Autolus Therapeutics to Present Three Clinical Data Updates at the American Society of Hematology (ASH) Annual Meeting 2022

November 3, 2022 at 9:31 AM EDT

- *obe-cel: poster presentation in B-ALL and B-NHL patients*
- *AUTO1/22: poster presentation in pediatric ALL patients*
- *AUTO4: poster presentation in T-Cell Lymphoma patients*

LONDON, Nov. 03, 2022 (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 three abstracts submitted to the American Society of Hematology (ASH) Annual Meeting, to be held December 10-13, 2022.

"We're looking forward to presenting follow up data from three of our clinical trials at ASH this year. Obe-cel continues to show a potentially best-in-class profile across a number of indications, and we will be presenting the encouraging safety, efficacy and long-term follow up of obe-cel in relapsed/refractory B-ALL as well as in the B-NHL cohorts from the ALLCAR19 study," **said Dr. Christian Itin, Chief Executive Officer of Autolus**. "For both AUTO1/22 in pediatric ALL patients and for AUTO4 in peripheral T Cell Lymphoma we will present longer follow up data."

Abstracts to be presented:

1. **Title: Safety, Efficiency and Long-Term Follow-up of AUTO1, a Fast-Off Rate CD19 CAR in Relapsed/Refractory B-Cell Acute Lymphoblastic Leukaemia and Other B-Cell Malignancies**
   LINK to abstract
   Session Title: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster II
   Session date and time: Sunday, December 11, 2022, 6:00 PM – 8:00 PM
   Session room: Ernest N. Morial Convention Center, Hall D
   Publication Number: 3318
   Presenting Author: Dr. Claire Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

   Summary: obe-cel (AUTO1) has demonstrated an excellent safety profile across 3 reported trials, with low levels of CRS/ICANS. Overall, obe-cel has a tolerable safety profile in patients with r/r B-cell cancers despite high disease burden. In the B-ALL cohort of the ALLCAR19 study, long-term follow-up indicates that a subset of patients continue in remission post- obe-cel without need for further anti-leukemia therapy. In both indolent and aggressive NHL and in CLL, obe-cel shows excellent ORR and CAR engraftment/persistence. Additional patients, updated data and longer follow up will be presented.

2. **Title: Dual Antigen Targeting with Co-Transduced CD19/22 CAR T Cells May Prevent Antigen-Negative Relapse after CAR T Cell Therapy for Relapsed/Refractory ALL (AUTO1/22)**
   LINK to abstract
   Session Title: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster III
   Session date and time: Monday, December 12, 2022, 6:00 PM – 8:00 PM
   Session room: Ernest N. Morial Convention Center, Hall D
   Publication Number: 4650
   Presenting Author: Dr. Sara Ghorashian, MD, PhD, Hon clinical senior lecturer, UCL Great Ormond Street Institute of Child Health

   Summary: CD19 negative escape is a major cause of relapse after CD19 CAR T cell therapy for relapsed/refractory (r/r) pediatric ALL. To overcome this challenge, AUTO1/22 builds on the favorable safety profile and excellent persistence of obe-cel by combining it with an additional CD22 targeting CAR. As of 21 July 2022, 12 pediatric ALL patients have been treated with AUTO1/22. Overall, at a median follow-up of 8.7 months (range 1-15 months), 6/10 responding patients remain in MRD negative CR at last follow-up. Importantly, antigen-negative relapse has not been observed.

3. **Title: First in Human Study of AUTO4, a TRBC1-Targeting CAR T-Cell Therapy in Relapsed/Refractory TRBC1-Positive Peripheral T-Cell Lymphoma**
   LINK to abstract

Session Title: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster III
Session date and time: Monday, December 12, 2022, 6:00 PM – 8:00 PM
Session room: Ernest N. Morial Convention Center, Hall D
Publication Number: 4634
Presenting Author: Dr Kate Cwynarski, Consultant Haematologist University College London Hospitals (UCLH)

Summary: Peripheral T cell lymphomas (PTCL) are typically aggressive, treatment resistant, and associated with poor prognosis. Finding the right target is challenging because there is a lack of tumor-specific antigens, and pan-T cell depletion leads to immunosuppression. T cell lymphoma is clonal, and tumor cells express either TRBC1 or TRBC2. AUTO4 targets TRBC1+ cells, which allows part of the T cell compartment to be retained. This study is ongoing, with additional patients due to be treated to define the recommended phase 2 dose using the new manufacturing process.

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 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. Designed to have a fast target binding off-rate to minimize excessive activation of the programmed T cells, obe-cel 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 Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL. Autolus has progressed obe-cel to the FELIX trial, a potential pivotal trial for adult ALL.

About AUTO1/22
AUTO1/22 is a novel dual targeting CAR T cell-based therapy candidate based on obe-cel. It is designed to combine the enhanced safety, robust expansion & persistence seen with the fast off rate CD19 CAR from obe-cel with a high sensitivity CD22 CAR to reduce antigen negative relapses. This product candidate is currently in a Phase 1 clinical trial called CARPALL for patients with r/r pediatric ALL. [NCT02443831]

About AUTO4
AUTO4 is a programmed T cell product candidate in clinical development for T cell lymphoma, a setting where there are currently no approved programmed T cell therapies. AUTO4 is specifically designed to target TRBC1 derived cancers, which account for approximately 40% of T cell lymphomas, and is a complement to the AUTO5 T cell product candidate, which is in pre-clinical development. AUTO4 has been tested in a Phase 1 clinical trial, LibRA1 for patients with peripheral T cell Lymphoma.

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 obe-cel 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; expectations regarding the initiation, design and reporting of data from clinical trials; expectations regarding regulatory approval process for any product candidates; the collaboration between Autolus and Blackstone; the discovery, development and potential commercialization of potential product candidates including obe-cel using Autolus' technology and under the collaboration agreement; the therapeutic potential for Autolus in next generation product developments of obe-cel in B-cell malignancies; the potential and timing to receive milestone payments and pay royalties under the strategic collaboration; and the Company's anticipated cash runway. 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 10, 2022, 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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