Autolus Therapeutics Reports First Quarter 2023 Financial Results and Operational Progress

May 4, 2023

- *Obe-cel, a potentially transformational treatment for relapsed/refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL), on track for next data update at ASCO and EHA, with a Biologics License Application (BLA) submission to the US FDA planned by end of the year*
- *Establishing core distribution capabilities required to commercialize a CAR T-cell therapy in the US by selecting Cardinal Health as commercial distribution partner*
- *Purpose-built commercial manufacturing facility on track to commence Good Manufacturing Practice (GMP) operations in H2 2023*
- *Conference call to be held today at 8:30 am EDT/1:30 pm BST*

LONDON, May 04, 2023 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its operational and financial results for the quarter ended March 31, 2023.

"It has been a busy quarter as we continue to execute on delivering on our obe-cel strategy in order to bring this innovative and potentially transformative treatment to an underserved adult Acute Lymphoblastic Leukemia (ALL) patient population," **said Dr. Christian Itin, Chief Executive Officer of Autolus.** "We look forward to presenting data from all patients treated in the FELIX study in an oral presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, as well as data at the European Hematology Association (EHA) 2023 Congress, both in June, with longer term follow up data expected at the American Society of Hematology (ASH) meeting at the end of the year."

"Meanwhile, we continue to advance plans for the submission of a BLA for obe-cel at the end of the year and working towards commercial launch in 2024, subject to required regulatory approval. Post period end we selected Cardinal Health as the US commercial distribution partner for obe-cel and we continue to build out our own commercial infrastructure as we look to on-board centers over the course of this year. Our purpose-built commercial manufacturing facility is on track for the commencement of Good Manufacturing Practice (GMP) operations in H2 2023 with an initial capacity of up to 2,000 batches per year, which we predict will be sufficient to serve global demand in adult ALL."

Key obe-cel Updates:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL – The FELIX Study*
  - Oral presentations of the FELIX pivotal study to be presented at ASCO and EHA. The Company expects data from the FELIX study to form the basis of a BLA submission for obe-cel to the FDA at the end of 2023 and plans to present longer term follow up data and subgroup analysis data at the American Society of Hematology (ASH) meeting in late 2023, as well as at medical conferences in H1 2024.

Obe-cel trials in collaboration with University College London

- *Obe-cel in r/r adult B-ALL patients – Phase 1 ALLCAR19 Study*
  - Long term follow-up data were presented at the Tandem Meetings: Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). The data demonstrated that 35% of adult B-ALL patients remained in complete remission at a median follow up of 36 months without the need for additional anti-leukemia therapy.
- *Obe-cel in r/r B-NHL and CLL patients – Phase 1 ALLCAR19 Extension Study*
  - Data presented at the ASH meeting in December 2022 demonstrated the potentially best-in-class profile of obe-cel supported by the data observed in B-cell non-Hodgkin lymphoma (NHL), with continued high levels of clinical activity paired with an encouraging tolerability profile across diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), follicular lymphoma (FL) and chronic lymphocytic leukemia (CLL). Patients continue to be enrolled into the study and the Company expects to publish the full results in a peer-reviewed journal.
- *Obe-cel in Primary CNS Lymphoma patients – Phase 1 CAROUSEL Study*
  - Data presented at the EHA meeting in June 2022 demonstrated first activity in primary CNS lymphoma. The study is fully enrolled, and the Company expects to publish the full results in a peer-reviewed journal.

- *AUTO1/22 in pediatric B-ALL patients – Phase 1 CARPALL Study*
    - Data presented at the European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting in April 2023 by the Company's UCL collaborators, showed favorable safety profile and good efficacy in a heavily pre-treated cohort of patients. Importantly, there were no observed antigen negative relapses observed as of the data cut-off date, indicating that the combining of our optimized CD22 CAR design with the CD19 CAR used in obe-cel may be effective in preventing antigen-loss driven relapse in pediatric B-ALL. The preclinical data supporting this program was published in *Molecular Therapy* in March 2023.

Early-stage pipeline – leveraging academic collaborations to generate opportunity for non-dilutive funding

- *AUTO4 in T Cell Lymphoma patients – Phase 1/2 LibrA T1 Study*
    - Autolus has optimized the manufacturing process for AUTO4 and is enrolling additional patients into the trial to evaluate this manufacturing change. The next update is planned as an oral presentation at the International Conference on Malignant Lymphoma in June 2023.

