Autolus Therapeutics Reports First Quarter 2024 Financial Results and Business Updates

May 17, 2024 at 7:00 AM EDT

- *Longer follow up and subset analyses from the pivotal FELIX Phase 2 data to be presented in oral presentations at ASCO and EHA*
- *Two patients enrolled in Phase 1 Systemic Lupus Erythematosus (SLE) trial; study on track for initial data end of 2024*
- *Market Authorization Application (MAA) for obe-cel in r/r adult ALL accepted by European Medicines Agency (EMA)*
- *Conference call to be held today at 08:30 am EDT/13:30 pm BST: conference call participants should pre-register using the link at the bottom of this press release*

LONDON, May 17, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces its operational and financial results for the first quarter ended March 31, 2024.

“We continue to engage with the FDA in the regulatory review process for obecabtagene autoleucel (obe-cel) in adult ALL as we head towards the PDUFA target action date of November 16, 2024, and are driving commercial readiness activities across the Company," **said Dr. Christian Itin, Chief Executive Officer of Autolus.** “We’re also delighted that our abstracts from the pivotal FELIX Phase 2 trial have been accepted for oral presentations at ASCO and EHA this year and we look forward to sharing further long-term data and additional subset analyses.”

“In addition, the first two patients have been enrolled into our dose confirmation trial (CARLYSLE) of obe-cel in Systemic Lupus Erythematosus (SLE) and the study is on track for initial data by end of 2024.”

Key obe-cel updates and anticipated milestones:

- *Obe-cel in relapsed / refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL) – The FELIX Study*
  - Obe-cel Biologics License Application (BLA) for r/r B-ALL submitted to the FDA in November 2023; PDUFA target action date of November 16, 2024. A marketing authorization application (MAA) to the European Medicines Agency (EMA) was accepted in April 2024. For the UK we are evaluating a filing based on an international recognition procedure.
  - Pooled analysis of the FELIX Phase 1b/2 study presented at ASH in December 2023 demonstrated prolonged event free survival and low overall immunotoxicity across all cohorts in r/r B-ALL, and particularly in patients with low leukemic burden at lymphodepletion.
  - Further long-term data from the FELIX study including additional subset analysis will be presented in oral and poster presentations at the American Society of Clinical Oncology annual meeting (ASCO – May 31 – June 4, 2024), and European Hematology Association congress (EHA – June 13 – 16, 2024) respectively.
- *Obe-cel in B-cell mediated autoimmune diseases*
  - The Phase 1 dose confirmation study (CARLYSLE) in refractory systemic lupus erythematosus (SLE) patients is ongoing. Two patients have been enrolled and Autolus continues to expect initial clinical data in late 2024.

Pipeline clinical trials, in collaboration with University College London (UCL), updates and anticipated milestones:

- *AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study*
  - AUTO8 is a next-generation product candidate for multiple myeloma, which includes two CARs for the multiple myeloma targets, BCMA and CD19. Initial data from the MCARTY Phase 1 study in multiple myeloma presented at ASH in December 2023 showed AUTO8 was well tolerated, with responses observed in all patients. Enrollment of the initial cohorts are complete and further updates from the MCARTY study are anticipated in H2 2024.
- *AUTO6NG in Neuroblastoma – Phase 1 MAGNETO Study*
  - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. A Phase 1 clinical study in children with r/r neuroblastoma was opened for enrollment in the fourth quarter of 2023.

Strategic developments:

- In February 2024, BioNTech and Autolus announced a strategic CAR T cell therapy collaboration to advance their pipelines and expand late-stage programs, for $50 million cash upfront and up to $582 million in potential option exercise and milestone payments. Additionally, Autolus sold $200 million of ADSs to BioNTech in a concurrent private placement financing transaction.
- In February 2024, Autolus completed an underwritten offering in the United States at a price of $6.00 per ADS, for total gross proceeds of $350 million before underwriting fees and offering expenses.

Operational Updates:

- In March 2024, The Nucleus manufacturing facility in Stevenage obtained a Manufacturer's Importation Authorization (MIA), together with the accompanying GMP certificate. This authorization enables Autolus to manufacture products for global commercial and clinical supply at The Nucleus, effective as of March 18, 2024.
- In April 2024, Autolus announced that the European Medicines Agency (EMA) had accepted its Marketing Authorization Application (MAA) for obe-cel for patients with relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL). The MAA submission was based on data from the pivotal Phase 2 FELIX study of obe-cel in adult r/r B-ALL.
- In April 2024, Autolus entered into a distribution services agreement with a subsidiary of Cardinal Health to support the ordering and distribution of obe-cel in the United States, following the receipt of regulatory approval.
- In April 2024, Autolus announced the appointment of Mike Bonney as Chairman of the Board, and Ravi Rao M.D., as Non-Executive Director. John H. Johnson advised the Board of his decision to step down from his role as Chairman of the Board and Non-Executive Director, effective April 1, 2024.

