Autolus Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Operational Progress

- Conference call to be held on March 3, 2020 at 8:30 am EST/1:30 pm GMT -

LONDON, March 3, 2020 -- 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, 2019.

"It has been an exciting year of progress for Autolus concluding with the presentation of encouraging AUTO 1 and AUTO 3 clinical data at the ASH conference in December 2019. AUTO1 is poised for a pivotal Phase 2 clinical trial starting in the first half of 2020, and AUTO3 is progressing to a Phase 2 decision point in mid-2020," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "Supported by a strong balance sheet and alongside the two lead programs, we also continue to advance our next generation programs towards key near-term value inflection points."

Key Pipeline Updates:

- *AUTO1 in adult lymphocytic leukemia (ALL).* Data presented at the American Society of Hematology (ASH) demonstrated that AUTO1, a novel fast off CD19 CAR, was well-tolerated with a high level of clinical activity. As of the most recent cut-off date of November 25, 2019, of the 15 patients evaluable for efficacy, 13 patients (87%) achieved minimal residual disease, or MRD, negative complete responses at one month and all patients had ongoing CAR T cell persistence at last follow-up. 10 of the 15 evaluable patients (67%) remain disease-free at a median follow up of 11 months (range of 0.5 month - 21 months). Of the 16 patients dosed, ten patients were dosed with AUTO1 manufactured using our semi-automated, fully enclosed system for manufacturing. In this cohort, nine patients were evaluable and achieved MRD negative complete responses of 100%. The median follow-up in this cohort was 6.7 months (range of 1.1 month-14.5 months). The event free survival or EFS and overall survival or OS data are preliminary considering the small number of patients.

  In October 2019 the U.S. Food and Drug Administration, or FDA, granted orphan drug designation for AUTO1 for the treatment of ALL.

- *AUTO3 in Diffuse large B-cell lymphoma (DLBCL).* Data were presented at ASH with an update provided in a keynote lecture at EHA-EBMT 2nd European CAR T Cell Meeting. These data support the encouraging early indications of durability and high level of activity previously reported and show the potential for a differentiated product profile. As of the data cut-off date of January 21, 2020 (data availability as of January 28, 2020), 18 patients in the ALEXANDER Phase 1/2 clinical trial of AUTO3 were evaluable for safety and efficacy with

minimum 28-day follow-up. In the cohorts dosed at 450 x 10^6 AUTO3 cells plus pembrolizumab, five out of seven patients (ORR=71%) achieved a response (complete response + partial response) and four out of seven patients (CRR=57%) achieved a complete response. Across all dose levels, seven out of eight complete responders (87%) had ongoing complete responses at a median follow up of six months (range of one month - 18 months). All seven out of seven complete responders (100%) treated with AUTO3 and pembrolizumab have ongoing complete responses as of January 21, 2020 at a median follow up of three months (range of one month - 18 months). AUTO3 was generally well tolerated, with no patients experiencing dose limiting toxicity, and there were no treatment-related deaths. Notably, none of the patients treated in the higher dose cohorts experienced any high grade CRS or any neurotoxic events of any grade, which may provide AUTO3 with a safety profile suitable for the outpatient setting, and allow for a significant expansion of the market opportunity compared to CAR T therapies currently approved for DLBCL.

- *AUTO6NG in neuroblastoma.* Pre-clinical data presented at the Society for Immunotherapy of Cancer (SITC) from the Company's next generation GD2-targeting CAR T cell therapy, demonstrates the utility of three modules added to the clinically active and validated AUTO6 GD-2 targeting CAR that not only improve CAR T persistence but also combat the immunosuppressive tumor microenvironment.

Operational and Corporate Highlights:

- Completed public offerings in April 2019 and January 2020 raising net proceeds of approx. $184 million.

- Presented clinical data on our lead programs AUTO1 and AUTO3 in four oral presentations at Annual American Society of Hematology (ASH) conference in December 2019.

- Presented non-clinical data for our most advanced next generation solid tumor program AUTO6NG at the annual meeting of the Society for Immunotherapy Conference (SITC) in November 2019, highlighting a suite of activity enhancing programming modules built into the clinically active AUTO6 program.

- Licensed the PRIME (proliferation-inducing and migration-enhancing) technology from Noile-Immune Biotech, Inc. in November 2019, which can provide our next-generation solid tumor CAR T programs the ability to activate the patient's immune system against the cancer cells.

- Initiated manufacturing at the Cell and Gene Therapy Catapult site in Stevenage, UK, in March 2019, and delivering clinical products for patients in both Europe and the US.

Key Upcoming Clinical Milestones:

- Initiation of the pivotal program of AUTO1 in adult ALL on track – dosing of first patients in the first half of 2020.

- Go/no go decision on Phase 2 initiation of AUTO3 in DLBCL expected in mid-2020.

- Interim Phase 1 data in T cell lymphoma with AUTO4 in the second half of 2020.

- Report data from multiple clinical and pre-clinical programs at key medical conferences throughout the year and progress additional next generation programs through pre-clinical into clinical development.

- Expansion of the Company's suite of cell programming technologies to include programming modules designed for allogeneic applications, with the first novel allogeneic program expected to enter the clinic in the fourth quarter of 2020.

Financial Results for the Quarter and Year Ended December 31, 2019

Cash and equivalents at December 31, 2019 totaled $210.6 million, before adjusting for the public offering in January 2020 of approximately $75 million net. This compared to $217.5 million at December 31, 2018.

