Autolus Therapeutics Reports Second Quarter 2021 Financial Results and Operational Progress

August 5, 2021 at 7:00 AM EDT

- Conference call to be held on August 5, 2021 at 8:30 am ET/1:30 pm BST -

LONDON, Aug. 05, 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 June 30, 2021.

"We are very encouraged by the obe-cel data in adult acute lymphoblastic leukemia (ALL) and in B-cell non-Hodgkins Lymphoma (B-NHL) presented at the European Hematology Association (EHA) Virtual Congress in June. In adult patients with ALL, event-free survival stabilized at 50% with 12 months follow up and was sustained at 24 months. These data indicate that obe-cel may be the first stand-alone therapy in adult ALL with curative potential in a last line setting. The FELIX trial is progressing well, and we expect pivotal data during 2022," said Dr. Christian Itin, chief executive officer of Autolus. "Additional data were presented at EHA for obe-cel in indolent B-NHL indicating a high level of clinical activity combined with a well manageable safety profile. Further data in patients with aggressive B-NHL and chronic lymphocytic leukemia (CLL) are expected by the end of the year."

Key Pipeline Updates:

- *Obe-cel in relapsed / refractory (r/r) adult B-Acute Lymphocytic Leukemia (ALL).*
  - Data presented at EHA in June 2021 from the ALLCAR19 trial in r/r adult ALL patients demonstrated that obe-cel was generally well tolerated, with no patients experiencing Grade 3 or higher cytokine release syndrome (CRS). Three patients (15%), all of whom had high leukemia burden (>50% blasts), experienced Grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) that resolved swiftly with steroids. Of the 20 patients treated with obe-cel, 17 (85%) achieved minimum residual disease (MRD)-negative complete remission (CR) at one month. Most notably, as of the data cutoff date of May 17, 2021, the durability of remissions is encouraging. Across all treated patients, event free survival (EFS) at twelve months and twenty-four months was 50.2% with median EFS not being reached.

- *Obe-cel in other relapsed/refractory B-NHL – ALLCAR19 extension (Cohort D)*
  - Data presented at EHA in June 2021 in r/r B-NHL (Follicular Lymphoma (FL) and Mantle Cell Lymphoma (MCL)) patients demonstrated that, as of the data cut-off date of May 17, 2021, 9 r/r B-NHL patients (7 FL, 2 MCL) infused with obe-cel achieved a complete metabolic remission and, apart from one, all evaluable patients remained in CR. Obe-cel has a tolerable safety profile in adult patients with r/r FL and MCL, despite high disease burden. Grade 1 CRS was reported in 4 patients and Grade 2 CRS in 1 patient. No ICANS of any grade was observed in the trial.

- *Obe-cel in high grade B-NHL and CLL – ALLCAR19 extension (Cohorts B & C)*
  - The ALLCAR extension trial also involves two cohorts of patients with high grade B-NHL (DLBCL) and CLL. These cohorts are progressing well and Autolus plans to present updated data at the 63rd American Society of Hematology (ASH) Meeting in December 2021.

- *Autolus received preferred regulatory access for obe-cel from UK Medicines and Healthcare products Regulatory Agency (MHRA) and European Medicines Agency (EMA):*
  - Autolus received an innovative licensing and access pathway (ILAP) designation from the MHRA for obe-cel being investigated in the ongoing FELIX trial in ALL.
  - Autolus received PRIority MEdicines (PRIME) designation from the EMA.
  - These designations are designed to accelerate the review of a promising therapy targeting an unmet medical need. Data from the FELIX trial is expected in 2022, which, if positive, could enable Autolus to file for accelerated approval.

- *AUTO4 in Peripheral T Cell Lymphoma (PTCL).*
  - Autolus received ILAP designation from the MHRA for AUTO4 being investigated in PTCL.
  - AUTO4 Phase 1 clinical trial is progressing through dose escalation and Autolus expects to provide a next data update in the first half of 2022.

Operational Highlights:

- Post the period end, in July 2021, Autolus announced an agreement with Moderna, Inc., a biotechnology company

pioneering messenger RNA (mRNA) therapeutics and vaccines, granting Moderna an exclusive license to develop and commercialize mRNA-based therapeutics incorporating Autolus' proprietary binders to up to four immuno-oncology targets. Under the terms of the agreement, Autolus would be eligible to receive an upfront payment for each target licensed by Moderna and development and commercial milestone payments for each product successfully commercialized. In addition, Autolus will be entitled to receive royalties on net sales of all products commercialized under the agreement. The use of the technology in Moderna's mRNA platform underscores Autolus' leadership in the development of innovative differentiated binder and cell programming technologies.

