Autolus Therapeutics Announces New Data Showcasing Clinical Progress of AUTO3 in B Cell Malignancies

December 8, 2019 at 9:15 AM EST

Preliminary data on AUTO3 in DLBCL demonstrate safety and feasibilty of CD19 and CD22 dual targeting CAR T

90% complete response and 100% overall survival at 12 months in CAR T naive pediatric ALL patients dosed with AUTO3

Investor call to be held December 9 at 8:30 am ET / 1:30 pm GMT to review data

LONDON, Dec. 08, 2019 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL) announced today new data highlighting progress on AUTO3, the first-in-human bicistronic CD19 and CD22 CAR, in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) and pediatric acute lymphoblastic leukemia (ALL). The data were presented at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, FL.

"DLBCL is an aggressive and rapidly progressing cancer, and early response is critical to ensuring positive outcomes for these patients. The data from the AMELIA trial of AUTO3 in pediatric ALL has informed us on the encouraging role of dual antigen targeting in reducing target-negative relapses and delivering high levels of complete molecular remission with well-tolerated safety," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "We look forward to advancing AUTO3 to a decision point in relapsed/refractory DLBCL by the mid-point of next year."

Title: Phase 1/2 study of AUTO3, the first bicistronic chimeric antigen receptor (CAR) targeting CD19 and CD22 followed by an anti-PD1 in patients with relapsed/refractory (r/r) Diffuse Large B Cell Lymphoma (DLBCL): Results of cohort 1 and 2 of the ALEXANDER study (Abstract # 246)

Dr. Kirit Ardeshna, consultant hematologist, Department of Hematology, University College London Hospital NHS Foundation Trust, gave an oral presentation with updated data from the ALEXANDER Phase I/2 study of AUTO3, the first bicistronic CAR T targeting CD19 and CD22 followed by an anti-PD1, in Diffuse Large B Cell Lymphoma (DLBCL). The trial is divided into a phase 1 safety cohort and a phase 2 efficacy cohort, and is designed to assess safety (incidence of ≥ Grade 3 toxicity occurring within 75 days of AUTO3 infusion) and other primary and secondary endpoints including overall response and other safety, efficacy and product generation measures.

In the dose escalation phase, 16 patients were treated, with 4 patients dosed at 50 x 10^6 cells without pembrolizumab; 11 patients were dosed at escalating doses of AUTO3 with pembrolizumab administered at day 14 as follows: 3 at 50 x 10^6 cells, 4 at 150 x 10^6 cells, and 4 at 450 x 10^6 of AUTO3; and 1 patient was dosed with 450 x 10^6 cells with pembrolizumab administered 1 day before AUTO3 infusion. Fourteen patients were evaluable at one month.

AUTO3 was well-tolerated, with no patients experiencing ≥ Grade 3 cytokine release syndrome (CRS) with primary infusion and 1 of 14 experiencing Grade 3 neurotoxicity that resolved swiftly with steroids. There were no pembrolizumab immune-related toxicities and the majority of grade 3 or higher adverse events were hematological. Low levels of serum cytokines are consistent with the observed low levels of CRS and neurotoxicity.

Across all tested doses 5 patients achieved a complete response, with 4 of 5 complete responses ongoing, the longest at 18 months. All CRs were achieved without need for steroid or tocilizumab-based management of the patients or ICU level care.

"The phase 1 preliminary data on AUTO3, the novel and first in human bicistronic CD19 and CD22 CAR in relapsed/refractory DLBCL, show that the dual targeting approach appears safe, with 0% severe CRS (≥ grade 3). The duration of complete response is impressive as well and provides hope that AUTO3 may reduce the high rates of relapse seen with CD19 CAR Ts," said Dr. Anas Younes, Chief, Lymphoma Service at Memorial Sloan Kettering Cancer Center.

AUTO3 – (Poster) - Phase 1/2 AMELIA clinical trial of AUTO3 in patients with relapsed/refractory pediatric acute lymphoblastic leukemia (pALL) (Abstract # 2620)

Professor Persis Amrolia, lead investigator and Consultant in Bone Marrow Transplant at Great Ormond Street Hospital (GOSH) and NIHR Research Professor of Transplantation Immunology at UCL Great Ormond Street Institute of Child Health (ICH), presented data from the AMELIA trial, a Phase 1/2, open-label, multi-center study to characterize the safety and clinical activity of AUTO3 in pediatric and young adult patients with relapsed/refractory ALL. The study recruited a total of 18 patients to the active dose (≥ 3 x 10^6 /kg) cohorts, and product was manufactured successfully for 14 of the 15 patients (93%) who underwent leukapheresis. Eleven patients were treated with AUTO3, manufactured using a semi-automated closed manufacturing process. Ten of 11 patients were CAR T cell-naive, while 1 had previously received CAR T cell therapy.

AUTO3 was well-tolerated overall, with no patients experiencing ≥ Grade 3 CRS and no patients experiencing ≥ Grade 2 neurotoxicity, in doses ≥3x10^6 /kg CAR-T cells. No AUTO3-related deaths were reported.

Among the 10 CAR T-naïve patients, at a median follow-up time of 9.7 months (range 1.8- 18), 9 of 10 patients (90%) achieved a complete response, and 8 of 10 (80%) achieved complete molecular remission by PCR. Estimated overall survival at 12 months was 100%. There are 2 ongoing patients in complete molecular remission at 12 and 15 months post-AUTO3 infusion, respectively. The most common cause of relapse was due to loss of CAR T-cell persistence. The median persistence of CAR-T cells in blood was 170 days.

Investor call to discuss data on Monday, December 9

Autolus management will host an investor conference call on Monday, December 9, at 8:30 a.m. EST/ 1:30pm GMT, to review the data presented at ASH.

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 9796038. 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 9796038.

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 pediatric ALL in the AMELIA clinical trial and in diffuse large B cell lymphoma in the ALEXANDER clinical trial.

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.

Forward-Looking Statement

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, as well as statements regarding the anticipated development of Autolus' product candidates, including its intentions regarding the timing for providing further updates on the development of its product candidates, and the sufficiency of its cash resources. 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 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 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.

Investor and media contact:
Silvia Taylor
Vice President, Corporate Affairs and Communications
Autolus
+1-240-801-3850
s.taylor@autolus.com

UK:
Julia Wilson
+44 (0) 7818 430877
j.wilson@autolus.com

Source: Autolus Therapeutics plc