Scientific Publications:

- In January 2024, Autolus announced the publication of a paper in ACS Chemical Biology entitled: '*Designer small molecule control system based on Minocycline induced disruption of protein-protein interaction*' - Jha et al., ACS Chemical Biology (2024) doi:10.1021/acschembio.3c00521; [Link]
- In February 2024, Autolus announced the publication of a paper in Nature Communications entitled: '*Structure-Guided Engineering of Immunotherapies Targeting TRBC1 and TRBC2 in T Cell Malignancies*' – Ferrari et al., Nat Commun 15, 1583 (2024) doi:10.1038/s41467-024-45854-3; [Link]
- In March 2024, Autolus announced the publication of a paper in Blood Cancer Journal entitled: '*Dual T-cell constant β chain (TRBC)1 and TRBC2 staining for the identification of T-cell neoplasms by flow cytometry* – Horna et al., Blood Cancer J. 14, 34 (2024) doi: 10.1038/s41408-024-01002-0; [Link]

2024 Expected News Flow:

Obe-cel FELIX data update at ASCO, EHA & ASH	May, June & Dec 2024
Obe-cel Marketing Authorization Application to MHRA	Second half 2024
Obe-cel U.S. FDA PDUFA target action date	November 16, 2024
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study	Late 2024

Financial Results (Unaudited) for the Quarter Ended March 31, 2024

Cash and cash equivalents at March 31, 2024, totaled $758.5 million, as compared to $239.6 million at December 31, 2023.

Total operating expenses, net for the three months ended March 31, 2024, were $38.8 million, as compared to $39.1 million, for the same period in 2023.

Research and development expenses increased from $27.4 million to $30.7 million for the three months ended March 31, 2024, compared to the same period in 2023. This change was primarily due to increases in operating costs related to the Company's new commercial manufacturing facility, employee salaries and related costs, clinical trial costs related to obe-cel, and a decrease in our U.K. reimbursable R&D tax credits claimable through the U.K. small and medium-sized entity (SME) scheme. These were partially offset by decreases in professional consulting fees, legal fees, manufacturing costs related to obe-cel clinical supply, information technology infrastructure fees and general office expenses.

General and administrative expenses increased from $9.3 million to $18.2 million for the three months ended March 31, 2024, compared to the same period in 2023. This increase was primarily due to salaries and other employment-related costs driven by an increase in general and administrative headcount supporting the overall growth of the business, primarily relating to pre-commercialization activities.

Net loss was $52.7 million for the three months ended March 31, 2024, compared to $39.8 million for the same period in 2023. The basic and diluted net loss per ordinary share for the three months ended March 31, 2024, totaled $(0.24), compared to a basic and diluted net loss per ordinary share of $(0.23) for 2023.

Autolus estimates that, with its current cash and cash equivalents and proceeds received from the strategic alliance with BioNTech and the private placement and underwritten equity financing, it is well capitalized to drive the full launch and commercialization of obe-cel in r/r adult ALL as well as to advance its pipeline development plans, which includes providing runway to data in the first pivotal study of obe-cel in autoimmune disease.

Financial Results for the Quarter Ended March 31, 2024
Selected Unaudited Condensed Consolidated Balance Sheet Data
(In thousands)

	March 31 2024	December 31 2023
Assets		
Cash and cash equivalents	$ 758,529	$ 239,566
Total current assets	$ 804,298	$ 275,302
Total assets	$ 901,436	$ 375,381
Liabilities and shareholders' equity		
Total current liabilities	$ 43,985	$ 44,737
Total liabilities	$ 319,406	$ 263,907
Total shareholders' equity	$ 582,030	$ 111,474

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

	Three Months Ended March 31,	
	2024	2023
License revenues	$ 10,091	$ 1,292
Operating expenses:		
Research and development	(30,671)	(27,388)
General and administrative	(18,177)	(9,284)
Loss on disposal of property and equipment	-	(3,768)
Total operating expenses, net	**(38,757)**	**(39,148)**
Total other expenses, net	**(13,941)**	**(677)**
Net loss before income tax	**(52,698)**	**(39,825)**
Income tax benefit	8	14
Net loss	**(52,690)**	**(39,811)**
Other comprehensive income (loss):		
Foreign currency exchange translation adjustment	58	5,641
Total comprehensive loss	**$ (52,632)**	**$ (34,170)**
Basic and diluted net loss per ordinary share	$ (0.24)	$ (0.23)
Weighted-average basic and diluted ordinary shares	222,170,707	173,825,825

Conference Call
Management will host a conference call and webcast at 08:30 am EDT/13:30 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 and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, Autolus is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of hematological malignancies, solid tumors and autoimmune diseases. For more information, please visit www.autolus.com

About obe-cel (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. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. In clinical trials of obe-cel, this "fast off-rate" profile reduced toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024. A regulatory submission to the EMA was accepted in April 2024. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL.

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel enrolled 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 was overall response rate, and the secondary endpoints included duration of response, MRD negative CR rate and safety. The trial enrolled over 100 patients across 30 of the leading academic and non-academic centers in

the United States, United Kingdom and Europe. [NCT04404660]

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 I clinical trial for patients with r/r pediatric ALL. [NCT02443831]

About AUTO6NG
AUTO6NG is a next generation programmed T cell product candidate in development for the treatment of both neuroblastoma and other GD2-expressing solid tumors. 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. A Phase 1 clinical trial of AUTO6NG in children with relapsed/refractory neuroblastoma was opened for enrollment in the fourth quarter of 2023.

About AUTO8
AUTO8 is a 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 designed for improved killing of target cells that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel, with the aim of inducing deep and durable responses and extending the durability of effect over other BCMA CARs currently in development. This product candidate is currently in a Phase I clinical trial for patients with r/r multiple myeloma. [NCT04795882]

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding Autolus' development and commercialization of its product candidates, timing of data announcements and regulatory submissions, its cash resources and the market opportunity for obe-cel. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, but are not limited to, the risks that Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early clinical trials are not always being predictive of future results; the cost, timing and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; and possible safety and efficacy concerns. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus' actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 21, 2024 as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Autolus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing Autolus' views as of any date subsequent to the date of this press release.

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