- *AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study*
    - AUTO8 is a next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. In collaboration with UCL, the Company initiated a study in Q1 2022. Patients continue to be enrolled and initial data is expected in 2023.

- *AUTO6NG in Neuroblastoma*
    - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. In collaboration with UCL, the Company is planning on initiating a clinical trial of AUTO6NG in 2023.

Key Operational Updates during Q1 2023

- The Company's new 70,000 square foot commercial manufacturing facility in Stevenage, UK has continued to progress on track. Key equipment installation and validation were completed by Autolus in Q1 2023 enabling operational qualifications commencing in Q2 2023. Activities are on track for the commencement of GMP operations in H2 2023. The facility has been designed for a capacity of 2,000 batches per year with the option to expand capacity as needed.

- Autolus is on schedule to complete the development work and report generation for the Chemistry Manufacturing and Controls (CMC) package planned to be submitted to the FDA. All work including process qualification activities in the new Stevenage facility is on track for submission of a BLA by the end of 2023.

- Announced a collaboration with Cabaletta Bio in January 2023. Autolus received an upfront payment for non-exclusive access to the RQR8 safety switch for use in Cabaletta's CD19-CAR T cell therapy program for the treatment of autoimmune disease, with the potential for near term option exercise fees and development and regulatory milestone payments. In addition, Autolus is entitled to receive royalties on net sales of all Cabaletta cell therapy products that incorporate the RQR8 safety switch.

- Announced two changes to the Board of Directors. The Company's non-executive Chairman, John H. Johnson, who has held the role since September 2021, will not stand for re-election at Autolus' upcoming annual shareholder meeting. Additionally, Dr. Jay T. Backstrom, who has served on Autolus' Board of Directors since August 2020, stepped down from Autolus' Board of Directors at the end of February 2023.

- Dr. Lucinda Crabtree will step down as CFO in August 2023. A search for a successor is under way.

Post Period End:

- Autolus selected Cardinal Health to provide core distribution capabilities required for U.S. commercialization of CAR T-cell therapies. Under the proposed agreement, Cardinal Health 3PL Services will establish essential capabilities for Autolus to commercialize a CAR T-cell therapy in the US, including a depot model that allows Autolus to maintain custody and physically position product closer to treatment sites during finalization of product release, with the goal of shortening vein-to-delivery times. In addition, Cardinal Health will help provide seamless order-to-cash capabilities.

- Autolus hosted a Virtual Capital Markets Day on Thursday, April 27, 2023, where members of the Executive Management Team and Key Opinion Leaders presented on the obe-cel commercial opportunity and positioning. A replay of the event is available on the Autolus website.

- In April 2023 Autolus announced data from the AUTO1/22 in a clinical trial of pediatric ALL patients at the EBMT Annual Meeting. This followed the publication of the preclinical work supporting this program in March in *Molecular Therapy*, 'Dual

targeting of CD19 and CD22 against B-ALL using a novel high sensitivity aCD22 CAR.'

- In April 2023 Autolus announced the publication of a paper in *Molecular Therapy Nucleic Acids*, 'Novel Fas-TNFR chimeras that prevent Fas ligand-mediated kill and signal synergistically to enhance CAR T-cell efficacy. The paper outlined how Fas-CD40 chimera can render T cell therapies resistant to FasL-mediated cell death and improve their effectiveness against solid tumors.

- In April 2023, Autolus moved funds to additional highly rated liquid money market funds. The limit to any one counterparty is less than 25% of the Company's total cash and cash equivalents balance.

Financial Results for the First Quarter Ended March 31, 2023

Cash and cash equivalents and restricted cash at March 31, 2023, totaled $343.4 million, as compared to cash of $382.8 million at December 31, 2022.

Net total operating expenses for the three months ended March 31, 2023, were $43.1 million, which included license revenue income of $1.3 million, as compared to net total operating expenses of $41.8 million, which included grant income of $0.2 million, for the same period in 2022.

