Autolus Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Progress

March 4, 2021

Conference call to be held on March 4, 2021 at 8:30 am ET/1:30 pm GMT

LONDON, March 04, 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 fourth quarter and full year ended December 31, 2020.

"Autolus' primary focus is on delivering the potential pivotal AUTO1 program and the company starts 2021 in a position of financial strength, having raised a total of $131 million in gross proceeds this quarter, giving us a cash runway into the first half of 2023," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "We are excited about the unique characteristics of AUTO1 and the significant commercial opportunity that adult Acute Lymphoblastic Leukemia represents. Furthermore, we are committed to building additional value by capitalizing on the unique clinical profile of AUTO1 in additional B Cell malignancies and by progressing our pipeline of CAR T cell therapies, including AUTO1/22 in pediatric ALL, AUTO4 in peripheral T cell Lymphoma and AUTO6NG in solid tumors. As such, we expect multiple clinical proof of concept read outs during 2021 and 2022."

Key Pipeline Updates:

- *AUTO1 in relapsed / refractory (r/r) adult B-Acute Lymphocytic Leukemia (ALL)*. Positive data from the ALLCAR Phase 1 clinical trial was presented at the 62nd American Society of Hematology (ASH) Annual Meeting in December 2020, demonstrating that, as of the November 12, 2020 data cut-off date, AUTO1 was well tolerated, with no patients experiencing ≥ Grade 3 cytokine release syndrome (CRS). Three patients (15%), all of whom had high leukemia burden (>50% blasts), experienced Grade 3 neurotoxicity (NT) that resolved swiftly with steroids. Of the 19 patients evaluable for efficacy, 16 (84%) patients achieved minimum residual disease (MRD)-negative complete response (CR) at one month. Most notably, the durability of remissions is highly encouraging. Across all treated patients, event free survival (EFS) at six and 12 months is 69% and 52% respectively. Median EFS and overall survival (OS) had not been reached at a median follow up of 16.9 months (range up to 30.5 months). Data from the potential pivotal program, FELIX, is expected in 2022.

- *AUTO1 in indolent B cell Non-Hodgkin Lymphoma (NHL) (cohort 1), high grade B-NHL (cohort 2) and chronic lymphocytic leukemia (CLL) (cohort 3).* Autolus reported positive AUTO1 data at the 62nd American Society of Hematology (ASH) Annual Meeting in December 2020. As of the data cut-off date of November 12, 2020, four patients in Cohort 1 had been infused with AUTO1. AUTO1 was well tolerated, with no patients experiencing ≥ Grade 2 CRS and no patients experiencing NT of any grade. All four patients achieved a Complete Metabolic Response (CMR). Autolus is planning to present updated data on AUTO1 in indolent B-cell lymphoma indications at the European Hematology Association (EHA) Congress in June 2021.

- *AUTO1/22 in pediatric ALL*. The first patient was dosed in the extension cohort of the CARPALL clinical trial in Q4 2020. Autolus plans to provide a data update in Q4 2021.

- *AUTO3 in relapsed/refractory diffuse large B cell lymphoma (DLBCL).* Positive data from the Phase 1 ALEXANDER clinical trial was presented at the 62nd American Society of Hematology (ASH) Annual Meeting in December 2020 demonstrating, as of the October 30, 2020 data cut-off date, AUTO3 was well tolerated, with low rates of CRS and NT. Across all 49 patients, there was only one case of Grade 3 CRS with primary infusion, and only three cases of NT were reported, with two being ≥ Grade 3. As of the data cut-off date, none of the patients achieving a complete response (CR) experienced any NT and all cases of NT observed were seen in a setting of disease progression and with confounding factors. Autolus plans to seek a partner for this program.

- *AUTO4 in Peripheral T Cell Lymphoma (PTCL).* AUTO4 will continue, in 2021, to be evaluated in a dose escalation phase of a Phase 1/2 clinical trial in 2021. Autolus expects to provide a next data update in H2 2021.

- *AUTO5 in Peripheral T Cell Lymphoma*. Positive preclinical data were presented at the American Association for Cancer Research II (AACR) Annual Meeting in June 2020. The data highlight the specificity and selectivity of the Autolus T cell lymphoma product candidate, AUTO5. Autolus expects to initiate a Phase 1 clinical trial in H2 2021.

- *AUTO6NG in small cell lung cancer (SCLC).* Positive preclinical data were presented at the AACR Annual Meeting in June 2020. Autolus has designed enhancing modules to specifically overcome tumor microenvironment (TME) defenses in solid tumor settings. The new data reported at the AACR meeting suggest that AUTO6NG can overcome the immune suppressive mechanisms in the TME. Autolus plans to progress AUTO6NG for evaluation in GD2 positive tumors into the clinic in H2 2021.

