Autolus Therapeutics to Present Clinical Data Updates at the American Society of Hematology (ASH) Annual Meeting 2023 in Two Oral Presentations and Two Poster Presentations

November 2, 2023 at 9:01 AM EDT

- *obe-cel: oral presentation – pooled analysis of the ongoing FELIX Phase Ib/II study*
- *AUTO8: oral presentation of MCARTY Phase I Study*
- *obe-cel: poster presentation - pooled analysis from ALLCAR19 and FELIX Phase Ib studies and ALLCAR19 extension*
- *obe-cel: poster presentation - CMC demonstrating the robustness of obe-cel manufacturing*

LONDON, Nov. 02, 2023 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces the online publication of four abstracts submitted to the American Society of Hematology (ASH) Annual Meeting, to be held December 9 to 12, 2023.

"We look forward to presenting data from a number of our clinical trials at ASH this year, with obe-cel continuing to show a potentially best-in-class profile across several indications," **said Dr. Christian Itin, Chief Executive Officer of Autolus.** "Importantly, ahead of our expected BLA filing later this year, we will be presenting safety, efficacy and longer follow up data of obe-cel in relapsed/refractory B-ALL from the FELIX phase Ib and the pivotal phase II study, a pooled analysis from the ALLCAR19 and FELIX Phase Ib studies and the ALLCAR19 extension study, as well as data demonstrating the robustness of obe-cel's manufacturing process. Additionally, we will be presenting the first AUTO8 clinical data from the MCARTY Phase I study in multiple myeloma."

Oral Presentations:

1. **Title: Obecabtagene Autoleucel (obe-cel, AUTO1) for Relapsed/Refractory Adult B-cell Acute Lymphoblastic Leukemia (R/R B-ALL): Pooled Analysis of the Ongoing FELIX Phase Ib/II Study**
   Session Title: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Expanding Disease Targets for CAR-T Cell Therapies
   Session date and time: Saturday, December 9, 2023, 3:15 PM PT
   Session room: San Diego Convention Center, Room 6B
   Publication Number: 222
   Presenting Author: Dr. Claire Roddie, MD, PhD, FRCPath, Associate Professor Haematology and Honorary Consultant Haematologist, Cancer Institute, University College London (UCL)

   Summary:
   Obe-cel is an autologous chimeric antigen receptor (CAR) T cell product with a novel CD19 binding domain conferring a fast antigen off-rate designed for an improved benefit risk ratio.
   In this session, pooled analysis of data from all patients treated to date in the FELIX study will be presented, with an extended follow up. Data continued to demonstrate high rates of CR/CRi and a favorable safety profile. Additionally, subgroup analysis data suggests better outcomes in patients with low leukemia burden at screening/lymphodepletion, with higher rates of deep MRD negative complete remission and no Gr ≥3 CRS and one Gr ≥3 ICANS.

2. **Title: Development of a Phase I Study Evaluating the Activity of Modular CAR T for Multiple Myeloma (MCARTY) Targeting BCMA and CD19 for Improved Persistence**
   Session Title: 703. Cellular Immunotherapies: Basic and Translational: Cellular Immunotherapy: Preclinical and Translational Insights
   Date and time: Saturday, December 9, 2023, 4:15 PM PT
   Session room: San Diego Convention Center, Room 6A
   Publication Number: 350
   Presenting Author: Dr. Lydia Lee, Consultant Haematologist & Senior Clinical Research Fellow, University College London, Research Department of Haematology (UCLH)

   Summary:
   AUTO8 is a dual targeting autologous CAR T therapy targeting BCMA and CD19 using two independently expressed CARs for multiple myeloma. In the MCARTY study, we demonstrate dual CD19/BCMA targeting, alongside feasibility of clinical grade manufacture by double-transduction. Clinical responses were seen in 6 of 6 evaluable patients.

