

12 November 2025

**Syncona Limited**  
**("Syncona" or the "Company")**

**Autolus Therapeutics Reports Third Quarter 2025 Financial Results and Business Updates**

Syncona Ltd, a leading life science investor, notes that its portfolio company Autolus Therapeutics plc (Nasdaq: AUTL) ("Autolus") announced its operational and financial results for the third quarter ended 30 September 2025. Key highlights are as follows:

- The company reported Q3 2025 AUCATZYL® net product revenue of 21.1 million and deferred revenue of 7.6 million; 60 authorized treatment centres achieved ahead of target
- Clinical execution and data generation to support market growth and expansion continues; data in severe refractory systemic lupus erythematosus (srSLE) show no ICANS or high-grade CRS, demonstrate achievement of definition of remission in SLE (DORIS) in 83% (n=5/6) of patients and complete renal response (CRR) in 50% (n=3/6) of patients
- Leadership team bolstered to support next phase of growth and optimization of business operations

Autolus' announcement is copied below and can be accessed at the company's investor website at <https://www.autolus.com/investor-relations/news>. To listen to the webcast and view the accompanying slide presentation, please go to: <https://www.autolus.com/investor-relations/events/>.

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*Forward-looking statements - this announcement contains certain forward-looking statements with respect to the portfolio of investments of Syncona Limited. These statements and forecasts involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors that could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. In particular, many companies in the Syncona Limited portfolio are conducting scientific research and clinical trials where the outcome is inherently uncertain and there is significant risk of negative results or adverse events arising. In addition, many companies in the Syncona Limited portfolio have yet to commercialise a product and their ability to do so may be affected by operational, commercial and other risks.*

*Syncona Limited seeks to achieve returns over the long term. Investors should seek to ensure they understand the risks and opportunities of an investment in Syncona Limited, including the information in our published documentation, before investing.*

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- Leadership team bolstered to support next phase of growth and optimization of business operations
- Conference call to be held today at 8:30 am EST / 1:30 pm GMT; conference call participants should pre-register using the link at the bottom of this press release

**LONDON & Gaithersburg, MD, November 12, 2025** – Autolus Therapeutics plc (Nasdaq: AUTL), an early commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation programmed

T cell therapies, announces its operational and financial results for the third quarter ended September 30, 2025.

"Through three quarters of launch, we are encouraged by our progress to increase the overall market in r/r B-ALL, reaching patients who previously may not have been considered for CAR T therapy. With mounting experience we see physician enthusiasm for AUCATZYL increasing, validated by real world data from the ROCCA Consortium to be presented at the ASH Annual Meeting in December," said **Dr. Christian Itin, Chief Executive Officer of Autolus**. "Despite an expected temporary lag in Q3 sales based on the change in CMS reimbursement policy that occurred in Q2, we executed well on new patient starts and project a strong full year of sales."

**Dr. Itin continued,** "Building on our strong commercial and manufacturing performance, we enter our next phase of growth for obe-cel focused on three key objectives. First, increasing market share within the indicated adult ALL population; second, based on strong Phase 1 data sets we are conducting potential pivotal studies in pediatric ALL and in severe lupus nephritis to broaden the utility and commercial opportunity of obe-cel; and finally, we continue to innovate on manufacturing technology as a foundation for further expansion of access to CAR T therapies."

