Autolus Therapeutics Announces Preliminary Unaudited Fourth Quarter and Full Year 2025 Net Product Revenue, Pipeline Advancements and Outlook for 2026

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- *Company expects preliminary unaudited AUCATZYL® net product revenue of approximately $24 million for the fourth quarter of 2025 and approximately $75 million for the full year of 2025*
- *Autolus anticipates full year 2026 AUCATZYL® net product revenue of $120 million to $135 million*
- *Independent real-world AUCATZYL® data from ROCCA consortium confirm high level of clinical activity with favorable safety profile*
- *Focus for 2026 is:*
    - *Driving AUCATZYL® top line growth*
    - *Optimizing manufacturing operation to improve gross margin and innovating on next generation manufacturing platform*
    - *Progressing the CATULUS, LUMINA and BOBCAT trials to expand the utility of obe-cel in pediatric hem-oncology and autoimmune indications*

LONDON and Gaithersburg, Md., Jan. 12, 2026 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation programmed T cell therapies, today announced preliminary unaudited net product revenue from sales of AUCATZYL® (obecabtagene autoleucel; obe-cel) for the fourth quarter and full year of 2025. The Company also announced pipeline advancement updates and anticipated future milestones.

AUCATZYL® 2025 Preliminary Unaudited Net Product Revenues, Commercial Updates and 2026 Revenue Guidance

Dr. Christian Itin, Chief Executive Officer of Autolus, said: "We had a successful launch of AUCATZYL in the US with full year sales well above expectations and more than 60 centers offering treatment. We established reliable, high-quality product delivery with short and consistent turn-around time. Parallel to the launch and independent from the Company, the ROCCA consortium collected real-world data for AUCATZYL in adult r/r B-ALL patients and presented initial data at ASH 2025. The real-world data confirmed a high level of clinical activity and a favorable safety profile for AUCATZYL consistent with prior clinical trial results, and we believe this positive customer experience will be a key driver for the future growth of AUCATZYL in 2026.

"In addition to our launch of AUCATZYL in the US, we obtained regulatory approvals in the UK and EU. We successfully navigated the challenging pricing and reimbursement process with NICE, establishing cost effectiveness of AUCATZYL for the NHS and initiating our commercial launch in the UK in December under routine commissioning – a first for a CAR T therapy in the UK."

Based on preliminary unaudited financial information, Autolus expects net product revenue from sales of AUCATZYL to be approximately $24 million[1] for the fourth quarter of 2025. Net product revenues for the full year of 2025, the first year of commercial sales, are expected to be approximately $75 million[1]. The Company plans to report its fourth quarter and full year 2025 financial results in March 2026.

For 2026, the Company projects net product revenue for AUCATZYL of between $120 million to $135 million.

Pipeline Updates and Upcoming Clinical Milestones

Dr. Matthias Will, Chief Development Officer of Autolus, said: "In 2025 we reported strong initial clinical data for the Phase 1 CATULUS trial in pediatric r/r B-ALL patients and in the Phase 1 CARLYSLE trial in patients with severe lupus erythematosus. Both data sets form a compelling basis for progressing those studies in pediatric B-ALL and in lupus nephritis to Phase 2. With this strong foundation of clinical data, Phase 2 studies enrolling and demonstrated commercial and manufacturing capabilities, we believe Autolus is well positioned to drive growth with obe-cel in additional and significant indications."

Obe-cel data in pediatric r/r B-ALL

- Preliminary data from the CATULUS Phase 1 trial of obe-cel in pediatric relapsed or refractory (r/r) B-ALL patients were presented at the American Society of Hematology (ASH) Annual Meeting. Obe-cel demonstrated high remission rates in pediatric patients with high-risk r/r B-ALL with overall response rate (ORR) of 95.5%. Low rates of high-grade cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) were observed, consistent with obe-cel's adult safety profile. Autolus is now advancing obe-cel into the Phase 2 portion of the trial and expects to have the trial fully enrolled in the first half of 2027.