Poster Presentations:

1. **Title: Long-Term Efficacy and Safety of Obecabtagene Autoleucel (obe-cel) in Adult Patients (pts) with Relapsed/Refractory B-cell Acute Lymphoblastic Leukemia ([R/R B-ALL]; Pooled Analysis from ALLCAR19 and FELIX Phase Ib Studies) or Other B-cell Malignancies (ALLCAR19 Extension Study)**
   Session Title: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
   Session date and time: Saturday, December 9, 2023, 5:30 PM - 7:30 PM PT
   Session room: San Diego Convention Center, Halls G-H
   Publication Number: 2114
   Presenting Author: Dr. Claire Roddie, MD, PhD, FRCPath, Associate Professor Haematology and Honorary Consultant Haematologist, Cancer Institute, University College London (UCL)

   Summary:
   The clinical activity of obe-cel has been explored in adults with R/R B-ALL in a Phase I study (ALLCAR19), and a Phase Ib/II study (FELIX). Additionally, obe-cel has been tested in patients with R/R B-cell chronic lymphocytic leukemia (B-CLL) and R/R B-cell non-Hodgkin lymphoma (B-NHL).
   Data from the pooled analysis of r/r ALL patients treated with obe-cel in the ALLCAR19 and FELIX Ib studies demonstrate that after a median follow up of >3 years approximately 30% of patients remain in remission without subsequent transplant. In the CLL and NHL cohorts of the ALLCAR19 study and with >2 years follow up, the studies show durable responses and a low incidence of serious infections. In summary, obe-cel shows durable remissions in a range of B-cell malignancies with an excellent and consistent safety profile.

2. **Title: Delivery of Obecabtagene Autoleucel (obe-cel, AUTO1) for the FELIX Pivotal Study Demonstrating Robust Cell Processing, Robust Release Testing, and Reliable Logistics, Together with Readiness for Sustainable Patient (pt) Care**
   Session Title: 711. Cell Collection and Processing: Poster III
   Session date and time: Monday, December 11, 2023, 6:00 PM - 8:00 PM PT
   Session room: San Diego Convention Center, Halls G-H
   Publication Number: 4892
   Presenting Author: Michael Merges VP, Process Development, Autolus

   Summary:
   The FELIX study successfully demonstrated the robust operability of obe-cel manufacturing, QC and logistics processes, meeting target V2C (time from leukapheresis to quality release) and V2D (time from leukapheresis to delivery of product to the hospital). All apheresis starting material was successfully processed despite the multitude of constraints posed by the COVID-19 pandemic. Further optimization and improvements made during the study increased reliability, consistency and precision of the manufacturing process, and supported the development of a new obe-cel manufacturing facility with greater production capacity that aims to achieve a ≥95% manufacturing success rate with ≤15-day V2C times.

Abstracts can be viewed via the ASH abstract portal

About Autolus Therapeutics plc
Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer and autoimmune disease. 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 target 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, solid tumors and autoimmune diseases. For more information, please visit www.autolus.com.

About obe-cel (AUTO1)
Obe-cel 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. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. Clinical trials of obe-cel have demonstrated that this “fast off-rate” profile reduces toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, are being prepared for regulatory submissions with the FDA and EMA. In collaboration with Autolus’ academic partner, UCL, obe-cel is currently being evaluated in a Phase I clinical trials for B-NHL.

About obe-cel FELIX clinical trial
Autolus’ Phase Ib/2 clinical trial of obe-cel enrolled adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase Ib component prior to proceeding to the single arm, Phase 2 clinical trial. The primary endpoint is overall response rate, and the secondary endpoints include duration of response, MRD negative CR rate and safety. The trial enrolled over 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

About AUTO8
AUTO8 is our next-generation product candidate for multiple myeloma which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other BCMA CARs currently in development.

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 development of Autolus' product candidates, the status of clinical trials (including, without limitation, expectations regarding the data that is being presented, the expected timing of data releases and development, as well as completion of clinical trials) and development timelines for the Company's product candidates. 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 COVID-19 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 7, 2023, 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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