### **Product and Pipeline Updates:**

- **AUCATZYL® Launch**
  - o Autolus reported net product revenue of 21.1 million for the three months ended September 30, 2025 and deferred revenue of 7.6 million as of September 30, 2025.
  - o The Company has 60 centers fully activated in the U.S. as of November 12, 2025, achieving the target of 60 activated centers prior to year-end.
  - o Patient access to AUCATZYL continues to increase, with coverage secured for greater than 90% of total U.S. medical lives.
  - o Data from the ROCCA (Real-World Outcomes Collaborative for CAR T in Adult ALL) database evaluating patient characteristics, toxicity and response after real-world administration of AUCATZYL (obecabtagene autoleucel) and TECARTUS (brexucabtagene autoleucel) for relapsed acute lymphoblastic leukemia with r/r ALL will be presented at the American Society of Hematology (ASH) Annual Meeting.
- **Obe-cel data in pediatric r/r B-ALL**
  - o Data from the ongoing Phase Ib/II CATULUS study evaluating the safety and efficacy of obe-cel in patients under 18 years with CD19-positive r/r B-ALL or B-cell Non-Hodgkin Lymphoma (NHL) will be presented at the American Society of Hematology Annual Meeting. Data show the safety profile of obe-cel in pediatric patients is consistent with that previously reported in adults, with low rates of high-grade cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Overall response rate (ORR) was high at 95% and nearly 90% of responders had ongoing remission at data cut-off. Additional data will be presented in a poster presentation at the ASH Annual Meeting on December 7, 2025, from 6:00 - 8:00pm ET.
  - o In October 2025, the U.S. Food and Drug Administration (FDA) granted regenerative medicine advanced therapy (RMAT) designation to obe-cel for the treatment of pediatric patients with r/r B-ALL. The RMAT designation is a program created under the 21st Century Cures Act to accelerate development and regulatory review of regenerative medicine therapies, including cell therapies, intended to treat serious or life-threatening diseases.
- **Obe-cel in lupus nephritis (LN)**
  - o [Data from the Phase 1 CARLYSLE clinical trial were presented](#) on October 28, 2025, at the American College of Rheumatology (ACR) Convergence 2025. Data in severe refractory systemic lupus erythematosus (srSLE) suggests obe-cel is well tolerated with no ICANS or high-grade CRS. Preliminary efficacy data demonstrate achievement of definition of remission in SLE (DORIS) in 83% (n=5/6) of patients and complete renal response (CRR) in 50% (n=3/6) of patients. All responses and remissions are ongoing with no evidence of disease activity at a median follow-up of 8.9 months (range 6-13.8 months).
  - o Additional findings from the ongoing CARLYSLE study will be presented in an oral presentation at the American Society of Hematology (ASH) Annual Meeting 2025 on December 8, 2025, at 11:30am ET. Data show the B-cell reconstitution profiles suggest that obe-cel may induce a reset of pathologic autoimmunity. Updated Phase 1 data with longer follow-up, and data in patients who received 100×10<sup>6</sup> CAR T-cells will be presented.
  - o The Company has previously aligned with the FDA on the Phase 2 trial design and potential registrational path to approval. Data to date supported progressing into the Phase 2 LUMINA trial. The first patient is expected to be dosed prior to year-end 2025.
- **Obe-cel in progressive MS**
  - o Autolus is advancing obe-cel into initial clinical development 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 multiple sclerosis. The primary endpoint is to assess safety and tolerability of obe-cel. Key secondary endpoints include evaluating the preliminary efficacy of obe-cel using change from baseline in standard efficacy measures.
- **Early-stage pipeline programs and collaborations**
  - o In November 2025, Moderna announced that the first patient has been dosed in a Phase 1/2 study of mRNA-2808, an investigational mRNA-based T-cell engager for participants with relapsed or refractory multiple myeloma. mRNA-2808 utilizes an Autolus proprietary binder that was licensed to Moderna in 2022.
  - o Long term follow up from the AUTO8 MCARTY study in multiple myeloma will be presented in a poster presentation at the ASH Annual Meeting:

**Abstract ID:** abs25-14286

**Title:** CAR-T cells co-targeting BCMA and CD19 in RRMM: Results from the UKMRA Phase 1 MCARTY

**Abstract:** CAR T cells targeting B2M and CD19 in relapsed/refractory multiple myeloma

**Date:** December 7, 06:00 PM - 08:00 PM EST

**Location:** OCCC - West Halls B3-B4

**Presenting Author:** Lydia Lee, MBBS, MRCP, MRCPATH (Haem), PhD

The first patient in the AUTO8 ALARIC study in AL Amyloidosis is expected to be dosed prior to year-end 2025.