Obe-cel in lupus nephritis (LN)

- Data from the ongoing Phase 1 CARLYSLE trial in patients with severe refractory systemic lupus erythematosus (srSLE) were reported at the American Society of Hematology (ASH) Annual Meeting. All patients show deep B-cell depletion after infusion, suggesting an immune reset. No ICANS or high-grade CRS were observed in the nine patients evaluable for safety.
- Data support progressing obe-cel as a treatment for LN and 50 million cells was selected as the recommended Phase 2 dose. Autolus has previously aligned with the US Food and Drug Administration (FDA) on a Phase 2 trial design in LN and potential registrational path to approval. The LUMINA trial is now enrolling.

Obe-cel in progressive multiple sclerosis (MS)

- Autolus is advancing obe-cel into initial clinical development to explore treatment in progressive MS. The first patient in the BOBCAT trial was dosed in October 2025. The Phase 1 trial, expected to include up to 18 adult patients, will determine the safety, tolerability, and preliminary efficacy of obe-cel in participants with refractory progressive forms of MS. Initial data from the trial are expected to be reported at the end of 2026.

AUTO8 in light-chain amyloidosis

- The first patient was dosed in the Phase 1 ALARIC trial in AL amyloidosis and initial data is expected to be reported at the end of 2026.

Operational Updates & 2026 Outlook

Dr. Christian Itin concluded: “Our 2026 commercial focus for AUCATZYL is to build on the strong center presence and positive physician experience to drive top line growth, while improving margins by reducing our manufacturing costs per batch. Our development focus is on progressing our pivotal pediatric ALL CATLULUS and lupus nephritis LUMINA studies and the exploratory BOBCAT study in progressive multiple sclerosis. Our plans for innovation will focus on manufacturing technology and European market access.”

Increasing patient numbers in 2026 will improve manufacturing plant utilization and together with operational efficiencies, Autolus expects a shift from previously reported negative gross margin to positive gross margin in 2026.

Autolus has initiated an overall manufacturing life cycle plan to facilitate additional cost reductions and gross margin improvements as the Company plans to expand obe-cel into new indications and pursue larger market opportunities. The initiatives are focused on: 1) optimizing the Company’s current manufacturing operating model; 2) enhancing automation opportunities for the Company’s existing manufacturing process; and 3) developing a next-generation manufacturing platform with a step change in the cost and capacity profile. The Company plans to provide a detailed update on these plans in mid-2026.

Based on current operating plans, including anticipated AUCATZYL® net revenues, Autolus expects that its current and projected cash, cash equivalents and marketable securities will be sufficient to fund the Company’s operations into Q4 2027.

Financial Disclosure Advisory[1]
This press release contains certain estimated preliminary unaudited financial results for the fourth quarter and year ended December 31, 2025. These estimates are based on the information available to the Company at this time. The Company’s financial closing procedures for the fourth quarter and year ended December 31, 2025 are not yet complete and, as a result, actual results may vary from the estimated preliminary results presented here due to the completion of the Company’s financial closing and audit procedures. The estimated preliminary financial results have not been audited or reviewed by the Company’s independent registered public accounting firm. These estimates should not be viewed as a substitute for the Company’s full interim or annual financial statements.

About Autolus Therapeutics plc
Autolus Therapeutics plc (Nasdaq: AUTL) is a 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 better recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has a marketed therapy, 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 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 on November 8, 2024, and was granted conditional marketing authorization by MHRA in the UK and EMA in the EU in 2025.

INDICATION
AUCATZYL® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **Cytokine Release Syndrome (CRS) occurred in patients receiving AUCATZYL. Do not administer AUCATZYL to patients with active infection or inflammatory disorders. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS *[see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.1)].***

- **Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), including fatal or life-threatening reactions, occurred in patients receiving AUCATZYL, including concurrently with CRS or after CRS resolution. Monitor for neurologic signs and symptoms after treatment with AUCATZYL. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage neurologic toxicities. Provide supportive care and/or corticosteroids, as needed *[see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.2)].***

- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies *[see Warnings and Precautions (5.8)].***

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS)

Cytokine Release Syndrome (CRS) occurred following treatment with AUCATZYL. CRS was reported in 75% (75/100) of patients including Grade 3 CRS in 3% of patients. The median time to onset of CRS was 8 days following the first infusion (range: 1 to 23 days) with a median duration of 5 days (range: 1 to 21 days). The most common manifestations of CRS included fever (100%), hypotension (35%), and hypoxia (19%).

