Autolus Therapeutics Presents New Data on obe-cel in r/r Indolent B Cell Lymphomas and gives an update of obe-cel in r/r Adult ALL at the European Hematology Association Virtual Congress

June 11, 2021

Obe-cel achieves 100% complete remission rate in a cohort of indolent B Cell Non-Hodgkin lymphoma patients with excellent CAR T engraftment, expansion, and persistence

No ICANS or high grade Cytokine Release Syndrome observed

Durability of response in ALL patients continues to support potential for transformational therapy in adult ALL

Conference Call to be held on Friday, June 11, 2021 at 8:30 am ET / 1:30 pm BST

LONDON, June 11, 2021 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced a poster presentation related to AUTO1 (obecabtagene autoleucel, obe-cel) in relapsed / refractory (r/r) indolent B cell lymphomas (IBCL) and included an update of duration of response in r/r adult Acute Lymphoblastic Leukemia (ALL) patients at the European Hematology Association (EHA) Virtual Congress 2021.

"The stabilization of event-free survival at 50% between 12 months and 24 months of follow-up supports the curative potential of obe-cel as a standalone therapy for some adult ALL patients," said Dr. Christian Itin, chief executive officer of Autolus. "The early data we presented in indolent B cell non-Hodgkin lymphoma indicate a high level of clinical activity combined with a manageable safety profile and could represent a significant opportunity to expand the benefits of obe-cel treatment to a broader population of patients with B cell malignancies."

Title: Early safety and efficacy findings of AUTO1 (CAT19), a fast-off rate CD19 CAR, in Relapsed/Refractory Indolent B Cell Lymphomas

Presenter: Clare Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

Session Date and Time: Friday, June 11, 2021 at 9.00 a.m. CEST

Relapsed / refractory (r/r) indolent B cell lymphomas
As of the data cut-off date of May 17, 2021, 13 patients in Cohort D with r/r IBCL had been enrolled in the study and product was successfully manufactured for 12 patients, with one patient's cells ongoing in manufacture. As of the data cut-off date, 9 r/r IBCL patients had received AUTO1 infusion. Three patients were pending infusion (including the patient noted above) and one patient died prior to lymphodepletion due to a Covid-19 infection. Obe-cel was well tolerated and demonstrated a favorable safety profile in adult patients with r/r low grade B-cell lymphoma, despite high disease burden. All treated patients achieved a complete metabolic remission and had robust CAR T engraftment, expansion, and persistence.

Grade 1 cytokine release syndrome (CRS) was reported in 4 patients and Grade 2 CRS in 1 patient. No immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade was observed in the study. At a median follow-up of 6 months (range 4.0-8.1m), eight of nine patients were disease free at last follow-up with one patient who relapsed at month 6 but was rescued with radiotherapy. One patient died of a COVID-19 infection at month 5.6 whilst in complete metabolic remission.

Relapse / refractory adult Acute Lymphoblastic Leukemia
As of the data cut-off date of May 17, 2021, 20 patients in Cohort A with r/r ALL had received obe-cel. The therapy was well tolerated, with no patients experiencing Grade 3 or higher CRS. Three patients (15%), all of whom had high leukemia burden (>50% blasts), experienced Grade 3 ICANS that resolved swiftly with steroids.

Of the 20 patients evaluable for efficacy, 17 (85%) of patients achieved minimum residual disease (MRD)-negative complete remission (CR) at one month. Most notably, the durability of remissions is highly encouraging. Across all treated patients, event free survival (EFS) at twelve months and twenty-four months is 50.2% with median EFS not being reached.

Conference Call
Management will host a conference call and webcast today at 8:30 am ET/1:30 pm BST to discuss the data presented at EHA. To listen to the webcast and view the accompanying slide presentation, please go to the events section of Autolus' website.

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 3697562. 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 3697562.

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 (obecabtagene autoleucel)
AUTO1 is a CD19 CAR T cell investigational therapy designed to overcome the limitations in clinical activity and safety 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. In collaboration with our academic partner, UCL, AUTO1 is currently being evaluated in a Phase 1 clinical trial in adult ALL and B-NHL. The company has also progressed AUTO1 to the FELIX study, a potential pivotal study.

About AUTO1 FELIX study
The FELIX Phase 1b/2 clinical trial is enrolling adult patients with relapsed / refractory ALL. The trial has a short Phase 1b component prior to proceeding to a single arm Phase 2 clinical trial. The primary endpoint is overall response rate, and the key secondary endpoints include duration of response, MRD negative CR rate and safety. The trial will enroll approximately 100 patients across approximately 30 of the leading academic and non-academic centers in the United States, United Kingdom 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 Autolus' development of the AUTO1 program; the future clinical development, efficacy, safety and therapeutic potential of its product candidates, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical activity and milestones; and expectations regarding the initiation, design and reporting of data from clinical trials. 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 4, 2021, 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 Autolus 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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