- o Autolus' translational programs with UCL continue to fuel its early-stage pipeline, providing a cost-efficient path to development to support long-term growth.

### **Operational Updates:**

Autolus announced leadership team changes to support the next phase of commercial growth, margin improvement and market expansion.

- Cintia Piccina was appointed U.S. Chief Commercial Officer and Country General Manager to lead ongoing momentum in AUCTAZYL® U.S. launch and drive future growth. Cintia brings to Autolus extensive cellular therapy experience having led teams that successfully launched and commercialized multiple products in Novartis, Bluebird/2seventy bio, Allovir and Adaptimmune, where she was most recently the Chief Commercial Officer.
- Miranda Neville was appointed Chief Technical Officer to drive manufacturing optimization, succeeding David Brochu who will continue as an advisor. Ms. Neville joined Autolus in 2018 from the consulting firm AllianceBIO where she spent four years as a Partner and supported several clinical stage and commercial biopharmaceutical companies. Ms. Neville began her career at Human Genome Sciences (HGS). She spent 10 years at HGS in a variety of roles including Manufacturing, Engineering & Program Management, prior to its acquisition by GlaxoSmithKline.
- Patrick McIlvenny was appointed Senior Vice President, Finance and Chief Accounting Officer. Before joining Autolus, Mr. McIlvenny served as Senior Vice President, Chief Accounting Officer for Horizon Therapeutics plc, until the acquisition of Horizon by Amgen, and in various finance roles of increasing responsibilities at Ardagh Group S.A and Elan Corporation plc. Prior to joining Elan, Mr. McIlvenny worked with PricewaterhouseCoopers and Deloitte. Mr. McIlvenny is a Fellow of the Institute of Chartered Accountants in England and Wales.

Dr. Itin commented, "Our new team members bring a breadth of leadership experience and will focus on market growth, strategic planning and operational excellence driving growth and efficiency of the ALL business. We are grateful to our prior team members who were instrumental in setting our organization on the right course for a successful launch."

### **Summary of Anticipated News Flow:**

ALL: Initial clinical data from CATULUS trial in pediatric ALL December 7, 2025

SLE: Longer-term follow up data from CARLYSLE trial December 8, 2025

LN: Expect to dose first patient in Phase 2 LUMINA trial By year-end 2025

ALA: Expect to dose first patient in Phase 1 ALARIC trial in AL amyloidosis By year-end 2025

ALL: acute lymphoblastic leukemia

SLE: systemic lupus erythematosus

LN: lupus nephritis

ALA: light-chain amyloidosis

### **Financial Results for the Quarter Ended September 30, 2025**

Product revenue, net for the three months ended September 30, 2025, was 21.1 million. Deferred revenue balance at September 30, 2025, was 7.6 million, representing product that was shipped and received by centers but not yet dosed.

Cost of sales for the three months ended September 30, 2025, totaled 28.6 million. This amount includes the cost of all commercial product delivered to the authorized treatment centers, including product delivered but not yet recorded as product revenue which is captured as deferred revenue. Additionally, cost of sales includes any cancelled orders in the period, patient access program product, inventory reserves and write-offs and 3<sup>rd</sup> party royalties for certain technology licenses.

Research and development expenses decreased from 40.3 million to 27.9 million for the three months ended September 30, 2025, compared to the same period in 2024. This change was primarily due to commercial manufacturing-related employee and infrastructure costs shifting to cost of sales and inventory.

Selling, general and administrative expenses increased from 27.3 million to 36.3 million for the three months ended September 30, 2025, compared to the same period in 2024. This increase was primarily due to salaries and other employment-related costs, driven by increased headcount supporting commercialization activities.

Loss from operations for the three months ended September 30, 2025, was 71.6 million, as compared to 67.9 million for the same period in 2024.

Net loss was 79.1 million for the three months ended September 30, 2025, compared to 82.1 million for the same period in 2024. Basic and diluted net loss per ordinary share for the three months ended September 30, 2025, totaled (0.30), compared to basic and diluted net loss per ordinary share of (0.31) for the same period in 2024.

