# Autolus Therapeutics Reports First Quarter 2021 Financial Results and Operational Progress

May 6, 2021

**- Conference call to be held on May 6, 2021 at 8:30 am ET/1:30 pm BST -**

LONDON, May 06, 2021 (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, 2021.

"We have had a productive first quarter and are on track for multiple clinical read outs during the remainder of this year and into 2022," said Dr. Christian Itin, chief executive officer of Autolus. "We are excited by the unique characteristics of AUTO1 and encouraged by what we believe is the significant clinical benefit AUTO1 can offer for patients with relapsed/refractory (r/r) Acute Lymphoblastic Leukemia (ALL). AUTO1 is being evaluated in the P1b/2 FELIX study in adult ALL patients with data expected in 2022. In addition, AUTO1 is being explored in patients with B-NHL and in primary CNS lymphoma, and we are also evaluating AUTO1/22 in pediatric ALL patients. Finally, several programs are expected to enter the clinic in 2021, including our next generation program AUTO6NG in Neuroblastoma, setting up clinical news flow for 2022 and beyond."

**Key Pipeline Updates:**

- *AUTO1 in relapsed / refractory (r/r) adult B-Acute Lymphocytic Leukemia (ALL).*
  - The International Nonproprietary Name (INN) name (obecabtagene autoleucel, or obe-cel) was published.
  - Autolus received PRIority MEdicines (PRIME) designation from the European Medicines Agency (EMA) for AUTO1 being investigated in the ongoing FELIX Phase 1b/2 clinical trial in ALL. This designation is designed to accelerate the review of a promising therapy targeting unmet medical need. Data from this potentially pivotal program is expected in 2022, which, if positive, could enable us to file for accelerated approval.

- *AUTO1 in indolent B cell Non-Hodgkin Lymphoma (NHL) (cohort 1), high grade B-NHL (cohort 2) and chronic lymphocytic leukemia (CLL) (cohort 3).*
  - The trial is progressing well and Autolus will present updated data at the European Hematology Association (EHA) Congress in June 2021.

- *AUTO4 in Peripheral T Cell Lymphoma (PTCL).*
  - Autolus received innovative licensing and access pathway (ILAP) designation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for AUTO4, which is currently being studied in a Phase 1 clinical trial in PTCL. As with the AUTO1 PRIME designation, this is intended to accelerate the review of a promising therapy targeting unmet medical need. Autolus expects to provide a next data update in the second half of 2021.

- *Partnerable Coronavirus Disease (COVID-19) Project.* Autolus' research team has developed a potentially universal SARS-CoV2 decoy receptor with virus neutralizing activity against SARS-CoV2 and its variants and also active against SARS-CoV1.

**Operational Highlights:**

- In the first quarter of 2021, Autolus sold an aggregate of 1,718,506 ADSs in offerings under its Open Market Sales Agreement[SM] with Jefferies LLC, for net proceeds of approximately $15.3 million.

- Successful closing of a follow-on public offering raising net proceeds to Autolus, after underwriting discounts and offering expenses, of $106.9 million in February 2021, taking total net cash raised in Q1 2021 to approximately $122.2 million.

- As announced in Autolus' business update in January 2021, Autolus has realigned its research and development resources to prioritize the AUTO1 program and plans to partner the AUTO3 program before progressing it into the next phase of development.

- Also announced in Autolus' business update in January 2021, the company adjusted its workforce and infrastructure footprint, including an overall reduction in headcount of approximately 20%. Autolus expects to realize cash savings, on an annualized basis, of approximately $15 million with the operational changes fully implemented.

- In March 2021, Autolus announced it was establishing global commercial launch manufacturing capacity in the UK, enabling the company to leverage the expertise and skill base of its U.K. employees. As a result, future commercial supply will be provided by a combination of the existing clinical trial manufacturing facility at The Cell and Gene Therapy Catapult (CGTC) facility and a new Autolus facility. This revised strategy aims to deliver a less capital-intensive commercial manufacturing infrastructure at a lower cost base. In conjunction, Autolus announced the termination of its lease for the manufacturing and office facility in, Rockville, MD, resulting in a cash payment to Autolus of $2.0 million.

- Dr Muhammad Al-Hajj, Senior Vice President, Translational Sciences, left the Company in April 2021. The company would like to thank Dr. Al-Hajj for his contributions and wishes him well in the future.

- Post the period end, Dr Martin Murphy was appointed non-executive chairman of Autolus.

**Key Upcoming Clinical Milestones:**

- AUTO1 updates in 2021 on ALLCAR19 in patients with r/r B-NHL and longer term follow up of the fully enrolled r/r aALL cohort.

- AUTO1 - Currently enrolling a potentially pivotal Phase 1b/2 clinical trial (FELIX) in r/r adult ALL patients with data expected in 2022.

- Updates on Phase 1 programs AUTO1/22 in pediatric ALL, as well as AUTO4 in TRBC1+ Peripheral TCL, in 2021.

- Phase 1 trials are expected to be initiated in 2021 with AUTO1 in Primary CNS Lymphoma, AUTO5 in TRBC2+ Peripheral TCL, AUTO6NG in Neuroblastoma, and AUTO8 in Multiple Myeloma.

