Autolus Therapeutics Presents Positive Results from Pivotal Phase 2 FELIX study in adult r/r B-ALL at ASCO

June 2, 2023 at 7:00 AM EDT

- 76% of patients treated with obe-cel in the FELIX study achieved a response (CR/CRi), primary endpoint has been met based on previously communicated interim analysis
- Potential best in class tolerability, with very low levels of high-grade CRS and ICANS
- Robust and reliable manufacturing and logistics, with 84% of enrolled patients receiving obe-cel
- Analyst call to be held today, June 2, 2023 at 4.00 pm ET/9.00 pm BST

LONDON, June 02, 2023 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces the presentation of top-line data from the Pivotal Phase 2 FELIX study of obe-cel in adult r/r B-cell Acute Lymphoblastic Leukemia (B-ALL) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

In the pivotal morphological cohort of the FELIX trial, 112 patients with r/r adult ALL were enrolled and 94 (84%) patients were dosed with obe-cel. Of the dosed patients, 76% patients achieved a complete response (CR) or CR with incomplete haematological recovery (CRi), and 97% of the responders with evaluable samples were in deep remission with no detectable minimal residual disease (MRD). Furthermore, at a 9.5-month median follow up, 61% of responders remained in ongoing remission without new anti-cancer therapies. CAR T cellular kinetics demonstrate excellent CAR T engraftment and persistence and are consistent with the prior ALLCAR19 study.

Safety analysis demonstrated a potentially best-in-class tolerability profile with Grade ≥3 cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) in 3% (3/94) and 7% (7/94) of patients, respectively. Most of the toxicity was seen in patients with high disease burden. Notably, 6 of 7 Grade ≥3 ICANS were observed among patients with very high tumor burden of more than 75% bone marrow blasts at lymphodepletion. Overall, Grade ≥3 adverse events occurred in 79% of patients, with neutropenia (36.2%), and thrombocytopenia (25.5%) most commonly reported.

Manufacturing was reliable and consistent, with product released for 94% of leukapheresed patients and median turnaround times of 21 days from vein to release.

“We are very encouraged by the outcome of the FELIX study. Obe-cel shows low immunotoxicity, high complete remission rates and excellent CAR T expansion and persistence in adult B-ALL. These data are consistent with the prior ALLCAR19 study and suggest that obe-cel has the potential for long-term clinical benefit in adult B-ALL patients without additional therapies,” **said Dr. Claire Roddie, Associate Professor at UCL, Honorary Consultant Haematologist at UCLH**.

“We are pleased that our pivotal FELIX study confirms the attractive product profile for obe-cel, combining a high level of clinical activity with an excellent safety profile which we know is critical for this highly pre-treated and frail patient population. Conducting this study through the pandemic was a pressure test for obe-cel's product profile and our ability to deliver obe-cel reliably under difficult circumstances. We would like to thank patients, their care givers, nurses and treating physicians for their participation in the FELIX study,” **said Dr. Christian Itin, Chief Executive Officer of Autolus.**

“With the Nucleus, our commercial manufacturing facility, well advanced in validation we look forward to submitting a BLA towards the end of this year and working with the FDA to get obe-cel to patients as soon as possible.”

ASCO Oral Presentation, abstract #7000:

Title:	**Safety and efficacy of Obecabtagene autoleucel (obe-cel, AUTO1), a fast-off rate CD19 CAR 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, 2.00 pm –2.12 pm ET, 7.00 pm – 7.12 pm BST
Presenting Author:	Dr. Claire Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

Additional data from the FELIX study will be presented as an Oral Presentation at the upcoming European Hematology Association (EHA) meeting:

Title:	**Safety and efficacy of Obecabtagene autoleucel (obe-cel, AUTO1), a fast-off rate CD19 CAR in relapsed/refractory adult B-Cell acute lymphoblastic leukemia (r/r B-ALL): Topline results of the pivotal FELIX study**
Presentation ID:	**S262**

Session date and time:	Saturday, June 10, 2023, 11.00 am – 11.15 am ET, 4.00 pm – 4.15 pm BST
Presenting Author:	Dr. Claire Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

Conference Call

Autolus will host a conference call and webcast today for analysts at 4.00 pm ET/9.00 pm BST to summarize the ASCO data. Conference call participants should pre-register using this link to receive the dial-in numbers and a personal PIN, which are required to access the conference call.

A simultaneous audio webcast and replay will be accessible on the events section of Autolus' website.

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 enrolled 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 enrolled over 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 and continued development of Autolus' obe-cel program; the planned submission of a Biologics License Application for obe-cel by the end of 2023; and the Company's manufacturing capabilities, including the completion and validation of the Nucleus facility. 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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