Autolus Therapeutics presents longer-term follow-up and additional data analysis of Pivotal Phase 2 FELIX study of obe-cel for adult r/r B-ALL in an oral presentation at ASCO

May 31, 2024 at 8:00 AM EDT

- The majority of patients that responded to obe-cel showed durable responses with the potential for a long-term plateau of survival outcomes
- 40% patients are in ongoing remission without subsequent stem cell transplant (SCT) or other intervention
- Ongoing CAR T persistence was associated with improved event-free survival
- Autolus will host a conference call and webcast to discuss the presented data on Saturday June 1, 2024 at 9:30 am EDT/8:30 am CDT/2:30 pm BST (details below)

LONDON, May 31, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces longer-term follow-up and additional data analysis from the pivotal Phase 1b/2 FELIX study of obecabtagene autoleucel (obe-cel) in relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL), being presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, (May 31 – June 4, 2024, Chicago).

“At 21 months of median follow up, we’re really pleased to be observing the potential for a long-term plateau of survival outcomes with obe-cel in the FELIX trial,” **said Dr. Christian Itin, Chief Executive Officer of Autolus.** “40% of patients are in ongoing remission without Stem Cell Transplant (SCT) or other therapy, and we continue to see evidence that ongoing CAR T persistence is associated with this event-free survival. This pattern is consistent with our Phase 1 ALLCAR19 data and provides further support that obe-cel, as a standalone therapy, can result in long-term survival and durable responses in adult patients with r/r ALL.”

The results of the FELIX trial have been submitted to the FDA as part of a BLA. The PDUFA target action date is November 16, 2024.

ASCO Oral Presentation, abstract #6504:
Title: Obecabtagene autoleucel (obe-cel, AUTO1) in adults with relapsed/refractory B-cell acute lymphoblastic leukemia (R/R B-ALL): Overall survival (OS), event-free survival (EFS) and the potential impact of chimeric antigen receptor (CAR)-T cell persistency and the potential impact of chimeric antigen receptor (CAR)-T cell persistency and consolidative stem cell transplantation (SCT) in the open-label, single-arm FELIX Phase Ib/II study
Session Title: Oral Abstract Session – Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
Session date and time: Friday, May 31, 2024, 14:45 – 17:45 EDT, 19:45 – 22:45 BST
Presenting Author: Dr Elias Jabbour, Professor, Department of Leukemia, Division of Cancer Medicine, MD Anderson Cancer Center, Houston, TX

Summary:
The ORR (CR/CRi) in all patients who received obe-cel in the FELIX study was 78% (99/127 patients). At the February 7, 2024, data cut-off date, the majority of ongoing responders showed durable responses. Among the responding patients, at a median follow up of 21.45 months (range: 8.6–41.4), 40% were in ongoing remission without subsequent SCT or other therapy, while 18% proceeded to subsequent SCT while in remission, 5% started new anti-cancer therapy while in remission and 36% relapsed or died. The median event-free survival (EFS) was 11.9 months and median overall survival (OS) was 23.8 months and the estimated 12-month EFS and OS rates were 49.5% and 61.1% respectively.

18 of 99 responders (18%) had SCT while in MRD-negative remission. 10 of the 18 (56%) had ongoing CAR T persistency prior to SCT, with eight of these 10 patients (80%) experiencing relapse or death post SCT. Eight out of 18 (44%) patients had lost CAR T persistency prior to SCT, with five of those eight patients (62%) experiencing relapse prior to SCT or death post SCT. Overall, consolidative SCT for patients post-obe-cel did not appear to improve EFS or OS.

CAR T persistence and B-cell aplasia were both associated with improved EFS compared with loss of persistency and B-cell recovery. Patients with loss of CAR T persistence had a 2.7 fold increased risk of relapse or death compared to patients with ongoing CAR T persistence. Patients who experienced B-cell recovery had a 1.7 fold increased risk of relapse or compared with patients without B-cell recovery. Among patients with CR/CRi beyond 6 months without SCT or new therapies, patients with ongoing CAR T persistence are associated with improved EFS vs. those with a loss of CAR T persistence.

In conclusion these data support the potential of a long-term plateau of survival outcomes in patients receiving obe-cel. At a median follow-up of 21.3 months 40% of responders are in ongoing remission without SCT or other therapy and ongoing CAR T persistence and B-cell aplasia were associated with improved EFS. This pattern is consistent with the Phase 1 ALLCAR19 data. Furthermore, SCT consolidation in remission following obe-cel did not appear to improve EFS or OS.

A conference call and webcast to discuss the presented data will be held at 9:30 am EDT/8:30 am CDT/2:30 pm BST on Saturday June 1, 2024. 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 and autoimmune disease. 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 target 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, solid tumors and autoimmune diseases. 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. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. In clinical trials of obe-cel, this "fast off-rate" profile reduced toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024. A regulatory submission to the EMA was made in the first half of 2024. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL.

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 was overall response rate, and the secondary endpoints included 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 Autolus' development and commercialization of its product candidates, timing of data announcements and regulatory submissions, its cash resources and the market opportunity for obe-cel. 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; and possible safety and efficacy concerns. 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 10-K filed with the Securities and Exchange Commission, or the SEC, on March 21, 2024 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. You should, therefore, not rely on these forward-looking statements as representing Autolus' views as of any date subsequent to the date of this press release.

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