- First exploratory allogeneic program expected to enter the clinic in 2021.

**Financial Results for the Quarter Ended March 31, 2021**

Cash at March 31, 2021 totaled $239.0 million, as compared to $153.3 million at December 31, 2020. In January 2021, the company sold 1.7 million ADSs under its Open Market Sales Agreement℠ with Jefferies LLC as sales agent, resulting in net proceeds of $15.3 million and in February 2021, the company sold 16.4 million ADSs representing 16.4 million ordinary shares in a follow-on, public offering, including the exercise in full by the underwriters of their option to purchase an additional 2.1 million ADSs, at a public offering price of $7.00 per ADS, yielding net proceeds of $106.9 million.

Net total operating expenses for the three months ended March 31, 2021 were $39.9 million, net of grant income of $0.3 million, as compared to net operating expenses of $38.6 million, net of grant income of $0.3 million, for the same period in 2020.

Research and development expenses decreased to $30.7 million for the three months ended March 31, 2021 from $31.3 million for the three months ended March 31, 2020. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to $30.7 million from $25.6 million. The increase in research and development cash costs of $5.1 million consisted primarily of (i) an increase in compensation and employment related costs, net of lower travel costs (as a result of restricted travel due to the ongoing COVID-19 pandemic), of $3.5 million due to a combination of an increase in employee headcount to support the advancement of our product candidates in clinical development and severance payments related to the reduction in workforce that began to take place during the quarter, (ii) an increase of $2.2 million in facilities costs related to the continued scaling of manufacturing operations, and (iii) an increase of $0.4 million related to cell logistics, which is offset by decreases in purchased materials in the amount of $0.6 million and project expenses of $0.4 million.

Non-cash R&D costs decreased to $36,000 for the three months ended March 31, 2021 from $5.7 million for the three months ended March 31, 2020. The decrease is primarily related to share-based compensation expense included in research and development expenses, which decreased by $6.2 million as a result of forfeitures of incentive share options related to employees affected by the reduction in workforce. This was offset by an increase in depreciation of $0.5 million.

General and administrative expenses increased to $8.7 million for the three months ended March 31, 2021 from $7.6 million for the three months ended March 31, 2020. Cash costs, which exclude depreciation expense as well as share-based expense compensation increased to $7.6 million from $5.9 million. The increase in general and administrative cash costs of $1.7 million related to an increase of (i) $0.4 million in facilities cost, (ii) an increase of $0.6 million in legal fees and audit fees, (iii) an increase of $0.3 million of expenses related to preparations for becoming a commercial stage company, and (iv) an increase of $0.4 million in compensation and employment related costs due to an increase in headcount, and severance payments related to the reduction in workforce that began to take place during the quarter.

Non-cash general and administrative costs decreased to $1.1 million for the three months ended March 31, 2021 from $1.7 million for the three months ended March 31, 2020. The decrease is attributed to share-based compensation expense as a result of the lower fair value of stock options recognized during the period. Loss on disposal of leasehold improvements of $0.7 million related to the leasehold improvements no longer being utilized in the facility in White City, London.

Interest income decreased by $0.5 million for three months ended March 31, 2021 due to lower interest rates for cash held on deposit. Other income decreased by $3.7 million for the three months ended March 31, 2021 from other income of $4.5 million for the three months ended March 31, 2020 to $0.8 million. There was a decrease of $5.6 million primarily due to the weakening of the U.S. dollar exchange rate relative to the pound sterling during the three months ended March 31, 2021 as compared to the three months ended March 31, 2020, offset by gains on lease terminations of $2.0 million, net of the related expenses.

Income tax benefit increased to $5.7 million for the three months ended March 31, 2021 from $3.7 million for the three months ended March 31, 2020 due to increased research and development credits. As research and development credits grew at a faster rate than our net loss before income tax, this led to a higher effective tax rate. Research and development credits are obtained at a maximum rate of 33.35% of our qualifying research and development expenses, and the increase in the net credit was primarily attributable to an increase in our eligible research and development expenses.

Net loss attributable to ordinary shareholders was $33.3 million for the three months ended March 31, 2021, compared to $29.9 million for the same period in 2020. The basic and diluted net loss per ordinary share for the three months ended March 31, 2021 totaled $(0.53) compared to a basic and diluted net loss per ordinary share of $(0.60) for the three months ended March 31, 2020.

Autolus estimates that its current cash on hand will provide the Company with a cash runway into the first half of 2023.

**Conference Call**

Management will host a conference call and webcast today at 8:30 am ET/1:30 pm BST to discuss the company's financial results and provide a general business update. To listen to the webcast and view the accompanying slide presentation, please go to the events section of Autolus' website.

The call may also be accessed by dialing (866) 679-5407 for U.S. and Canada callers or (409) 217-8320 for international callers. Please reference conference ID 7756178. After the conference call, a replay will be available for one week. To access the replay, please dial (855) 859-2056 for U.S. and Canada callers or (404) 537-3406 for international callers. Please reference conference ID 7756178.

