Autolus Therapeutics Unveils Expanded Next Generation Technology and Pipeline and Provides Key Update on AUTO3 Program in Pediatric ALL at R&D Day

March 26, 2019 at 6:00 AM EDT

Program and webcast – today, March 26, 2019 at 8:00 am ET

LONDON, March 26, 2019 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next generation programmed T cell therapies for the treatment of cancer, plans to present insights into the science behind tumor defense mechanisms and the company's novel programmed T cell therapy programs in development utilizing targeted, modular approaches designed to address these mechanisms at its inaugural R&D Day, today, in New York. In addition, the company plans to provide an update on its AUTO3 program in pediatric acute lymphocytic leukemia (pALL).

AUTO3 is the first dual-targeting CD19 and CD22 programmed T cell therapy in development for both pALL and relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Updated data from the ongoing AMELIA Phase 1/2 study in pALL demonstrates that 6 out of 6 (100%) patients treated at the highest dose (≥3 x10^6/kg) achieved minimal residual disease (MRD) negative complete responses (CR). Ongoing MRD negative CR remissions were noted in 4 out of 6 (67%) patients, with duration of up to 10 months as of February 2019, the date of latest data follow-up. There have been no reported CD19 or CD22 negative relapses in CAR T naïve patients. Data also showed that AUTO3 continues to be generally well tolerated with no ≥ Grade 3 CRS, no ICU admission, and no pressors or critical care support for CRS required. The Phase 2 portion of the study is expected to start in the second half of 2019. For more information about this trial and the inclusion criteria, visit www.ClinicalTrials.gov (NCT03289455).

"We are pleased to be hosting our inaugural R&D day, providing a unique opportunity to present an in-depth overview of our differentiated technology, multiple programs, market opportunities and the significant pipeline progress we have achieved, to date," stated Dr. Christian Itin, chairman and chief executive officer of Autolus. "We expect to report data on all of our active clinical programs at key medical conferences during 2019. Additionally, over the coming months, we expect to move two programs into registrational trials and to progress our next generation programs toward the clinic."

Today's R&D program will include the following presentations:

- Dr. Christian Itin, Chairman and Chief Executive Officer of Autolus – *Welcome and Overview*
- Dr. Samir N. Khleif, Director of the Loop Immuno-Oncology Lab and Biomedical Scholar and Professor of Oncology, Georgetown University Medical Center - *Immunotherapy, A Combinatorial Approach for Success*
- Dr. Muhammad Al-Hajj, Senior Vice President, Translational Sciences of Autolus – *Translational Aspects of Tumor Heterogeneity*
- Dr. Martin Pule, Chief Scientific Officer and Founder of Autolus and Clinical Senior Lecturer at University College London Cancer Institute – *Tackling Solid Tumors: A Modular Approach to T Cell Programming*
- Dr. Vijay Peddareddigari, Chief Medical Officer of Autolus – *Clinical Update: Current and Next Generation Programs*

A live video webcast of the event will be available beginning at 8:00 am ET today on the Events section of Autolus' website: https://www.autolus.com/investor-relations/news-events/events. An archived replay will be available on the website for one year.

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 two clinical studies, AMELIA and ALEXANDER.

AMELIA is a single-arm, open label, multi-center Phase 1/2 clinical trial of AUTO3 in patients up to 24 years of age with high-risk relapsed or refractory B-lineage. The trial is also enrolling patients who previously received CD19 or CD22 targeting therapies including other CAR T cell therapy. The purpose of this study is to test the safety and efficacy, including the complete remission rate or minimal residual disease (MRD) negative response, of AUTO3. Autolus expects to enroll up to 54 patients in this trial.

ALEXANDER is a single-arm, open label, multi-center Phase 1/2 clinical trial of AUTO3 in patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL). The purpose of this study is to test the safety and efficacy, including the overall response rate as per Lugano criteria, of AUTO3 followed by limited duration of consolidation with anti-PD1 antibody. Autolus expects to enroll up to 120 patients in this trial.

For more information about these trials and the inclusion criteria, visit www.ClinicalTrials.gov.

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.

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