Cytokine Release Syndrome (CRS) occurred following treatment with AUCATZYL. CRS was reported in 75% (75/100) of patients including Grade 3 CRS in 3% of patients. The median time to onset of CRS was 8 days (range: 1 to 23 days) with a median duration of 5 days (range: 1 to 21 days). Sixty-eight percent of patients (51/75) experienced CRS after the first infusion, but prior to the second infusion of AUCATZYL with a median time to onset of 6 days (range: 1 to 10 days). Among patients with CRS, the most common manifestations of CRS included fever (100%), hypotension (35%) and hypoxia (19%). The primary treatment for CRS was tocilizumab (73%; 55/75), with patients also receiving corticosteroids (21%; 16/75).

Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS. During and following treatment with AUCATZYL, closely monitor patients for signs and symptoms of CRS daily for at least 7 days following each infusion. Continue to monitor patients for CRS for at least 2 weeks following each infusion with AUCATZYL. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, immediately evaluate the patient for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines.

Neurologic Toxicities

Neurologic toxicities including Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which were fatal or life-threatening, occurred following treatment with AUCATZYL. Neurologic toxicities were reported in 64% (64/100) of patients, including Grade ≥ 3 in 12% of patients.

The median time to onset of neurologic toxicities was 10 days (range: 1 to 246 days) with a median duration of 13 days (range: 1 to 904 days). Fifty-five percent of patients (35/64) experienced neurologic toxicities after the first infusion but prior to the second infusion of AUCATZYL with a median time to onset of 6 days (range: 1 to 11 days). Among patients with neurologic toxicities, the most common symptoms (> 5%) included ICANS (38%), headache (34%), encephalopathy (33%), dizziness (22%), tremor (13%), anxiety (9%), insomnia (9%), and delirium (8%).

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS)

ICANS events occurred in 24% (24/100) of patients, including Grade ≥ 3 in 7% (7/100) of patients. Of the 24 patients who experienced ICANS, 33% (8/24) experienced an onset after the first infusion, but prior to the second infusion of AUCATZYL. The median time to onset for ICANS events after the first infusion was 8 days (range: 1 to 10 days) and 6.5 days (range: 2 to 22 days) after the second infusion, with a median duration of 8.5 days (range: 1 to 53 days). Eighty-eight percent (21/24) of patients received treatment for ICANS. All treated patients received high-dose corticosteroids and 42% (10/24) of patients received anti-epileptics prophylactically. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage ICANS.

During and following AUCATZYL administration, closely monitor patients for signs and symptoms of Neurologic Toxicity/ICANS. Following treatment with AUCATZYL, monitor patients daily for at least 7 days. Continue to monitor patients for at least 2 weeks following treatment with AUCATZYL. Avoid driving for at least 2 weeks after each infusion. Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity/ ICANS occur. At the first sign of Neurologic Toxicity/ICANS, immediately evaluate patients for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines.

Prolonged Cytopenias

Patients may exhibit cytopenias including anemia, neutropenia, and thrombocytopenia for several weeks after treatment with lymphodepleting chemotherapy and AUCATZYL. In patients who were responders to AUCATZYL, Grade ≥ 3 cytopenias that persisted beyond Day 30 following AUCATZYL infusion were observed in 71% (29/41) of patients and included neutropenia (66%, 27/41) and thrombocytopenia (54%, 22/41). Grade 3 or higher cytopenias that persisted beyond Day 60 following AUCATZYL infusion was observed in 27% (11/41) of patients and included neutropenia (17%, 7/41) and thrombocytopenia (15%, 6/41). Monitor blood counts after AUCATZYL infusion.

