Autolus Therapeutics to Present Clinical Data Updates at the American Society of Hematology (ASH) Annual Meeting 2024 in One Oral Presentation and Three Poster Presentations

November 5, 2024 at 9:00 AM EST

LONDON, Nov. 05, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, announces the online publication of four abstracts submitted to the American Society of Hematology (ASH) Annual Meeting, to be held from December 7-10, 2024, in San Diego.

"The FELIX study's rich data set continues to provide important information in shaping our understanding of the use of obe-cel to treat adult r/r B-ALL patients," **said Dr. Christian Itin, Chief Executive Officer of Autolus.** "We are presenting additional data at ASH that suggests deep molecular remission that may predict better outcomes; shows the impact of bridging therapy on outcomes; highlights the costs associated with managing CRS and ICANS; and how using hematotoxicity scores can help identify patients who are more likely benefit from treatment with obe-cel."

Abstract 194508 – Oral presentation:
Title: Obecabtagene autoleucel (obe-cel) for Adult Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia (R/R B-ALL): Deep Molecular Remission May Predict Better Outcomes
Session Name: 613. Acute Lymphoblastic Leukemias: Therapies Excluding Allogeneic Transplantation: Risk Stratification and CAR-T Therapies
Session date and time: Monday, December 9, 2024; 4:30 PM - 6:00 PM PT
Presentation Time: 5:00 PM
Session room: Marriott Marquis San Diego Marina, Marriott Grand Ballroom 5-6
Publication Number: 963
Presenting Author: Dr. Elias Jabbour, Professor, Department of Leukemia, Division of Cancer Medicine, MD Anderson Cancer Center, Houston, TX

Summary: In this session we report on the correlation between depth of measurable residual disease (MRD)-negative remission and clinical outcomes in patients treated with obe-cel. Data demonstrated that 84% of responders for whom MRD by next-generation sequencing (NGS) could be analyzed achieved MRD $<10^{-6}$ leukemic cells which was associated with more durable responses, and higher event free survival (EFS) and overall survival (OS) rates than those observed in patients with MRD $\geq 10^{-4}$ and between 10^{-4} and 10^{-6} leukemic cells. Patients who did not achieve MRD $<10^{-6}$ had poorer outcomes.

Abstract 201514 – Poster presentation:
Title: Obecabtagene autoleucel (obe-cel) for Adult Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia (R/R B-ALL) in the Open-Label, Multi-Center, Global, Single-Arm, Phase Ib/II FELIX study: The Impact of Bridging Therapies on CAR T-Cell Expansion and Persistence
Session Name: 704. Cellular Immunotherapies: Early Phase Clinical Trials and Toxicities: Poster II.
Session date and time: Sunday, December 8, 2024; 6:00 PM - 8:00 PM PT
Session room: San Diego Convention Center, Halls G-H
Publication Number: 3458
Presenting Author: Dr. Jae H Park, Leukemia Specialist & Cellular Therapist, Memorial Sloan Kettering Cancer Center, New York, NY, USA

Summary: Patients in the FELIX study received bridging therapy (BT) (chemotherapy with or without Inotuzumab ozogamicin (INO) or Tyrosine kinase inhibitors (TKI), single-agent INO, single-agent TKI, steroids, or rituximab) per investigator decision; use of blinatumomab as a BT agent was not permitted. Analysis of BT indicated that INO is effective in reducing disease burden prior to obe-cel infusion. No apparent differences in expansion and long-term persistence of obe-cel were observed based on any of the BT evaluated, suggesting that long-term persistence of obe-cel is possible irrespective of BT and independent of initial tumor burden at LD. Reduction in tumor burden at LD through BT with INO led to more favorable survival outcomes compared with BT without INO, while maintaining a tolerable safety profile. A limitation of this study is the small number of patients who received BT with INO. Further studies comparing BT with INO-containing therapies or chemotherapy are warranted.

Abstract 205694 – Poster presentation:
Title: Healthcare Resource Utilization and Costs Associated with Managing CRS and ICANS in Patients with Relapsed/Refractory Adult B-Cell Acute Lymphoblastic Leukemia Receiving Obecabtagene autoleucel (obe-cel)
Session Title: 704. Cellular Immunotherapies: Early Phase Clinical Trials and Toxicities: Poster III
Session date and time: Monday, December 9, 2024; 6:00 PM - 8:00 PM PT
Session room: San Diego Convention Center, Halls G-H
Publication Number: 4837
Presenting Author: Dr. Bijal D Shah, Associate Member in the Department of Malignant Hematology Moffitt Cancer Center, Tampa, FL, USA

Summary: A secondary analysis of the data from the FELIX study was conducted to evaluate Facility-Related Healthcare Resource Utilization (HCRU) as a result of cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS) and estimate the overall costs for managing these adverse events (AEs) among patients with r/r B-ALL. HCRU for patients with treatment-emergent CRS and/or ICANS was monitored for 6 months post obe-cel administration. Data from the analysis demonstrated that management costs for CRS and ICANS events generally increase with severity, but these events were rare in the FELIX study. Of note, medication usage (in particular tocilizumab) and hospitalization/intensive care unit (ICU) costs were key drivers of overall CRS and/or ICANS management costs.

Abstract 208028 – Poster presentation:

Title: Risk Factors Associated with Sub-Optimal Outcomes Following Obecabtagene autoleucel (obe-cel) for Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia (R/R B-ALL): What We Have Learned from the FELIX Trial
Session Name: 704. Cellular Immunotherapies: Early Phase Clinical Trials and Toxicities: Poster III
Session date and time: Monday, December 9, 2024; 6:00 PM - 8:00 PM PT
Session room: San Diego Convention Center, Halls G-H
Publication Number: 4845
Presenting Author: Dr. Claire Roddie, MD, PhD, FRCPath, Associate Professor Haematology and Honorary Consultant Haematologist, Cancer Institute, University College London (UCL)

Summary: Immune effector cell-associated hematotoxicity is the most common side effect of CAR T therapy but the pathophysiology of prolonged hematotoxicity is poorly understood and the lack of consensus for its treatment presents challenges. The CAR-HEMATOTOX (HT) model was developed in large B-cell lymphoma for risk-stratifying patients prior to CAR T therapy for hematotoxicity and outcomes. Using the HT model from the analysis from the study, the HT score was found to be correlated with disease burden. Risk-stratification for hematotoxicity, using pre-lymphodepletion clinical parameters, together with disease burden, has the potential to be a useful tool for identifying patients more likely to benefit from obe-cel treatment and experience reduced toxicity. Patients with high-risk HT scores had consistently worse outcomes than patients with low-risk HT scores, leading to the view that further studies are warranted.

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)
Obecabtagene autoleucel (obe-cel) is a B-lymphocyte antigen CD19 (CD19) chimeric antigen receptor (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 relapsed/refractory (r/r) Adult B-cell Acute Lymphoblastic Leukemia (B-ALL) patients. The results of the FELIX trial, a pivotal trial for adult B-ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024. In the EU a regulatory submission to the EMA was accepted in April 2024, while in the UK, an MAA was submitted to MHRA in July 2024. In collaboration with Autolus’ academic partner, University College London, obe-cel is currently being evaluated in a Phase 1 clinical trial for B-cell non-Hodgkin lymphoma (B-NHL).

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 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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