Autolus Therapeutics Presents Clinical Data Updates at the American Society of Hematology (ASH) Annual Meeting 2024

December 9, 2024 at 7:30 PM EST

LONDON, Dec. 09, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), an early commercial-stage biopharmaceutical company developing next-generation programmed T cell therapies, announces an oral presentation and three poster presentations at the American Society of Hematology (ASH) Annual Meeting, being held from December 7-10, 2024, in San Diego.

“Our oral presentation at ASH this year with data from the FELIX trial demonstrates that obe-cel treatment produces a high incidence of deep molecular remission in r/r adult ALL patients, which correlates with better outcomes and is associated with longer event free survival (EFS) and overall survival (OS),” **said Dr. Christian Itin, Chief Executive Officer of Autolus.** “We’re also presenting three posters that aim to further our understanding of the use of obe-cel in a real-world context, suggesting the positive clinical outcomes of obe-cel even after effective bridging therapy; the reduced healthcare resource utilization costs associated with lower severity of ICANS and CRS; and how hematotoxicity scores could help identify patients who are at higher risk for hematotoxicity 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: Obe-cel treatment produces a high incidence of deep remission, which is predictive of better clinical outcomes. The majority of responders to obe-cel achieved deep remission to MRD <10–6 level (84%, 57/68), measured by clonoSEQ® NGS assay. Deep MRD remission correlates with better outcomes and is associated with longer event free survival (EFS) and overall survival (OS). The largest EFS and OS benefit was seen with lower tumor burden at lymphodepletion.

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 & 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: Comparable expansion and long-term persistence of obe-cel was observed with all the bridging therapies evaluated, suggesting that long-term persistence of obe-cel is possible irrespective of the bridging therapy and independent of disease burden at lymphodepletion. Bridging therapy with inotuzumab ozogamicin was effective in reducing disease burden prior to lymphodepletion and obe-cel infusion. Reduction in disease burden at lymphodepletion through bridging therapy led to improved event-free survival and overall survival compared to bridging therapy without INO and maintained a tolerable safety profile.

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: Grade ≥3 cytokine release syndrome (CRS) and/or immune effector cell-associated neurotoxicity syndrome (ICANS) are associated with increased healthcare resource utilization (HCRU) and costs, but these events were rare in the FELIX study. Costs for adverse events generally increase with event severity. Medication usage and intensive care unit costs were key drivers of CRS and/or ICANS management costs. Obe-cel has the potential to optimize utilization of resources and reduce costs associated with CAR T-cell therapy for patients with R/R B-ALL as a result of the low incidence of Grade ≥3 CRS and/or ICANS.

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 & 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: The CAR-HEMATOTOX risk score correlated with disease burden in this patient population - patients with high-risk CAR-HEMATOTOX scores had consistently worse outcomes than patients with low-risk CAR-HEMATOTOX scores. Risk-stratification, using pre-lymphodepletion clinical parameters together with disease burden, has the potential to be a useful tool for identifying patients at a high risk for hematotoxicity who may benefit from obe-cel treatment.

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 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 in the pivotal cohort 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 products and product candidates. 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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