- Post the period end, in July 2021, Autolus announced the appointment of Edgar Braendle M.D., Ph.D., as chief development officer. Dr Braendle is an experienced oncologist who joined Autolus from Sumitomo Dainippon Pharma Oncology, where he held the position of Chief Medical Officer and Global Head of Development and was responsible for leading the global oncology development programs of Sumitomo Dainippon. He is part of Autolus' executive team and is leading the company's development organization. In addition, Wolfram Brugger M.D., Ph.D. joined Autolus as VP, Head of Clinical Development in June 2021. Wolfram is a highly experienced hematologist, medical oncologist, and internal medicine specialist with 21 years of academia and hospital-based clinical physician experience in hematological malignancies in Germany, including 15 years of leadership as Chief Medical Director at the teaching hospital of Freiburg University. Wolfram joined Autolus from MorphoSys, where he was Head of Global Clinical Programs and oversaw the development of Monjuvi (tafasitamab).

Key Upcoming Clinical Milestones:

- Obe-cel updates from the ALLCAR19 extension trial in patients with r/r B-NHL and longer term follow up of the fully enrolled r/r aALL cohort in H2 2021
- Obe-cel currently enrolling the FELIX trial in r/r adult ALL patients with pivotal data expected in 2022
- Updates on the obe-cel Phase 1 trial, CAROUSEL, in Primary CNS Lymphoma in Q1 2022
- Updates on the AUTO1/22 CARPALL extension trial in pediatric ALL in Q4 2021
- Updates on the AUTO4 Phase 1 trial in TRBC1+ Peripheral TCL in H1 2022
- Phase 1 trials are expected to be initiated in H2 2021 with AUTO8 in Multiple Myeloma
- Phase 1 trials are expected to be initiated in H1 2022 with AUTO6NG in solid tumors and AUTO5 in TRBC2+ Peripheral TCL
- First exploratory allogeneic development candidate expected to enter the clinic in 2021

Financial Results for the Quarter Ended June 30, 2021

Cash at June 30, 2021, totaled $216.4 million, as compared to $239.0 million at March 31, 2020. During the three months ended June 30, 2021, the company issued an aggregate of 2,069,466 ADSs under its Sales Agreement with Jefferies for net proceeds, after underwriting discounts and offering expenses, of $14.3 million.

Net total operating expenses for the three months ended June 30, 2021 were $37.7 million, net of grant income and license revenue of $1.6 million, as compared to net operating expenses of $39.5 million, net of grant income of $0.3 million, for the same period in 2020.

Research and development expenses increased to $32.1 million for the three months ended June 30, 2021, from $31.3 million for the three months ended June 30, 2020. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to $29.2 million from $26.5 million. The increase in research and development cash costs of $2.7 million consisted primarily of (i) an increase in compensation and employment related costs of $0.7 million due to severance payments related to the reduction in workforce that started in the first quarter, and offset by a reduction in employment costs due to a decrease in headcount, (ii) an increase of $1.0 million in facilities costs related to the continued scaling of manufacturing operations, (iii) an increase of $0.9 million related to purchased materials, (iv) an increase of $0.3 million related to cell logistics, and (v) an increase of $0.3 million related to IT infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations. This was offset by a decrease of $0.4 million in clinical costs and $0.1 million of legal expenses.

Non-cash costs decreased to $2.9 million for the three months ended June 30, 2021, from $4.8 million for the three months ended June 30, 2020. The decrease is primarily related to share-based compensation expense included in research and development expenses, which decreased by $2.8 million as a result of the lower fair value of stock options recognized during the period, combined with forfeitures of incentive share options and unvested RSUs related to employees affected by the reduction in workforce. This was offset by an increase in depreciation of $0.9 million.

General and administrative expenses decreased to $7.2 million for the three months ended June 30, 2021, from $8.5 million for the three months ended June 30, 2020. Cash costs, which exclude depreciation expense as well as share-based expense compensation decreased to $6.6 million from $6.7 million. The decrease in general and administrative cash costs of $0.1 million related to decreases of (i) $0.3 million related to the reduction in workforce that began to take place in the first quarter, which reduced the headcount, and (ii) $0.3 million of expenses related to preparations for

becoming a commercial stage company. These decreases were offset by an increase of $0.5 million in legal fees and directors & officers liability insurance premiums.

