NICE Recommends AUCATZYL® (obecabtagene autoleucel) as a Treatment Option for Adult Patients (≥26 years) with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (R/R B-ALL)[1]

November 25, 2025 at 4:00 AM EST

AUCATZYL® will be available through routine commissioning by the UK National Health Service (NHS)

LONDON, Nov. 25, 2025 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), an early commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation programmed T cell therapies, announces that the National Institute for Health and Care Excellence (NICE) has published draft guidance[1] recommending AUCATZYL® (obecabtagene autoleucel, or "obe-cel") [2] for use in the National Health Service (NHS) in England and Wales as a treatment option for adult patients (≥26 years) with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (r/r B-ALL). AUCATZYL will be available through routine commissioning by the NHS. Autolus intends to launch AUCATZYL in England and Wales imminently. Autolus also intends to pursue patient access to AUCATZYL through the Scottish Medical Consortium.

Dr. Christian Itin, Autolus Chief Executive Officer, said: "We believe AUCATZYL represents an important new treatment option for eligible adult r/r B-ALL patients. NHS clinical centres and UK patients participated in the development of AUCATZYL and we are looking forward to supporting patients and physicians in England and Wales now with the commercial product."

The UK Medicines and Healthcare products Regulatory Agency (MHRA) granted conditional marketing authorisation for AUCATZYL in April 2025.[3] The MHRA authorisation of AUCATZYL was based on the results of the FELIX study, an open-label, multi centre, single arm study in adult patients with relapsed or refractory B-cell acute lymphoblastic leukaemia, the results of which were published in the New England Journal of Medicine in November 2024.[4]

Henny Braund, Chief Executive of Anthony Nolan, said: "B-cell ALL is an aggressive disease with a poor prognosis, and there remains a need for additional treatment options. Today's announcement marks an important step towards enabling more patients in England and Wales to access this CAR T therapy. Anthony Nolan, together with our partners Leukaemia Care and Leukaemia UK, welcomes this progress and looks forward to working with the NHS to help make AUCATZYL available to adult relapsed or refractory B-cell ALL patients in due course."

Fiona Hazell, CEO, Leukaemia UK, said: "We are delighted that NICE has recommended AUCATZYL for use within the NHS in treating adults with relapsed or refractory B-cell acute lymphoblastic leukaemia. This represents an important development in the availability of treatment options for people affected by this type of leukaemia. This decision reflects the value of collaboration between Leukaemia UK, Anthony Nolan and Leukaemia Care to ensure patient voices were included in the NICE evaluation process. We're especially proud of our patient representative, whose compelling testimony was a vital part of the process. Leukaemia UK is proud to have contributed to this outcome, and we remain committed to supporting innovation and improving access to treatments that bring hope to people affected by leukaemia."

Obecabtagene autoleucel is an autologous CD19 CAR T cell therapy with a proprietary CD19 CAR, invented by a team led by Dr. Martin Pule, at University College London, along with collaborators at Great Ormond Street Hospital and University College London Hospitals. For further information regarding obecabtagene autoleucel, the Summary of Product Characteristics (SmPC), including a full list of side effects and adverse reactions, is available here.

About Autolus Therapeutics plc
Autolus Therapeutics plc (Nasdaq: AUTL) is an early commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation T cell therapies and candidates 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 and controlled T cell therapies that are designed to recognize target cells, break down their defense mechanisms and eliminate these cells. For more information, please visit www.autolus.com.

About AUCATZYL® (obecabtagene autoleucel, obe-cel)
AUCATZYL is a B-lymphocyte antigen CD19 (CD19) chimeric antigen receptor (CAR) T cell therapy designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T cell therapies. AUCATZYL is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. AUCATZYL was approved by the FDA for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia in November 2024, and was granted conditional marketing authorisation by MHRA in the UK and EMA in the EU in 2025. This means that further evidence on this medicinal product is awaited.

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 therapeutic potential and expected clinical benefits of AUCATZYL/obe-cel (obecabtagene autoleucel) for adult patients with r/r B-ALL and obe-cel in additional indications including LN and progressive MS; Autolus' ability to generate revenues from AUCATZYL, which is dependent upon maintaining significant market acceptance among physicians, patients and healthcare payors; the effect of payor reimbursement determinations and other market conditions on Autolus' ability to recognize revenue from AUCATZYL sales; Autolus' ability to obtain and maintain regulatory approval for obe-cel for adult r/r B-ALL in additional territories and the timing thereof; expectations regarding the commercialization and marketing of AUCATZYL for adult r/r B-ALL, including expanding into additional territories and the related timing of reaching patients in such territories; the development of obe-cel in autoimmune

indications and of additional product candidates, including statements regarding the initiation, timing, progress and the results of clinical studies or trials and related preparatory work; the period during which the results of clinical studies or trials will become available; commercialization, marketing and manufacturing capabilities and strategy for AUCATZYL; the timing or likelihood of regulatory filings and approvals for product candidates, along with regulatory developments in the US, EU, the UK and other foreign countries; size and growth potential of the markets for AUCATZYL and product candidates, if approved; and estimates regarding expenses, future revenue, capital requirements and needs for additional financing. 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 the impact of worsening macroeconomic conditions on Autolus' business, financial position, strategy and anticipated milestones, including Autolus' ability to conduct ongoing and planned clinical trials; Autolus' ability to obtain a clinical supply of current or future product candidates or commercial supply of AUCATZYL or any future approved products; Autolus' ability to obtain and maintain regulatory approval of its product candidates, including AUCATZYL and potential expansions into additional indications; Autolus' ability and plans in continuing to establish and expand a commercial infrastructure in the US and to successfully launch, market and sell AUCATZYL and any future approved products; Autolus' ability to successfully expand the approved indications for AUCATZYL or obtain marketing approval for AUCATZYL in additional geographies in the future; the delay of any current or planned clinical trials, whether due to patient enrollment delays or otherwise; Autolus' ability to successfully demonstrate the safety and efficacy of its product candidates and gain approval of its product candidates on a timely basis, if at all; competition with respect to market opportunities; the risk 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; 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 20, 2025 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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[1] NICE (2025), Final Draft Guidance, Obecabtagene autoleucel for treating relapsed or refractory B-cell precursor acute lymphoblastic leukaemia

[2] Autolus (2025), Summary of Product Characteristics, Aucatzyl 410 x 10^6 Cell Dispersion for infusion, https://www.medicines.org.uk/emc/product/100818/smpc#gref

[3] MHRA (2025), Public Assessment Report, Aucatzyl 410 x 10^6 Cell Dispersion for infusion, obecabtagene autoleucel, PLGB 46113/0001, Autolus Limited, https://mhraproducts4853.blob.core.windows.net/docs/adc68aea04685753e882423ead3d3965654e90ff

[4] Roddie et al (2024), Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukaemia, New England Journal of Medicine, 2024;391:2219-2230
https://www.nejm.org/doi/full/10.1056/NEJMoa2406526