Autolus Therapeutics Announces Publication of Data from the FELIX study of obe-cel in r/r Adult B-ALL Patients in The New England Journal of Medicine

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- *High overall response rate: 76.6% of patients in the pivotal cohort achieved CR/Cri following treatment with obe-cel with a median follow-up of 20.3 months*
- *Low incidence of immune-related toxicity: Grade ≥ 3 CRS and ICANS were observed in 2.4% and 7.1% of infused patients respectively*
- *High rates of durable response: 12-month event free survival of 49.5% in all patients who received at least one infusion*

LONDON, Dec. 02, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), an early-commercial stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that the *New England Journal of Medicine* has published data 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). The data demonstrate high rates of durable responses with low incidence of grade ≥3 immune-related toxicity.

“With its low rates of serious side effects coupled with compelling long-term survival data and durable responses, obe-cel offers real hope for adult lymphoblastic leukemia patients,” **said Dr. Claire Roddie, MD, PhD, FRCPath, Lead investigator of the FELIX study and Associate Professor of Haematology at the University College London (UCL) Cancer Institute.** “Obe-cel’s durable responses were particularly observed in patients with low-intermediate bone marrow burden, including patients who did not receive consolidative allo-Stem Cell Transplant and there could be an opportunity to use obe-cel as earlier-line consolidation.”

“Adult ALL is an extremely aggressive cancer and patients with this disease historically suffer from poor outcome,” **said Elias Jabbour, MD, U.S. lead investigator of the FELIX study and professor of Leukemia, ALL Section Chief, at The University of Texas MD Anderson Cancer Center, Houston, Texas.** “The clinical benefit and improvements in survival demonstrated by obe-cel have the potential to redefine the standard of care in the adult relapsed/refractory B-ALL setting.”

Of the 153 r/r B-ALL patients enrolled patients in the FELIX study, 127 (83.0%) received at least one obe-cel infusion and were evaluable. Eligible patients underwent leukapheresis, and bridging therapy, except blinatumomab, was permitted at the investigator’s discretion. Obe-cel was administered in a bone marrow (BM) burden adjusted split dose following lymphodepletion, with a BM mandated prior to lymphodepletion to guide dosing. The second obe-cel dose was given in the absence of severe/unresolved toxicity.

The primary end point was overall remission (CR/CRi). In the pivotal cohort of patients, (cohort IIA (n=94)), the CR/CRi for patients who received at least one infusion of obe-cel was 76.6% Across all infused patients (n=127), of the 91/127 with ≥5% BM blasts pre-lymphodepletion, the CR/CRi was 74.7%. Median response duration for all infused patients was 21.2 months. Median event-free survival (EFS) was 11.9 months and the estimated 6- and 12-month event-free survival rates were 65.4% and 49.5%, respectively. BM burden pre-lymphodepletion correlated with median event-free survival; patients with low (<5% BM blasts), intermediate (≥5–≤75% blasts), and high (>75% blasts) BM burden had event-free survival rates at 12 months of 68.0%, 54.9% and 25.0%, respectively.

Median overall survival (OS) was 15.6 months and estimated 6- and 12-month overall survival rates were 80.3% and 61.1%, respectively. BM burden pre-lymphodepletion correlated with overall survival; patients with low, intermediate, and high BM burden had an overall survival rate at 12 months of 71.5%, 58.7% and 55.0%, respectively. BM burden before enrollment also influenced event-free and overall survival.

Of the 127 patients infused (pooled across all study cohorts), 99 patients responded. Of the responders, 18 patients (18.2%) proceeded to allo-Stem Cell Transplant (allo-SCT) while in remission at a median of 101 days post-obe-cel infusion. In 6/18 (33.3%), this was a second allo-SCT. Of 11 patients who had persisting CAR T cells before allo-SCT, and who had samples available post, none had CAR T cells detected following allo-SCT. There was no difference in event-free and overall survival observed between patients who received allo-SCT and those who did not.

Median duration of CAR T persistence by droplet digital PCR (ddPCR) in peripheral blood was 17.8 months.

Obe-cel was associated with minimal immunotoxicity. CRS and Immune effector cell-associated neurotoxicity syndrome (ICANS) rates (Grade ≥3) were 2.4% and 7.1%, respectively. Overall, 87 (68.5%) patients developed CRS, and 29 (22.8) developed ICANS. Severe ICANS post-obe-cel were seen as largely limited to patients with high BM burden pre-lymphodepletion. Intensive care unit (ICU) admissions occurred in 20 (15.7%) patients for a median of 5.5 days (range,1−37) of which 7/20 were admitted due to immunotoxicity management (5 ICANS, 2 CRS).

Obe-cel was approved by the Food & Drug Administration (FDA) under the brand name AUCATZYL® (obecabtagene autoleucel) on November 8, 2024. Marketing authorization applications (MAAs) for obe-cel [in adult r/r ALL] are being reviewed by the regulators in both the EU and the UK, with a submission to the European Medicines Agency (EMA) accepted in March 2024, and a submission accepted by the UK MHRA in August 2024.

Roddie C, et al "Obecabtagene autoleucel in B-cell acute lymphoblastic leukemia" N Engl J Med 2024; DOI: 10.1056/NEJMoa2406526

About Autolus Therapeutics plc
Autolus is a 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 an FDA approved product, AUCATZYL, and 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 FELIX clinical trial

Autolus' Phase 1b/2 clinical trial of obe-cel enrolled 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 was overall response rate, and the secondary endpoints included duration of response, MRD negative complete remission 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 market opportunity for AUCATZYL®, Autolus' development and commercialization of its product candidates, and the timing of data announcements and regulatory submissions. 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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