUTO3 including progress, expectations as to the reporting of data, conduct and timing. 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. These risks and uncertainties include, but are not limited to, the risks that Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early clinical trials are not always being predictive of future results; the cost, timing and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; possible safety and efficacy concerns; and the impact of the ongoing COVID-19 pandemic on Autolus' business. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus' 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 amended, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and Exchange Commission. 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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