Net total operating expenses for the twelve months ended December 31, 2019 were $146.1 million, net of grant income of $2.9 million, as compared to net operating expenses of $74.1 million, net of grant income of $1.5 million, for the same period in 2018. The increase was due, in general, to the increase in development activity, increased headcount primarily in our development and manufacturing functions, and the cost of being a public company.

Research and development expenses increased to $105.4 million for the year ended December 31, 2019 from $48.3 million for the year ended December 31, 2018. Cash costs, which exclude depreciation as well as share-based compensation, increased to $83.4 million from $41.5 million. The increase in research and development cash costs of $41.9 million consisted of an increase in compensation-related costs of $20.0 million, primarily due to an increase in headcount to support the advancement of our product candidates in clinical development and investment in manufacturing facilities and equipment, an increase of $4.1 million in research and manufacturing consumables, in part due to the migration and expansion of our research and process development laboratories from Forest House to our new location in the Media Works facility, preparations in advance of any potential disruption to supply arrangements that may occur due to Brexit, as well as validation and training costs as part of the start-up at the Catapult facility, an increase of $10.2 million in facility costs primarily related to the addition of Media Works and Catapult, an increase of $3.8 million in project expenses related to the activities necessary to prepare, activate, and monitor clinical trial programs, an increase of $1.5 million in consulting, contracting and license fees that includes a decrease in milestone payments of $0.5 million consisting of a milestone payable to UCL Business plc in 2018 and a milestone payable to

Noile-Immune Biotech Inc. in 2019, and an increase in IT and general office expenses of $2.3 million.

General and administrative expenses increased to $39.5 million for the year ended December 31, 2019 from $27.3 million for the year ended December 31, 2018. Cash costs, which exclude depreciation as well as share-based compensation increased to $26.6 million from $21.4 million. The increase of $5.2 million consisted primarily of an increase in compensation-related costs of $2.6 million due to an overall increase in headcount, an increase of $1.9 million in commercial costs, an increase in public company compliance costs of $1.0 million, an increase of $0.7 million in facility costs related to lease and maintenance costs, offset by decrease of $1.0 million in IT charges, project expenses, and other office expenses.

Net loss attributable to ordinary shareholders was $123.8 million for the twelve months ended December 31, 2019, compared to $57.9 million for the same period in 2018.

The basic and diluted net loss per ordinary share for the twelve months ended December 31, 2019 totaled $(2.88) compared to a basic and diluted net loss per ordinary share of $(1.48) for the twelve months ended December 31, 2018.

Autolus anticipates that cash on hand provides a runway into 2022.

Conference Call and Presentation Information

Autolus management will host a conference call today, March 3, at 8:30 a.m. EST/ 1:30pm GMT, to discuss the company's financial results and operational update.

To listen to the webcast and view the accompanying slide presentation, please go to:

https://www.autolus.com/investor-relations/news-and-events/events

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 1090568. 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 1090568.

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.

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' financial condition and results of operations, including its expected cash runway; the development of Autolus' product candidates, including statements regarding the timing of initiation, completion and the outcome of pre-clinical studies or clinical trials and related preparatory work, and the periods during which the results of the studies and trials will become available; Autolus' plans to research, develop, manufacture and commercialize its product candidates; the potential for Autolus' product candidates to be alternatives in the therapeutic areas investigated; and Autolus' manufacturing capabilities and strategy. 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. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our 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 well as discussions of potential risks, uncertainties, and other important factors in Autolus' future filings with the Securities and Exchange Commission from time to time. All information in this press release is as of the date of the release, and the company 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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Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	December 31,	
		(unaudited)
	2019	**2018**
Grant income	$ 2,908	$ 1,472
Gain on disposal		
Operating expenses:		
Research and development	(105,418)	(48,299)
General and administrative	(39,452)	(27,299)
Loss on impairment of leasehold improvements	(4,102)	-
Total operating expenses, net	(146,064)	(74,126)
Other income (expense):		
Interest income	2,542	2,011
Other Income / (expense)	4,514	5,752
Total other income (expense), net	7,056	7,763
Net loss before income tax	(139,008)	(66,363)
Income tax benefit	15,159	8,488
Net loss attributable to ordinary shareholders	$ (123,849)	$ (57,875)
Basic and diluted net loss per ordinary share	$ (2.88)	$ (1.48)
Weighted-average basic and diluted ordinary shares	43,065,542	39,163,413

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash	$ 210,643	$ 217,450
Restricted cash	787	105
Prepaid expenses and other current assets	37,826	15,411
Total current assets	249,256	232,966
Non-current assets:		
Property and equipment, net	28,164	19,968
Right of use asset, net	23,409	—
Long-term deposits	2,040	1,276
Deferred tax asset	410	—
Intangible assets, net	254	—
Total assets	$ 303,533	$ 254,210
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	1,075	2,022
Accrued expenses and other liabilities	21,398	19,054
Lease liability	2,511	—
Total current liabilities	24,984	21,076
Non-current liabilities:		
Lease liability	23,710	—
Long-term lease incentive obligation	—	207
Other long-term payables	—	285
Total liabilities	48,694	21,568
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized at December 31, 2019 and 2018, 44,983,006 and 40,145,617 shares issued and outstanding at December 31, 2019 and 2018	2	2
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2019 and 2018	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2019 and 2018	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at December 31, 2019 and 2018	—	—
Additional paid-in capital	500,560	361,311
Accumulated other comprehensive loss	(8,691)	(15,488)
Accumulated deficit	(237,150)	(113,301)
Total shareholders' equity	254,839	232,642
Total liabilities and shareholders' equity	$ 303,533	$ 254,210