Autolus Therapeutics presents additional data on AUTO3 in DLBCL during the ASCO20 Virtual Scientific Program

May 29, 2020

– Data continue to show encouraging clinical activity alongside tolerable safety to deliver a potentially highly differentiated product profile –

Conference call and webcast to be held Monday, June 1, 2020 at 8:30 am EDT / 1:30 pm BST

LONDON, May 29, 2020 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced new data highlighting progress on AUTO3, the company's CAR T cell therapy being investigated in the ALEXANDER study, a Phase 1/2 study in relapsed/refractory diffuse large B cell lymphoma (DLBCL), during the Annual Society of Clinical Oncology 2020 (ASCO20) Virtual Scientific Program beginning May 29.

"Data from the ALEXANDER trial of AUTO3, a CD19/CD22 dual-targeting CAR T product candidate in DLBCL have shown a complete response rate of 63% at the recommended Phase 2 dose range with an excellent safety profile," said Dr. Aravind Ramakrishnan, Medical Director, Bone Marrow Transplant and Cellular Therapy Program, Sarah Cannon Blood Cancer Center at St. David's South Austin Medical Center. "We are encouraged by the current study results and have begun enrollment in an outpatient cohort to assess how this approach may benefit a greater population of DLBCL patients."

As of the data cut-off date of April 27, 2020, 23 patients in the ALEXANDER Phase 1/2 clinical trial of AUTO3 were evaluable for safety and efficacy with a minimum of 28-days follow-up. AUTO3 was well tolerated, with no patients experiencing dose limiting toxicity, and there were no treatment-related deaths. At a dose of ≥ 150 x 10^6 cells across the 2 dosing regimens for pembrolizumab, a single dose of pembrolizumab on day minus 1 (D-1) or three doses of pembrolizumab starting on day 14 (D14), no patient experienced Grade 3 or higher Cytokine Release Syndrome (CRS) and no patient experienced neurotoxicity of any grade. At these doses, 11 out of 16 patients achieved a complete or partial response (ORR=69%), and 9 out of 16 achieved a complete response (CRR=56%) with all 9 complete responses ongoing at a median follow-up of 3 months (range 1-12 months). Additionally, at the recommended Phase 2 dose range of 150 - 450 x 10^6 cells with pembrolizumab D-1, 6 out of 8 patients achieved a complete response or partial response (ORR=75%), and 5 out of 8 patients achieved a complete response (CRR=63%).

"We are very pleased with the progression of AUTO3 in DLBCL, combining a high level of complete remissions with a safety profile supportive of outpatient use. We have not seen early relapses from complete remissions and are in the process of confirming the profile at the recommended Phase 2 regimen. Our 20 patient outpatient cohort has started, and the results are expected for the second half of 2020 and will further inform the design of the Phase 2 study," said Dr. Christian Itin, chairman and chief executive officer of Autolus.

Investor call on Monday June 1, 2020
Management will host a conference call and webcast at 8:30 am EDT/1:30 pm BST to discuss the ASCO data. To listen to the webcast and view the accompanying slide presentation, please go to: https://www.autolus.com/investor-relations/news-and-events/events.

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 4880556. 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 4880556.

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 AUTO3
AUTO3 is a programmed T cell therapy containing two independent chimeric antigen receptors targeting CD19 and CD22 that have each been independently optimized for single target activity. By simultaneously targeting two B cell antigens, AUTO3 is designed to minimize relapse due to single antigen loss in patients with B cell malignancies. AUTO3 is currently being tested in diffuse large B cell lymphoma in the ALEXANDER clinical trial, with a 20-patient cohort that was initiated in Q2 2020 to assess feasibility of treatment in an outpatient setting.

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' financial condition and results of operations, including its expected cash runway; the development of Autolus' product candidates, including statements regarding the timing of initiation, completion and the outcome of pre-clinical studies or clinical trials and related preparatory work, and the periods during which the results of the studies and trials will become available; Autolus' plans to research, develop, manufacture and commercialize its product candidates; the potential for Autolus' product candidates to be alternatives in the therapeutic areas investigated; and Autolus' manufacturing capabilities and strategy. 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 Autolus' Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 3, 2020 as well as discussions of potential risks, uncertainties, and other important factors in Autolus' 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.

Contact:

Lucinda Crabtree, PhD
Vice President, Investor Relations and Corporate Communications
+44 (0) 7587 372 619
l.crabtree@autolus.com

Julia Wilson
+44 (0) 7818 430877
j.wilson@autolus.com

Susan A. Noonan
S.A. Noonan Communications
+1-212-966-3650
susan@sanoonan.com

Source: Autolus Therapeutics plc