Research and development expenses decreased by $2.7 million to $31.3 million for the three months ended March 31, 2023 from $34.0 million for the three months ended March 31, 2022 primarily due to:

- a decrease of $5.5 million in clinical trial and manufacturing costs which is offset by an increase of $0.8 million in manufacturing material costs due to increased validation activities undertaken, primarily relating to our obe-cel clinical product candidate,
- a decrease of $0.2 million in depreciation and amortization related to property, plant and equipment and intangible assets due to the reduction in our depreciable asset base,
- a decrease of $0.1 million in legal fees and professional consulting fees in relation to our research and development activities,
- an increase of $1.4 million in salaries and other employment related costs including share-based compensation expense, which was mainly driven by an increase in the number of employees engaged in research and development activities,
- an increase of $0.7 million related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations, and
- an increase of $0.2 million in facilities costs related to our new manufacturing facility, the "Nucleus", in Stevenage, United Kingdom as well increase in costs related to maintaining our current leased properties.

General and administrative expenses increased by $1.3 million to $9.3 million for the three months ended March 31, 2023 from $8.0 million for the three months ended March 31, 2022 primarily due to:

- an increase of $0.7 million in salaries and other employment related costs including share-based compensation expenses, which was mainly driven by an increase in the number of employees engaged in general and administrative activities,
- an increase of $0.7 million in commercial readiness costs due to increased commercial readiness activities being undertaken,
- an increase of $0.1 in general office supplies and expenses facilities costs due to the increase in space utilized for general and administrative activities,
- a decrease of $0.2 million primarily related to a reduction in directors' and officers' liability insurance premiums, legal and professional fees.

For the three months ended March 31, 2023, we recognized a loss on disposal of property and equipment of $3.8 million related to fixed assets no longer being utilized in the manufacturing facility exited in Stevenage, United Kingdom. There were no such disposals for the three months ended March 31, 2022.

Other income, net decreased to $0.8 million from $0.9 million for the three months ended March 31, 2023 and 2022, respectively. The decrease of $0.1 million is primarily due to the recognition of a lease termination loss arising from the termination and exit of one of our manufacturing suites in Stevenage, United Kingdom.

Interest income increased to $3.4 million for the three months ended March 31, 2023, as compared to $28,000 for the three months ended March 31, 2022. The increase in interest income of $3.4 million primarily relates to the increase in interest rates on our interest-bearing bank accounts and short-term investments during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022.

Interest expense increased to $4.9 million for the three months ended March 31, 2023 as compared to $1.8 million for the three months ended March 31, 2022. Interest expense is primarily related to the liability for future royalties and sales milestones, net associated with our strategic collaboration agreement with Blackstone.

Net loss attributable to ordinary shareholders was $39.8 million for the three months ended March 31, 2023, compared to $37.1 million for the same period in 2022. The basic and diluted net loss per ordinary share for the three months ended March 31, 2023, totaled $(0.23) compared to a basic and diluted net loss per ordinary share of $(0.41) for the three months ended March 31, 2022.

Autolus estimates that its current cash and cash equivalents on hand and anticipated future milestone payment from Blackstone will extend the Company's runway into 2025.

Unaudited Financial Results for the Quarter Ended March 31, 2023

Condensed Consolidated Balance Sheet

(In thousands, except share and per share amounts)

	March 31 2023	December 31 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 343,027	$ 382,436
Restricted cash	328	325
Prepaid expenses and other current assets	50,530	43,010
Total current assets	**393,885**	**425,771**
Non-current assets:		
Property and equipment, net	34,667	35,209
Prepaid expenses and other non-current assets	465	2,176
Operating lease right-of-use assets, net	26,861	23,210
Long-term deposits	1,821	1,832
Deferred tax asset	2,272	2,076
Total assets	**459,971**	**490,274**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	353	531
Accrued expenses and other liabilities	34,463	40,797
Operating lease liabilities, current	4,821	5,038
Total current liabilities	**39,637**	**46,366**
Non-current liabilities:		
Operating lease liabilities, non-current	22,495	19,218
Liability related to future royalties and sales milestones, net	130,805	125,900
Other long-term payables	114	116
Total liabilities	**193,051**	**191,600**
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 authorized as of March 31, 2023 and December 31, 2022; 173,074,510 shares issued and outstanding at March 31, 2023 and December 31, 2022	8	8
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	1,010,041	1,007,625
Accumulated other comprehensive loss	(33,257)	(38,898)
Accumulated deficit	(709,990)	(670,179)
Total shareholders' equity	**266,920**	**298,674**
Total liabilities and shareholders' equity	**$ 459,971**	**$ 490,274**

Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Grant income	$ —	$ 166

License revenue	1,292	—
Operating expenses:		
Research and development	(31,344)	(33,963)
General and administrative	(9,284)	(7,987)
Loss on disposal of property and equipment	(3,768)	—
Total operating expenses, net	**(43,104)**	**(41,784)**
Other income, net	782	860
Interest income	3,446	28
Interest expense	(4,905)	(1,790)
Total other expense, net	(677)	(902)
Net loss before income tax	**(43,781)**	**(42,686)**
Income tax benefit	3,970	5,624
Net loss attributable to ordinary shareholders	**(39,811)**	**(37,062)**
Other comprehensive loss:		
Foreign currency exchange translation adjustment	5,641	(7,455)
Total comprehensive loss	**$ (34,170)**	**$ (44,517)**
Basic and diluted net loss per ordinary share	$ (0.23)	$ (0.41)
Weighted-average basic and diluted ordinary shares	173,825,825	90,914,175

Conference Call
Management will host a conference call and webcast at 8:30 am EDT/1:30 pm BST to discuss the company's financial results and provide a general business update. 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.

About Autolus Therapeutics plc
Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer. Using a broad suite of proprietary and modular T cell programming technologies, the Company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize cancer 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 and solid tumors. For more information, please visit www.autolus.com.

About obe-cel (AUTO1)
Obe-cel is a CD19 CAR T cell investigational therapy designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T cell therapies. Designed to have a fast target binding off-rate to minimize excessive activation of the programmed T cells, obe-cel may reduce toxicity and be less prone to T cell exhaustion, which could enhance persistence and improve the ability of the programmed T cells to engage in serial killing of target cancer cells. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL. Autolus has progressed obe-cel to the FELIX trial, a pivotal trial for adult ALL.

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel is enrolling adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase 1b component prior to proceeding to the single arm, Phase 2 clinical trial. The primary endpoint is overall response rate, and the secondary endpoints include duration of response, MRD negative CR rate and safety. The trial is designed to enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

About AUTO1/22
AUTO1/22 is a novel dual targeting CAR T cell based therapy candidate based on obe-cel. It is designed to combine the enhanced safety, robust expansion and persistence seen with the fast off rate CD19 CAR from obe-cel with a high sensitivity CD22 CAR to reduce antigen negative relapses. This product candidate is currently in a Phase 1 clinical trial for patients with r/r pediatric ALL. [NCT02443831]

About AUTO4
AUTO4 is a programmed T cell product candidate in clinical development for T cell lymphoma, a setting where there are currently no approved programmed T cell therapies. AUTO4 is specifically designed to target TRBC1 derived cancers, which account for approximately 40% of T cell lymphomas, and is a complement to the AUTO5 T cell product candidate, which is in pre-clinical development.

About AUTO5
AUTO5 is a programmed T cell product candidate in pre-clinical development for T cell lymphoma, a setting where there are currently no approved programmed T cell therapies. AUTO5 is specifically designed to target TRBC2 derived cancers, which account for approximately 60% of T cell lymphomas, and is a complement to the AUTO4 T cell product candidate currently in clinical development.

About AUTO6NG
AUTO6NG is a next generation programmed T cell product candidate in pre-clinical development. AUTO6NG builds on preliminary proof of concept data from AUTO6, a CAR targeting GD2-expression cancer cell currently in clinical development for the treatment of neuroblastoma. AUTO6NG incorporates additional cell programming modules to overcome immune suppressive defense mechanisms in the tumor microenvironment, in addition to endowing the CAR T cells with extended persistence capacity. AUTO6NG is currently in pre-clinical development for the potential treatment of both neuroblastoma and other GD2-expressing solid tumors.

About AUTO8
AUTO8 is our next-generation product candidate for multiple myeloma which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other BCMA CARs currently in development.

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 continued development of Autolus' AUTO1/22 program; the status of clinical trials (including, without limitation, expectations regarding the data that is being presented, the expected timing of data releases and development, as well as completion of clinical trials) and development timelines for the Company's 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; possible safety and efficacy concerns; and the impact of the ongoing COVID-19 pandemic on Autolus' business. 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 20-F filed with the Securities and Exchange Commission on March 7, 2023, 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.

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