Autolus Therapeutics Presents Initial AUTO3 Clinical Data from Phase 1/2 Clinical Trials in B cell Malignancies at the 60th ASH Annual Meeting

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- Initial results were presented from ongoing Phase 1/2 trials in pediatric acute lymphoblastic leukemia (AMELIA trial) and diffuse B cell lymphoma (ALEXANDER trial) -

LONDON, Dec. 2, 2018 /PRNewswire/ -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today highlighted updated results from its ongoing Phase 1/2 AMELIA clinical trial of AUTO3 in patients with relapsed/refractory pediatric acute lymphoblastic leukemia (pALL) and its ongoing Phase 1/2 ALEXANDER clinical trial in patients with relapsed/refractory diffuse large B cell lymphoma (DLBCL) presented at the 60thAmerican Society of Hematology (ASH) Annual Meeting, San Diego, California. AUTO3 is a dual-targeted therapy incorporating two separate chimeric antigen receptors (CARs). Observations from preclinical studies indicate that AUTO3 independently targets CD19 and CD22. AUTO3 is designed to reduce relapse driven by antigen loss, a key defense mechanism used by the tumor cells and the primary cause of relapse in pALL.

"The preliminary results of the AMELIA trial indicate that AUTO3, the first dual targeting CD19 and CD22 CAR T cell therapy under development for pediatric ALL, appears to have a manageable safety profile, with the potential to overcome target-negative relapse, a major limitation of current CD19-targeted therapies," said Professor Persis Amrolia, lead investigator and Consultant in Bone Marrow Transplant at Great Ormond Street Hospital (GOSH) and NIHR Research Professor of Transplantation Immunology at UCL Great Ormond Street Institute of Child Health (ICH).

"In the ALEXANDER trial, preliminary results indicate that AUTO3 followed by consolidation with a limited duration of anti-PD1 therapy appears to have a manageable safety profile at the doses evaluated. This is the first therapy that aims to address two emerging resistance mechanisms for non-Hodgkin lymphoma, target-negative relapse and checkpoint upregulation," said Dr. Anas Younes, Chief, Lymphoma Service at Memorial Sloan Kettering Cancer Center.

Simultaneous Targeting of CD19 and CD22: Phase 1 Trial of AUTO3, a Bicistronic Chimeric Antigen Receptor (CAR) T-cell Therapy, in Pediatric Patients with Relapse/Refractory B-cell Acute Lymphoblastic Leukemia (r/r B-ALL): AMELIA Trial (Abstract Number 279, oral presentation at 8:00AM on Sunday, December 2, 2018)

Dr. Amrolia reported on 10 patients with relapsed or refractory ALL who received an AUTO3 infusion as a single dose or split dose dependent on their tumor burden. Key inclusion criteria included age 1-24 years old with relapsed or refractory B-lineage ALL at high risk in first relapse or in second or greater relapse. Prior targeted therapies to CD19 and CD22 were not excluded. The average age of the 10 evaluable patients was 8.5 years, the median number of prior lines of therapy was 3. Product was successfully manufactured for all patients. AUTO3 was generally well tolerated with no ≥ Grade 3 CRS, no ICU admission, and no pressors or critical care support for CRS required. One case of Grade 3 neurotoxicity was observed which was considered unlikely related to AUTO3 and primarily attributed to prior intrathecal chemotherapy. Grade 3 or higher cytopenias lasting at least 30 days were noted in 4 out of 10 patients. Among the 10 evaluable patients at all dose levels, 8 out of 10 achieved MRD negative CR and higher response rates were observed at doses ≥3 x10^6/kg dose levels with all patients achieving MRD-negative remission. In the higher dose group, 4 out of 6 (67%) patients have an ongoing molecular CR and importantly, no loss of CD19 or CD22 was noted among relapsed patients. Initial data indicates response rates and persistence are dose dependant. Dose escalation is ongoing.

For more information about this trial and the inclusion criteria, visit www.ClinicalTrials.gov (NCT03289455).

Trial of AUTO3, the First Bicistronic Chimeric Antigen Receptor (CAR) Targeting CD19 and CD22, Followed By Anti-PD1 Consolidation in Patients with Relapsed/Refractory (r/r) Diffuse Large B Cell Lymphoma (DLBCL): Alexander Trial (Abstract Number 1679, poster presentation from 6:15 PM – 8:15PM on Saturday, December 1, 2018)

Dr. Kirit Ardeshna, principal investigator at University College London, UK, reported preliminary clinical data on safety and efficacy from this open-label, multi-center trial in patients with DLBCL treated with a single dose of AUTO3 followed by consolidation with anti-PD-1 antibody (pembrolizumab). Key inclusion criteria included histologically confirmed DLBCL, chemotherapy-refractory disease or relapse after at least two lines of therapy or after ASCT, and no prior allogeneic stem cell transplant. There were 7 patients evaluable for safety with at least 28 day follow up post-treatment. The median number of prior lines of therapy in these 7 evaluable patients was 3 (range was 2 to 4). All patients were treated at the starting dose of 50x10^6 transformed CAR T cells. Three patients received a consolidation with pembrolizumab, and 4 patients did not receive treatment with pembrolizumab. None of the treated patients developed CRS grade 3 or higher and one patient had neurotoxicity grade 3, considered possibly related to AUTO3. No dose limiting toxicities were observed and dose escalation continues. Six patients were evaluable for response, two achieved a CR and two a PR; two patients did not respond. The two CRs were ongoing at six and three months, respectively.

For more information about this trial and the inclusion criteria, visit www.ClinicalTrials.gov (NCT03287817).

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 trials, referred to as the AMELIA and

ALEXANDER trials.

The AMELIA trial 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 also is enrolling patients who previously received CD19 or CD22 targeting therapies including other CAR T cell therapy. The primary objective for Phase 1 is to assess the safety and tolerability of AUTO 3 administration as well as to identify the Phase 2 dose and schedule. The purpose of this trial 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.

The ALEXANDER trial 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 primary objective for the Phase 1 portion is to assess the safety and tolerability of AUTO3 administration as well as to identify the recommended Phase 2 dose and maximum tolerated dose (MTD) of AUTO3. The purpose of this trial 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 approximately 100 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.

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 progress, timing and results of the company's clinical trials and the anticipated clinical development of 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. 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 the company's Annual Report on Form 20-F filed on November 23, 2018 as well as discussions of potential risks, uncertainties, and other important factors in the company's 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.

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