Non-cash costs decreased to $0.6 million for the three months ended June 30, 2021, from $1.8 million for the three months ended June 30, 2020. The decrease is mainly attributed to share-based compensation expense as a result of the lower fair value of stock options recognized during the period, combined with forfeitures of incentive share options and unvested RSUs related to employees affected by the reduction in workforce.

Other income/(expense) decreased by $2.3 million for the three months ended June 30, 2021, from other income of $0.5 million for the three months ended June 30, 2020, to an other expense of $1.8 million. The decrease was primarily due to the weakening of the U.S. dollar exchange rate relative to the pound sterling during the three months ended June 30, 2021 as compared to the three months ended June 30, 2020.

Income tax benefit decreased to $6.4 million for the three months ended June 30, 2021 from $7.0 million for the three months ended June 30, 2020 due to a decrease in the research and development expenditures which were qualifying for the quarter. As research and development credits fell at a faster rate than our net loss before income tax, this led to a lower 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 $33.2 million for the three months ended June 30, 2021, compared to $32.1 million for the same period in 2020. The basic and diluted net loss per ordinary share for the three months ended June 30, 2021 totaled $(0.47) compared to a basic and diluted net loss per ordinary share of $(0.62) for the three months ended June 30, 2020.

Autolus estimates that its current cash on hand will provide the Company with a cash runway into H1 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 9757293. 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 9757293.

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

About Obe-cel FELIX trial
The FELIX 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 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 the future clinical development, efficacy, safety, and therapeutic potential of obe-cel, 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. 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 June 30, 2021

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Grant income	$ 138	$ 293	$ 407	$ 631
License revenue	1,507	—	1,507	—
Operating expenses:				
Research and development	(32,131)	(31,328)	(62,862)	(62,615)
General and administrative	(7,237)	(8,509)	(15,975)	(16,123)
Loss on disposal of leasehold improvements	—	—	(672)	—
Total operating expenses, net	(37,723)	(39,544)	(77,595)	(78,107)
Other (expense) income:				
Interest income (expense)	42	(47)	85	463
Other (expense) income	(1,849)	525	(1,011)	5,009
Total other (expense) income, net	(1,807)	478	(926)	5,472
Net loss before income tax	(39,530)	(39,066)	(78,521)	(72,635)
Income tax benefit	6,357	7,021	12,081	10,717
Net loss attributable to ordinary shareholders	(33,173)	(32,045)	(66,440)	(61,918)
Other comprehensive income (loss):				
Foreign currency exchange translation adjustment	1,542	(1,819)	2,815	(19,520)
Total comprehensive loss	(31,631)	(33,864)	(63,625)	(81,438)
Basic and diluted net loss per ordinary share	$ (0.47)	$ (0.62)	$ (1.00)	$ (1.22)
Weighted-average basic and diluted ordinary shares	70,832,077	52,041,340	66,663,003	50,956,566

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

	June 30, 2021	**December 31, 2020**
Assets		
Current assets:		
Cash	$ 216,352	$ 153,299
Restricted cash	210	786
Prepaid expenses and other assets, current	52,944	42,899
Total current assets	269,506	196,984
Non-current assets:		
Property and equipment, net	34,190	38,046
Right of use assets, net	20,598	51,637
Long-term deposits	1,846	2,625
Prepaid expenses and other assets, non-current	2,760	3,033
Deferred tax asset	1,643	1,754
Intangible assets, net	112	158

Total assets	$ 330,655	$ 294,237
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	1,119	2,263
Accrued expenses and other liabilities	23,173	27,781
Lease liabilities	3,895	3,590
Total current liabilities	28,187	33,634
Non-current liabilities:		
Lease liabilities	18,786	50,571
Total liabilities	46,973	84,205
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 72,742,582 and 52,346,231, shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	3	3
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	732,290	595,016
Accumulated other comprehensive loss	(3,046)	(5,861)
Accumulated deficit	(445,683)	(379,244)
Total shareholders' equity	283,682	210,032
Total liabilities and shareholders' equity	$ 330,655	$ 294,237