



Autolus Therapeutics announces Pivotal Phase 2 FELIX study of obe-cel in adult r/r B-ALL selected for an oral presentation at ASCO

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LONDON, April 27, 2023 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that the abstract for the pivotal Phase 2 FELIX study of obecabtagene autoleucl (obe-cel) in relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL) has been selected for an oral presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, being held June 2 - 6, 2023, in Chicago.

ASCO Oral Presentation, abstract #7000:

Title: Safety and efficacy of Obecabtagene autoleucl (obe-cel, AUTO1), a fast-off rate CD19CAR in relapsed/refractory adult B-Cell acute lymphoblastic leukemia (r/r B-ALL): Topline results of the pivotal FELIX study

Session Title: Hematologic Malignancies — Leukemia, Myelodysplastic Syndromes, and Allotransplant

Session date and time: Friday, June 2, 2023, 14:00 – 17:00 EDT, 19:00 – 22:00 BST

Presenting Author: Dr. Claire Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

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

About obe-cel FELIX clinical trial

Autolus' Phase 1b/2 clinical trial of obe-cel is enrolling adult patients with relapsed / refractory 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 overall response rate, and the secondary endpoints include duration of response, 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 expected benefits of the Company's arrangement with Cardinal Health; the continued development of Autolus' obe-cel program, including the timing and content of clinical results obtained with obe-cel, and the presentation of such results; the planned submission of a Biologics License Application for obe-cel by the end of 2023; and the sufficiency of the Company's cash resources and its anticipated cash runway into 2025. 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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