- *AUTO7 in prostate cancer*. Positive preclinical data were presented at an oral presentation at the AACR Annual Meeting in June 2020. AUTO7 uses an optimized CAR to target cancer cells expressing PSMA, even at low levels, and includes modules introduced in AUTO6NG, with a module that activates immune responses at the tumor site through limited secretion of IL-12. The data presented at the AACR meeting demonstrated that AUTO7 is highly potent in cytotoxicity assays against cells expressing PSMA, even at low levels, and demonstrate the feasibility of this multi-modular cell programming approach in overcoming the immunotherapeutic challenges presented by advanced prostate cancer, which is typically otherwise an immunologically cold tumor. Autolus plans to progress AUTO7 into the clinic in H1 2022.

- *AUTO8 in multiple myeloma.* This program will be explored in a first clinical trial starting mid-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:

- Autolus sold 1,718,506 ADSs under its at-the-market program with Jefferies, for net proceeds of approximately $15.3 million, in January 2021.

- Successful closing of a public offering raising net proceeds to Autolus, after underwriting discounts and commissions, of $108.1 million in February 2021, taking total net cash raised in Q1 2021 to approximately $123.4 million.

- As announced in Autolus' business update in January 2021, the company will be prioritizing 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 will adjust its workforce and infrastructure footprint, which will involve an overall reduction in headcount of approximately 20%. The restructuring remains ongoing and Autolus expects to realize cash savings, on an annualized basis, of approximately $15 million per annum once the operational changes are fully implemented.

- As previously announced, Dr. Nushmia Khokhar, Senior Vice President, Clinical Development will be leaving the company in mid-March 2021 and Dr. Adam Hacker, Senior Vice President for Regulatory Affairs and Quality, left the Company in January 2021. The company would like to thank Drs. Khokhar and Hacker for their contributions and wishes them well in the future. A search for a Chief Medical Officer is ongoing.

- Appointment of Dr Jay T Backstrom to Autolus' Board of Directors, effective August 1, 2020. Dr Backstrom currently serves as EVP, Head of Research & Development at Acceleron Pharma Inc. and prior to that served as CMO and Head of Regulatory Affairs at Celgene Corporation.

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 Phase 1b/2 pivotal study (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 H1 2021.

Financial Results for the Quarter and Year Ended December 31, 2020

Cash at December 31, 2020 totaled $153.3 million, as compared to $210.6 million at December 31, 2019. 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 conducted a public offering of 16,428,572 ADSs representing 16,428,572 ordinary shares, including the exercise in full by the underwriters of their option to purchase an additional 2,142,857 ADSs, at a public offering price of $7.00 per ADS and net proceeds of $108.1 million.

Net total operating expenses for the twelve months ended December 31, 2020 were $168.1 million, net of grant income and license revenue of $1.7 million, as compared to net operating expenses of $146.1 million, net of grant income of $2.9 million, for the same period in 2019.

Research and development expenses increased to $134.9 million for the year ended December 31, 2020 from $105.4 million for the year ended December 31, 2019. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to $116.9 million from $83.4 million. The increase in research and development cash costs of $33.5 million consisted primarily of (i) an increase of $8.8 million in compensation and employment related costs, net of lower travel costs, due to an increase in employee headcount to support the advancement of our product candidates in clinical development and lessened travel due to the COVID-19 pandemic, (ii) an increase of $14.4 million in project expenses as a consequence of the advancement of our clinical portfolio which includes research and process development and manufacturing activities necessary to prepare, activate, and monitor clinical trial programs, (iii) an increase of $6.0 million in facilities costs related to the commencement of a lease for an additional manufacturing suite and the continued scaling of manufacturing operations, (iv) an increase of $4.0 million in IT infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations, (v) an increase of $0.5 million related to legal fees and (vi) an increase of $1.7 million related to cell logistics, which is offset by a reduction in materials purchases of $0.7 million and license fees of $1.1 million.

Non-cash Research & Development costs decreased to $18.1 million for the year ended December 31, 2020 from $22.0 million for the year ended December 31, 2019. The $3.9 million decrease is related to a decrease of $4.8 million share-based compensation expense as a result of a lower fair value of stock options recognized in the period, offset by a $0.9 million increase in depreciation.

General and administrative expenses decreased to $35.0 million for the year ended December 31, 2020 from $39.5 million for the year ended December 31, 2019. Cash costs, which exclude depreciation as well as share-based compensation increased to $27.4 million from $26.6 million. There were increases of $1.3 million related to D&O insurance costs and intellectual property and $0.1 million of facilities cost, offset by decreases of $0.5 million of compensation and other employment related costs and $0.1 million in general office expense.

