Autolus Therapeutics announces pivotal Phase 2 FELIX clinical trial has met primary endpoint at interim analysis

December 8, 2022

- *Obe-cel demonstrated Overall Remission Rate (ORR) of 70% in interim analysis of 50 patients with relapsed/refractory (r/r) adult Acute Lymphoblastic Leukemia (ALL)*
- *Encouraging safety data observed, with 3% ≥Grade 3 Cytokine Release Syndrome (CRS) and 8% ≥Grade 3 Immune effector cell-associated neurotoxicity syndrome (ICANS) in 92 patients treated*
- *Achievement of development milestone has triggered payment of $35m from Blackstone Life Sciences, announced in a separate press release today*
- *The trial has completed screening patients for entry into the morphological cohort*

LONDON, Dec. 08, 2022 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that the Phase 2 pivotal FELIX clinical trial of obecabtagene autoleucel (obe-cel) in relapsed/refractory (r/r) adult Acute Lymphoblastic Leukemia (ALL) has met its primary endpoint, based on a pre-planned interim analysis of 50 patients with morphological disease, as verified by an independent data monitoring committee (IDMC). The primary endpoint for the FELIX Phase 2 trial is the Overall Remission Rate (ORR), defined as the proportion of patients achieving Complete Remission (CR) and Complete Remission with Incomplete Blood Count Recovery (CRi) as assessed by an independent response review committee (IRRC).

Based on 50 patients evaluated for efficacy, the ORR for obe-cel was 70%. Obe-cel showed comparable expansion and initial persistence (median follow-up 6.4 months) to the data observed in the prior ALLCAR19 study. The safety analysis was based on 92 patients treated with obe-cel and evaluable for safety. The Company observed that 3% of patients experienced Grade 3 or higher CRS, whilst 8% experienced Grade 3 or higher ICANS, and 23% of patients experienced any grade ICANS.

“Obe-cel’s high level of anti-leukemia activity combined with a well manageable tolerability profile is a significant step forward in this underserved disease setting, which is characterized by the explosive growth of the leukemia and the poor condition of many patients,” **said Dr. Jae Park, Associate Attending Physician at Memorial Sloan Kettering Cancer Center.** “The expansion and initial persistence of obe-cel are encouraging from a long-term outcome perspective and I look forward to the next data update and the potential of obe-cel as a treatment for ALL.”

“We are really pleased with the consistency of data from the interim analysis of the FELIX study with our prior results from the ALLCAR19 study in adult patients with relapsed / refractory ALL,” **said Dr. Claire Roddie, Associate Professor Haematology, Cancer Institute, University College London (UCL)**.

“We are delighted to be announcing that our first pivotal trial conducted has met its primary endpoint based on our interim analysis, and we believe that we are one step closer to bringing this potentially innovative treatment to an underserved ALL patient population,” **said Dr. Christian Itin, Chief Executive Officer of Autolus.** “We look forward to supplementing this interim data with longer follow up data to more fully explore the clinical benefit of obe-cel, and to work towards the submission of a Biologics License Application (BLA) by the end of 2023 to the U.S. Food and Drug Administration (FDA).”

“We would like to thank patients and their families, our treating physicians and the clinical development and manufacturing teams for their trust, commitment and determination to deliver this study during a challenging pandemic-impacted environment.”

The trial has completed screening patients for entry into the morphological cohort as the pre-specified goal of approximately 90 patients enrolled has been reached, and Autolus plans to present the results from the FELIX trial at a medical conference in mid-2023, with longer follow up planned to be reported at the end of 2023.

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, Autolus 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 trial for B-NHL. Autolus has progressed obe-cel to the FELIX trial, a pivotal trial for r/r adult ALL.

About obe-cel FELIX clinical trial
Autolus’ Phase 1b/2 clinical trial of obe-cel is enrolling adult patients with r/r B-precursor ALL. The trial had a Phase 1b component prior to proceeding to the single arm, Phase 2 clinical trial. The primary endpoint is ORR, and the secondary endpoints include duration of response, minimal residual

disease (MRD) negative CR rate and safety. The trial is designed to enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom, and Europe. [NCT04404660]

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 continued development of Autolus' obe-cel program including timing of and expectations regarding planned readouts, expectations that the final data set will be confirmatory of the data from the interim analysis and the planned submission of a Biologics License Application by the end of 2023. 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.

Contact:

Olivia Manser
+44 (0) 7780 471568
o.manser@autolus.com

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

Susan A. Noonan
S.A. Noonan Communications
+1-917-513-5303
susan@sanoonan.com