Initial Results from Autolus Therapeutics' ALLCAR19 Phase 1/2 Trial in Adult Acute Lymphoblastic Leukemia Presented at the AACR Annual Meeting

April 1, 2019

Initial results from the trial show 88% molecular complete response at one month with well-tolerated safety profile

Management to Hold Conference Call on April 2, 2019 at 8:00am ET / 1:00pm BST

LONDON, April 01, 2019 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer, announced that Claire Roddie MB, PhD, FRCPath, honorary senior lecturer, Cancer Institute, University College London (UCL), presented today initial data from the ongoing Phase 1/2 ALLCAR19 trial of AUTO1 in adult acute lymphoblastic B cell leukemia (ALL) as a late-breaking poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2019 in Atlanta, Georgia.

Relapsed / refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) in adults is an area of significant unmet clinical need. Notably, no CD19 CAR T cell therapeutic has been approved to date for adults with r/r B-ALL. The key challenges identified in clinical studies testing standard CD19 CAR T-cells therapies in this setting are considerable toxicity associated with severe cytokine release syndrome (CRS) and high-grade neurological toxicity.

AUTO1 uses a novel CD19 binder that allows the CAR T cells to disengage rapidly after target cell encounter and kill. Preliminary data from the ongoing Phase 1/2 CARPALL trial of AUTO1 in pediatric ALL presented at the 1st European CAR T Meeting organized by European Hematology Association (EHA) in February 2019 indicated that AUTO1 has a well-tolerated safety profile and did not induce high grade CRS in pediatric patients.

As of the data cutoff date of March 18, 2019 in the ongoing Phase 1/2 ALLCAR19 trial of AUTO1 in adult ALL patients, 13 patients were leukapheresed, and products for 12 patients were manufactured, including 7 with Autolus' semi-automated, fully enclosed manufacturing process. Two patients are pending infusion. Among the 10 infused patients to date, the median age is 41 and 70% were male, with median lines of treatment of 4 (the range is 2-7). Five of the ten treated patients had ≥ 50% BM blasts and were considered to be high-risk for severe CRS. Patients received a split dose based on disease burden for a total dose of up to 410 million cells.

Safety results

Using the Lee criteria, there were no patients with severe CRS (≥ Grade 3), and 2 of 10 patients (20%) with Grade 2 CRS. Tocilizumab was used in 2 of 10 patients (20%). None of the patients were admitted to intensive care due to CRS. One patient developed delayed Grade 3 neurotoxicity following high levels of CAR T expansion, which was quickly reversed with steroids. Four patients died while enrolled in the trial, two due to progression of leukemia and two due to sepsis, a common complication of advanced ALL.

Efficacy results

Nine patients were evaluable for response at 1 month and 8 (88%) had a molecular complete response. One patient died of sepsis before the one-month evaluation point. At a median follow up of 5 months (range 0.62-10.6 months), 6/10 patients are alive and continue to be in molecular remission. There continues to be evidence of ongoing B cell aplasia and CAR T persistence.

"AUTO1 delivered promising early remission rates, CAR T cell expansion and persistence in this adult ALL trial cohort," said Dr. Roddie. "Despite enrolling patients with high tumor burden, we believe the safety profile in the trial appears to compare very favorably to other CD19 CARs and is consistent with the safety profile of AUTO1 observed in pediatric patients in the CARPALL trial."

"These data from the ALLCAR19 study of AUTO1 in relapsed refractory ALL, while early, are encouraging, with a high response rate we now associate with CAR T cell therapies, but with a potentially improved safety profile. If AUTO1 continues to be associated with a lower incidence of adverse events with additional patients treated, this could represent an important advance for more vulnerable adult patients, as side effects of these therapies, including serious cytokine release syndrome and neurotoxicity, limit our ability to treat these individuals." said Krishna Komanduri, M.D., Kalish Family Chair in Stem Cell Transplantation and Director, Adult Stem Cell Transplant Program at the Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine.

"The strong persistence of the CAR T cells over time, coupled with the low frequency of severe CRS events seen in these patients, represent encouraging initial data for AUTO1 in relapsed/refractory adult ALL," said Dr. Christian Itin, chairman and chief executive officer of Autolus Therapeutics. "We expect AUTO1 in adult ALL to move into a registration trial towards the end of this year."

For information about the ALLCAR19 trial, visit
https://clinicaltrials.gov/ct2/show/NCT02935257?term=ALLCAR19&rank=1

Conference Call Information
Autolus management will host a conference call featuring Dr. Roddie on Tuesday, April 2, 2019 at 8:00 am ET/ 1:00 pm BST to discuss the ALLCAR19 data presented at AACR. To listen to the webcast and view the accompanying slide presentation, please go to https://www.autolus.com/investor-relations/news-events/events.

The call may also be accessed by dialing 866-679-5407 (U.S.) or 409-217-8320 (international) and referencing conference ID 7679666. After the conference call, a replay will be available for one week. To access the replay, please dial 855-859-2056 (U.S.) or 404-537-3406 (international) and enter conference ID 7679666.

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, Autolus believes AUTO1 may reduce toxicity and be less prone to T cell exhaustion, which could enhance persistence and improve the T cells' abilities to engage in serial killing of target cancer cells. In 2018, Autolus signed a license agreement under which Autolus acquired global rights from UCL Business plc (UCLB), the technology-transfer company of UCL, to develop and commercialize AUTO1 for the treatment of B cell malignancies. AUTO1 is currently being evaluated in two Phase 1/2 trials, one in pediatric ALL and one in adult ALL.

About Adult Acute Lymphoblastic Leukemia
According to the American Cancer Society, acute lymphoblastic leukemia (ALL) is predicted to affect approximately 5,960 adults in the United States in 2018. Combination chemotherapy enables 90% of adult patients to experience CR (complete response). Despite this, the prognosis of adult ALL is still poor and has not changed significantly during the last two to three decades, with long-term remission rates limited to 30–40%. Approximately 50% of all adult ALL patients will relapse.

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.

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 company's product candidates and research programs including the company's ongoing and planned clinical developments of AUTO1 including its timeline to move into a registration trial. 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 the company's Annual Report on Form 20-F filed on November 23, 2018 as well as discussions of potential risks, uncertainties, and other important factors in the company's 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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