Cash, cash equivalents and marketable securities at September 30, 2025, totalled 367.4 million, as compared to 588.0 million at December 31, 2024. The decrease was primarily driven by net cash used in operating activities and impacted by a delayed cash receipt of approximately 20.1 million in the Company's 2023 R&D tax credit expected from the UK HMRC.

Autolus estimates that, with its current cash and cash equivalents and marketable securities, the Company is well capitalized to drive the launch and commercialization of obe-cel in r/r B-ALL and to generate data in the LN and pALL potential pivotal trials and MS Phase 1 trial

**Financial Results for the Period Ended September 30, 2025**  
**Selected Consolidated Balance Sheet Data**  
(In thousands)

	<b>September 30 2025</b>	<b>December 31 2024</b>
<b>Assets</b>		
Cash and cash equivalents	86,124	227,380
Marketable securities - Available-for-sale debt securities	281,289	360,643
Total current assets	514,577	660,929
Total assets	661,947	782,725
<b>Liabilities and shareholders' equity</b>		
Total current liabilities	83,071	60,743
Total liabilities	396,495	355,400
Total shareholders' equity	265,452	427,325

**Selected Consolidated Statements of Operations and Comprehensive Loss Data**  
(In thousands, except share and per share amounts)

	<b>Three Months Ended September 30, 2025</b>	<b>September 30, 2024</b>	<b>Nine Months Ended September 30, 2025</b>	<b>September 30, 2024</b>
Product revenue, net	21,144	-	51,049	-
License revenue	50	--	50	10,091
<b>Cost and operating expenses:</b>				
Cost of sales	(28,643)	-	(71,039)	-
Research and development expenses, net	(27,892)	(40,323)	(82,056)	(107,606)
Selling, general and administrative expenses	(36,280)	(27,330)	(96,079)	(67,410)
Loss on disposal of property and equipment	-	(223)	(3)	(223)
Impairment of operating lease right-of-use assets and related property and equipment	-	-	-	(414)
<b>Loss from operations</b>	<b>(71,621)</b>	<b>(67,876)</b>	<b>(198,078)</b>	<b>(165,562)</b>
<b>Total other (expenses) income, net</b>	<b>(6,965)</b>	<b>(14,196)</b>	<b>4,037</b>	<b>(27,428)</b>
<b>Net loss before income tax</b>	<b>(78,586)</b>	<b>(82,072)</b>	<b>(194,041)</b>	<b>(192,990)</b>
Income tax expenses	(532)	(22)	(3,155)	(66)
<b>Net loss attributable to ordinary shareholders</b>	<b>(79,118)</b>	<b>(82,094)</b>	<b>(197,196)</b>	<b>(193,056)</b>
Other comprehensive (loss) income, net of tax	(5,782)	27,010	24,254	28,094
<b>Total comprehensive loss</b>	<b>(84,900)</b>	<b>(55,084)</b>	<b>(172,942)</b>	<b>(164,962)</b>
Basic and diluted net loss per ordinary share	(0.30)	(0.31)	(0.74)	(0.77)
Weighted-average basic and diluted ordinary shares	266,141,431	266,084,589	266,136,518	255,480,521

## Conference Call

Management will host a conference call and webcast today at 8:30am EST/1:30pm GMT to discuss the company's financial results. Conference call participants should pre-register using this [link](#) to receive the dial-in numbers and a personal PIN, which are required to access the conference call. A simultaneous audio webcast and replay will be accessible on the events section of Autolus' website at <https://www.autolus.com/investor-relations-media/events/>.

## 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 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](http://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  $\geq 3$  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  $\geq 3$  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  $\geq 3$  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  $410 \times 10^6$  CD19 CAR-positive viable T cells (range: 10 to  $480 \times 10^6$  CD19 CAR-positive viable T cells with 90% of patients receiving the recommended dose of  $410 \times 10^6 \pm 25\%$ ).

The most common serious adverse reactions of any Grade (incidence  $\geq 2\%$ ) 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 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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