**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 AUTO1**
AUTO1 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, AUTO1 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 our academic partner, UCL, AUTO1 is currently being evaluated in a Phase 1 clinical trial in adult ALL and B-NHL. The company has also progressed AUTO1 to the FELIX study, a potential pivotal study.

**About AUTO1 FELIX study**
The FELIX Phase 1b/2 clinical trial is enrolling adult patients with relapsed / refractory ALL. The trial has a short Phase 1b component prior to proceeding to a single arm Phase 2 clinical trial. The primary endpoint is overall response rate, and the key secondary endpoints include duration of response, MRD negative CR rate and safety. The trial will enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe.

**About AUTO3**
AUTO3 is a programmed T cell investigational therapy containing two independent chimeric antigen receptors targeting CD19 and CD22 that have each been independently optimized for single target activity. AUTO3 is designed to combine a favorable safety profile with a reduced risk of relapse due to single antigen loss. AUTO3 is has been tested in diffuse large B cell lymphoma in the ALEXANDER clinical trial demonstrating a high level of clinical activity with a favorable safety profile. The ALEXANDER study included a 20-patient out-patient cohort and demonstrated feasibility of AUTO3 delivery in an outpatient setting.

**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.

**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' realigned business strategy, including specifically on the development of the AUTO1 program; the future clinical development, efficacy, safety and therapeutic potential of its product candidates, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical activity and milestones; expectations regarding the initiation, design and reporting of data from clinical trials; the efficacy, safety and therapeutic potential of AUTO3 and ability for Autolus to obtain a partner for next stages of clinical development; Autolus' needs for additional funding and ability to raise additional capital; Autolus' ability to attract and retain qualified employees and key personnel; the restructuring program and Autolus' expected cash savings as a result of the restructuring program and operational changes; and Autolus' expected cash runway. 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 4, 2021, 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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**Financial Results for the three months ended March 31, 2021**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2021** | **2020** |
| Grant income | $ 269 | $ 338 |
| **Operating expenses:** | | |
| Research and development | (30,731) | (31,287) |
| General and administrative | (8,738) | (7,614) |
| Loss on disposal of leasehold improvements | (672) | — |
| **Total operating expenses, net** | (39,872) | (38,563) |
| **Other income (expense):** | | |
| Interest income | 44 | 510 |
| Other income (expense) | 838 | 4,484 |
| **Total other income, net** | 882 | 4,994 |
| **Net loss before income tax** | (38,990) | (33,569) |
| Income tax benefit | 5,724 | 3,696 |
| **Net loss attributable to ordinary shareholders** | (33,266) | (29,873) |
| **Other comprehensive income (loss):** | | |
| Foreign currency exchange translation adjustment | 1,273 | (17,701) |
| **Total comprehensive loss** | $ (31,993) | $ (47,574) |
| Basic and diluted net loss per ordinary share | $ (0.53) | $ (0.60) |
| Weighted-average basic and diluted ordinary shares | 62,447,606 | 49,859,739 |

**Condensed Consolidated Balance Sheets (Unaudited)**
(In thousands, except share and per share amounts)

| | **March 31, 2021** | **December 31, 2020** |
|---|---|---|
| **Assets** | | |
| **Current assets:** | | |
| Cash | $ 239,012 | $ 153,299 |
| Restricted cash | 786 | 786 |
| Prepaid expenses and other assets, current | 48,262 | 42,899 |
| **Total current assets** | 288,060 | 196,984 |
| **Non-current assets:** | | |
| Property and equipment, net | 33,543 | 38,046 |
| Right of use assets, net | 21,199 | 51,637 |
| Long-term deposits | 1,836 | 2,625 |
| Prepaid expenses and other assets, non-current | 2,939 | 3,033 |
| Deferred tax asset | 2,034 | 1,754 |
| Intangible assets, net | 135 | 158 |
| **Total assets** | $ 349,746 | $ 294,237 |
| **Liabilities and shareholders' equity** | | |
| **Current liabilities:** | | |
| Accounts payable | 2,259 | 2,263 |
| Accrued expenses and other liabilities | 24,683 | 27,781 |
| Lease liabilities | 3,657 | 3,590 |

| | | |
|---|---|---|
| **Total current liabilities** | 30,599 | 33,634 |
| **Non-current liabilities:** | | |
| Lease liabilities | 19,580 | 50,571 |
| **Total liabilities** | 50,179 | 84,205 |
| | | |
| **Shareholders' equity:** | | |
| Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 70,515,354 and 52,346,231, shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively | 3 | 3 |
| Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2021 and December 31, 2020 | — | — |
| Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2021 and December 31, 2020 | 118 | 118 |
| Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2021 and December 31, 2020 | — | — |
| Additional paid-in capital | 716,544 | 595,016 |
| Accumulated other comprehensive loss | (4,588) | (5,861) |
| Accumulated deficit | (412,510) | (379,244) |
| **Total shareholders' equity** | 299,567 | 210,032 |
| **Total liabilities and shareholders' equity** | $ 349,746 | $ 294,237 |