# Autolus Therapeutics Presents Positive Results from AUTO4 in Relapsed/Refractory TRBC1-Positive Peripheral T-Cell Lymphoma

June 16, 2023

- At the highest dose 4 out of 4 PTCL patients achieved a response using the original manufacturing process (Process A)
- Ongoing complete metabolic responses in 2 out of 4 patients at 15 and 18-months post-dosing at the highest dose tested
- Presence of CAR T cells in the lymph nodes of patients suggest fast homing of CAR T cells to the tumor site, despite absence in the blood
- AUTO4 was well tolerated with no dose limiting toxicities

LONDON, June 16, 2023 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces clinical data of AUTO4 (Phase 1/2 LibrA T1 study), a TRBC1-targeting CAR T cell therapy in relapsed/refractory TRBC1-Positive Peripheral T-Cell Lymphoma (PTCL) at the International Conference on Malignant Lymphoma (ICML) being held June 13 to 17, 2023 in Lugano, Switzerland. PTCL is a rare and heterogeneous form of non-Hodgkin lymphoma.

The LibrA T1 trial is a single arm, open label, multi-center, Phase 1/2 study evaluating the safety and efficacy of AUTO4, a single dose intravenous CAR T cell treatment targeting TRBC1 in patients with relapsed or refractory TRBC1-positive selected PTCL. At the cutoff date of April 28, 2023, 19 patients were enrolled into the study and 13 were dosed. Using manufacturing process A, 10 patients were dosed. Using manufacturing process B, 3 additional patients were dosed very recently. Overall, the treatment was well tolerated with no dose limiting toxicities. In Process A, at the highest dose tested (450 x $10^6$ cell dose), 4 out of 4 patients achieved a response with 2 out of 4 remaining in ongoing complete metabolic response (CMR) at 15 and 18-months post-dose, respectively. Presence of CAR T cells in the lymph nodes of patients suggest fast homing of CAR T cells to the tumor site, despite absence in the blood. Efficacy data from Process B was not provided given median follow up is <3 months.

“There are limited options for patients with PTCL, so new treatments for this aggressive malignancy are desperately needed,” **said Dr. Kate Cwynarski, Chief Investigator, UCLH, London.** “The LibrA T1 study of AUTO4 is a novel approach using a CAR T cell designed to selectively target and eliminate T cells that include the malignant clone which harbors the TRBC1 receptor, while preserving the T cell compartment with the TRBC2 receptor which helps to maintain immune-competence. AUTO4 is well tolerated and the data to date in this early phase study are very promising.”

“AUTO4, with its unique targeting mechanism, represents an opportunity for advanced programmed T cell therapies that will make a difference in patients who traditionally suffer from severe immunosuppression as a result of current therapeutic options,” **said Dr. Edgar Braendle, Chief Development Officer of Autolus.** “This is a trial with a small number of patients, but with all 4 patients at the highest dose in the study achieving a response and 2 out of the 4 remaining in a complete metabolic response beyond 12 months, AUTO4 shows potential to provide a novel therapy option for PTCL patients.”

**Oral Presentation**

**Title: First in Human Study of AUTO4, a TRBC1-Targetting CAR T Cell Therapy in Relapsed/Refractory TRBC1-Positive Peripheral T-Cell Lymphoma**

**Abstract No:** 044 **–** Link to Abstract
**Session:** Peripheral T-cell Lymphomas
**Session Date and Time:** Thursday, June 15, 2023, 4.30 - 4.45pm CET

**Presenting Author:** Dr Kate Cwynarski, Consultant Haematologist University College London Hospitals (UCLH)

**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 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.

**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 expected benefits and continued development of Autolus’ obe-cel program; the planned submission of a Biologics License Application for obe-cel by the end of 2023; and the Company’s manufacturing capabilities, including the completion and validation of the Nucleus facility. 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 and Cardinal Health are unable agree on a definitive agreement, or that the arrangement described in such an agreement does not produce the desired results; Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; 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. 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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