Infections

Severe, including life-threatening and fatal infections occurred in patients after AUCATZYL infusion. Non-COVID-19 infections of all grades occurred in 67% (67/100) of patients. Grade 3 or higher non-COVID-19 infections occurred in 41% (41/100) of patients. AUCATZYL should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after AUCATZYL infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.
Grade 3 or higher febrile neutropenia was observed in 26% (26/100) of patients after AUCATZYL infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically

indicated.
Viral reactivation, potentially severe or life-threatening, can occur in patients treated with drugs directed against B cells. There is no experience with manufacturing AUCATZYL for patients with a positive test for human immunodeficiency virus (HIV) or with active hepatitis B virus (HBV) or active hepatitis C virus (HCV). Perform screening for HBV, HCV and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

Hypogammaglobulinemia
Hypogammaglobulinemia and B-cell aplasia can occur in patients after AUCATZYL infusion. Hypogammaglobulinemia was reported in 10% (10/100) of patients treated with AUCATZYL including Grade 3 events in 2 patients (2%).
Immunoglobulin levels should be monitored after treatment with AUCATZYL and managed per institutional guidelines including infection precautions, antibiotic or antiviral prophylaxis, and immunoglobulin replacement.
The safety of immunization with live viral vaccines during or following treatment with AUCATZYL has not been studied. Vaccination with live viral vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy treatment, during AUCATZYL treatment, and until immune recovery following treatment with AUCATZYL.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS)
HLH/MAS including fatal and life-threatening reactions occurred after treatment with AUCATZYL. HLH/MAS was reported in 2% (2/100) of patients and included Grade 3 and Grade 4 events with a time of onset at Day 22 and Day 41, respectively. One patient experienced a concurrent ICANS events after AUCATZYL infusion and died due to sepsis with ongoing HLH/MAS that had not resolved. Administer treatment for HLH/MAS according to institutional standards.

Hypersensitivity Reactions
Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO), an excipient used in AUCATZYL. Observe patients for hypersensitivity reactions during and after AUCATZYL infusion.

Secondary Malignancies
Patients treated with AUCATZYL may develop secondary malignancies. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes. Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Autolus at 1-855-288-5227 for reporting and to obtain instructions on the collection of patient samples for testing.

Adverse Reactions
The safety of AUCATZYL was evaluated in the FELIX study in which 100 patients with relapsed or refractory B-cell acute lymphoblastic leukemia (B-ALL) received AUCATZYL at a median dose of 410×10^6 CD19 CAR-positive viable T cells (range: 10 to 480×10^6 CD19 CAR-positive viable T cells with 90% of patients receiving the recommended dose of 410×10^6 +/- 25%).

The most common serious adverse reactions of any Grade (incidence ≥ 2%) included infections-pathogen unspecified, febrile neutropenia, ICANS, CRS, fever, bacterial infectious disorders, encephalopathy, fungal infections, hemorrhage, respiratory failure, hypotension, ascites, HLH/MAS, thrombosis and hypoxia. Nine patients (9%) experienced fatal adverse reactions which included infections (sepsis, pneumonia, peritonitis), ascites, pulmonary embolism, acute respiratory distress syndrome, HLH/MAS and ICANS. Of the 9 patients, five patients who died from infections had pre-existing and ongoing neutropenia prior to receiving bridging therapy, lymphodepletion chemotherapy treatment and/or AUCATZYL.

Please see full **Prescribing Information,** including **BOXED WARNING** and Medication Guide.

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' future expectations, plans and prospects, including the anticipated level of fourth quarter 2025 and full year 2025 AUCATZYL net product revenue and guidance on 2026 AUCATZYL net product revenue and gross margin; Autolus' anticipated cash runway; the expected timing of the release of Autolus' fourth quarter and full year 2025 financial results in March 2026; 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; 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, marketing and manufacturing 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; Autolus' plans to expand, develop and enhance its manufacturing activities; and Autolus' pursuit of expanded market access across Europe. 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 identified in the section titled "Risk Factors" in Autolus' Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC), on March 20, 2025 and its subsequent Quarterly Reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the SEC. 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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