Autolus Therapeutics presents additional data on AUTO3 in DLBCL during the 62nd ASH Annual Meeting

December 7, 2020

AUTO3 continues to show a differentiated product profile supporting outpatient administration

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

LONDON, Dec. 07, 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 AUTO3, the company's CD19 and CD22 dual targeting CAR T product candidate being investigated in the ALEXANDER study, a Phase 1/2 clinical study in relapsed/refractory diffuse large B cell lymphoma (DLBCL), during the American Society of Hematology (ASH) All-Virtual Annual Meeting, held between December 5-8, 2020.

As of the October 30, 2020 data cut-off date, 49 patients in the ALEXANDER study have been treated and were evaluable for safety. AUTO3 was observed to be well tolerated, with low rates of cytokine release syndrome (CRS) and neurotoxicity (NT). Across all 49 patients, there was only one case of Grade 3 CRS with primary infusion, and only three cases of NT were reported, with two being ≥ Grade 3. None of the patients achieving a complete response (CR) experienced any NT and all cases of NT were seen in a setting of disease progression and with confounding factors. No prophylactic measures of any kind have been used to manage patients in this study.

The majority of patients receiving AUTO3 in the outpatient setting did not require hospital admission. Those patients admitted were easily managed, with no patients requiring ICU care. Combined with the overall favorable safety data across the Phase 1 study, the profile of AUTO3 supports administration in an outpatient setting.

Across all dose levels, 43 patients were evaluable for efficacy, with an objective response rate (ORR) of 65% and a CR rate of 51%. Of the 29 evaluable patients receiving the recommended Phase 2 dose (a dose of ≥ 150 x 10^6 cells) and pre-conditioning with pembrolizumab at Day -1, the ORR was 66% and the CR rate was 55%. A subsequent analysis of these data suggested a superior response rate at higher dose levels, with 15 evaluable patients treated at 450 x 10^6 cells achieving an ORR of 87% and a CRR of 73%.

Across all cohorts in the study, 73% (16/22) of patients achieving a CR were without disease progression at a median follow up of 4 months (1 – 24 months). Of note, none of the five patients who achieved a CR in the cohort receiving three doses of pembrolizumab had disease progression.

"AUTO3 continues to have a tolerable and favorable safety profile when compared with approved CD19 CAR T therapies," said Dr. Aravind Ramakrishnan, Medical Director, Adult Blood and Marrow Transplant, Texas Transplant Institute at the Sarah Cannon Blood Cancer Center at St. David's South Austin Medical Center. "The complete response rate is high and the longest patient on the study is now over 2 years post treatment and remains in remission."

Dr. Christian Itin, chairman and chief executive officer of Autolus, added, "AUTO3 continues to show a high level of clinical activity across all dose levels and conditions evaluated in this expanded Phase 1 study. The favorable tolerability profile was confirmed in the outpatient cohort which supports the use of AUTO3 in an outpatient setting. This differentiated profile may widen the potential use of CAR T therapy in DLBCL. Based on these data, we are assessing a strategy that potentially optimizes the development path in r/r DLBCL and expect to update on next steps for AUTO3 in Q1 2021."

Investor call on Monday December 7, 2020
Management will host a conference call and webcast today 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 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 study, including a 20-patient cohort 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 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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