Non-cash General and Administrative costs decreased to $7.6 million for the year ended December 31, 2020 from $12.9 million for the year ended December 31, 2019. The decrease of $5.3 million is mainly attributed to lower share-based compensation expenses as a result of the lower fair value of share options recognized during the period.

Interest income decreased to $0.5 million for the year ended December 31, 2020 from $2.5 million for the year ended December 31, 2019. This decrease is due to the lower cash balances held during the year combined with lower interest rates for cash held on deposit. Other income decreased to $1.4 million for the year ended December 31, 2020 from $4.5 million for the year ended December 31, 2019 primarily due to a weakening of the U.S. dollar exchange rate relative to the pound sterling. The decrease of $4.6 million in the year ended December 31, 2020 was offset by lease termination gains of $1.5 million.

The Income tax benefit increased to $24.2 million for the year ended December 31, 2020 from $15.2 million for the year ended December 31, 2019 due to additional U.K. research and development tax credits receivable from HMRC. 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 the company's eligible research and development expenses.

Net loss attributable to ordinary shareholders was $142.1 million for the twelve months ended December 31, 2020, compared to $123.8 million for the same period in 2019. The basic and diluted net loss per ordinary share for the twelve months ended December 31, 2020 totaled $(2.76) compared to a basic and diluted net loss per ordinary share of $(2.88) for the twelve months ended December 31, 2019.

Autolus estimates that its current cash on hand, which includes the recent financings in January and February 2021, will extend the Company's runway into H1 2023.

Management will host a conference call and webcast at 8:30 am ET/1:30 pm GMT 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 2268057. 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 2268057.

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 study 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.

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.

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' refocused 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 development of Autolus' pipeline of next generation programs, including for solid tumor indications, in collaboration with its academic partners, including expectations as to the reporting of data, conduct and timing; the efficacy, safety and therapeutic potential of AUTO3 and ability for Autolus to obtain a partner for next stages of clinical development; 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 3, 2020, as amended, 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 Year Ended December 31, 2020

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

	For the Year Ended December 31,		For the three-months ended December 31,	For the Year Ended September 30,
	2020	2019	2018	2018
Grant income	$ 1,473	$ 2,908	$ 296	$ 1,407
License revenue	242	—	—	—
Operating expenses:				
Research and development	(134,888)	(105,418)	(17,713)	(36,150)
General and administrative	(34,972)	(39,452)	(7,593)	(22,790)
Loss on impairment of leasehold improvements	—	(4,102)	—	—
Total operating expenses, net	(168,145)	(146,064)	(25,010)	(57,533)
Other income (expense):				
Interest income	536	2,542	660	1,532
Other income (expense)	1,352	4,514	1,097	3,970
Total other income, net	1,888	7,056	1,757	5,502
Net loss before income tax	(166,257)	(139,008)	(23,253)	(52,031)
Income tax benefit	24,163	15,159	2,605	7,280
Net loss attributable to ordinary shareholders	(142,094)	(123,849)	(20,648)	(44,751)
Other comprehensive (loss) income:				
Foreign currency exchange translation adjustment	2,830	6,797	(5,568)	(6,071)
Total comprehensive loss	(139,264)	(117,052)	(26,216)	(50,822)
Basic and diluted net loss per ordinary share	$ (2.76)	$ (2.88)	$ (0.52)	$ (1.42)
Weighted-average basic and diluted ordinary shares	51,558,075	43,065,542	39,366,634	31,557,034

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash	$ 153,299	$ 210,643
Restricted cash	786	787
Prepaid expenses and other current assets	42,899	37,826
Total current assets	196,984	249,256
Non-current assets:		
Property and equipment, net	38,046	28,164
Prepaid expenses and other non-current assets	3,033	—
Right of use asset, net	51,637	23,409
Long-term deposits	2,625	2,040
Deferred tax asset	1,754	410
Intangible assets, net	158	254
Total assets	$ 294,237	$ 303,533
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	2,263	1,075
Accrued expenses and other liabilities	27,781	21,398
Lease liability	3,590	2,511
Total current liabilities	33,634	24,984
Non-current liabilities:		
Lease liability	50,571	23,710
Total liabilities	84,205	48,694
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized at December 31, 2020 and 2019, 52,346,231 and 44,983,006 shares issued and outstanding at December 31, 2020 and 2019	3	2
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2020 and 2019	—	—

Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2020 and 2019	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at December 31, 2020 and 2019	—	—
Additional paid-in capital	595,016	500,560
Accumulated other comprehensive loss	(5,861)	(8,691)
Accumulated deficit	(379,244)	(237,150)
Total shareholders' equity	210,032	254,839
Total liabilities and shareholders' equity	$ 294,237	$ 303,533