Autolus Therapeutics to Present Three Clinical Data Updates on obecabtagene autoleucel (obe-cel) in relapsed/refractory (r/r) B-Cell acute lymphoblastic leukemia (ALL) patients at the 2024 European Hematology Association (EHA) Congress

June 14, 2024 at 7:00 AM EDT

LONDON, June 14, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces three abstracts to be presented at the European Hematology Association (EHA) Congress, June 13-16, 2024.

“We are looking forward to presenting longer-term data from adult patients with r/r ALL treated with obe-cel in the FELIX study,” **said Dr. Christian Itin, Chief Executive Officer of Autolus**. “The data indicate that with a median follow up of 21.5 months long-term event free and overall survival are stabilizing at around 40%, suggesting that obe-cel can potentially deliver durable responses as a single agent.”

Oral presentation:

1. **Title: obecabtagene autoleucel in adult relapsed/refractory B cell acute lymphoblastic leukemia: Survival and potential impact of CAR T-cell persistence and stem cell transplantation in the FELIX study**
   Session Title: s419 Acute lymphoblastic leukemia - Clinical 1: Immunotherapy: antibodies and CAR-T cells
   Session date and time: Friday, June 14 from 14:45 - 16:00 CEST
   Session room: N104
   Final Abstract Code: S114
   Presenting Author: Dr. Claire Roddie
   Summary of Findings: This is an encore presentation of the findings presented at ASCO 2024. The overall response rate (ORR) (Complete Response/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 21.5 months (range: 8.6–41.4), 40% were in ongoing remission without subsequent stem cell therapy (SCT) or other non-protocol specified 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.

   These data support the potential of a long-term plateau of survival outcomes in patients receiving obe-cel. 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.

Poster presentations:

1. **Title: obecabtagene autoleucel (obe-cel, AUTO1) for relapsed/refractory adult B-cell acute lymphoblastic leukemia (R/R B-ALL): The impact of inotuzumab (INO)-containing bridging therapy on treatment outcomes**
   Session Title: Poster session
   Session date and time: Friday, June 14 from 18:00 - 19:00 CEST
   Final Abstract Code: P418
   Presenting Author: Dr. Jae H. Park
   Summary of Findings: INO-containing bridging therapies were effective in reducing BM disease prior to lymphodepletion and administration of obe-cel. Our data suggests that reducing BM blasts as much as possible prior to lymphodepletion predicts EFS and OS outcomes; however, patients with high disease burden at screening are still at higher risk of relapse overall. Bridging therapy with INO was utilized in patients with higher disease burden (median 81.5% blasts at screening vs 40% in bridging therapy w/o INO group) and helped minimize the risk of CRS and ICANS without increasing liver toxicity. Choice of bridging therapy prior to obe-cel treatment, though influenced by clinical care variables, may impact outcomes for patients with R/R B-ALL. Further studies comparing bridging with INO-containing therapies or chemotherapy are warranted.

2. **Title: Droplet digital PCR and flow cytometry sensitivity for measuring CAR T-cell kinetics in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia treated with obecabtagene autoleucel**
   Session Title: Poster session
   Session date and time: Friday, June 14 from 18:00 - 19:00 CEST

Final Abstract Code: P1469
Presenting Author: Dr. Claire Roddie
Summary of Findings: A strong correlation was observed between flow cytometry and ddPCR assays for assessment of CAR T levels in peripheral blood. ddPCR is a more sensitive technology than flow cytometry for monitoring CAR T persistence. Flow cytometry assays developed specifically for CAR T monitoring may be sufficiently sensitive to be of clinical relevance. Our data suggest that loss of CAR T persistence is associated with shorter EFS and may be taken into consideration, together with other parameters such as measurable residual disease (MRD), to help inform clinical monitoring post-obe-cel infusion. A validation cohort using an appropriately developed CAR T marking flow cytometry assay versus a ddPCR assay would be required to conclude on the most appropriate methods to inform clinical outcomes.

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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