Autolus Therapeutics Reports First Quarter 2019 Financial Results and Operational Progress

- Conference Call to be held on May 14, 2019 at 8:30 am EST/1:30 pm BST-

LONDON, May 14, 2019 -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its financial and operational results for the first quarter ended March 31, 2019.

Key first quarter highlights include:

Clinical and Regulatory

- In April, Autolus announced the presentation of initial data from the ongoing Phase 1/2 ALLCAR19 trial of AUTO1 in adult acute lymphoblastic B cell leukemia (ALL) at the American Association for Cancer Research (AACR) Annual Meeting 2019 in Atlanta, Georgia. As of the data cutoff date of March 18, 2019, 13 patients were leukapheresed, and products for 12 patients were manufactured, including 7 with Autolus' semi-automated, fully enclosed manufacturing process. Using the Lee criteria, there were no patients with severe cytokine release syndrome (CRS) (≥ Grade 3), and only 2 of 10 patients (20%) with Grade 2 CRS. Tocilizumab was used in 2 of 10 patients (20%). None of the patients were admitted to intensive care due to CRS. One patient developed delayed Grade 3 neurotoxicity following high levels of CAR T expansion, which resolved promptly following administration of steroids. Four patients died while enrolled in the trial, two due to progression of the disease and two due to sepsis, a common complication of advanced ALL. Nine patients were evaluable for response at 1 month with 9 (88%) achieving a molecular complete response. One patient died of sepsis before the one-month evaluation point. At a median follow up of 5 months (range 0.62-10.6 months), 6/10 patients are alive and continue to be in molecular remission and there continues to be evidence of ongoing B cell aplasia and CAR T persistence.

- In April, Autolus announced that the United States Food and Drug Administration granted orphan drug designation to autologous enriched T-cells genetically modified with a retroviral vector to express two chimeric antigen receptors targeting CD19 and CD22 (AUTO3) for the treatment of ALL.

- Autolus hosted an R&D Day in New York City in March for the investment community. The event provided an update on Autolus' current clinical programs and highlighted the

company's approach to drive molecular innovation and next-generation programed T cell products for hematological and solid tumor indications.

- During the March R&D Day, Autolus provided updated data from the ongoing AMELIA Phase 1/2 study of AUTO3 in pediatric ALL which demonstrated that 6 out of 6 (100%) patients treated at the highest dose (≥3 x10^6/kg) achieved minimal residual disease (MRD) negative complete responses (CR). Ongoing MRD negative CR remissions were noted in 4 out of 6 (67%) patients, with duration of up to 10 months as of February 2019, the date of latest data follow-up. There have been no reported CD19 or CD22 negative relapses in CAR T naïve patients. Data also showed that AUTO3 continues to be generally well tolerated with no ≥ Grade 3 CRS, no intensive care admission, and no pressors or critical care support for CRS required.

Manufacturing and Product Delivery

- In March, manufacturing for clinical studies commenced at the Cell and Gene Therapy Catapult Manufacturing Centre in Stevenage, United Kingdom.

Corporate Highlights

- In April, Autolus completed an underwritten public offering of 4,830,000 American Depositary Shares ("ADSs") representing 4,830,000 ordinary shares, at a public offering price of $24.00 per ADS, which includes an additional 630,000 ADSs issued upon the exercise in full of the underwriters' option to purchase additional ADSs. Aggregate net proceeds to Autolus, after underwriting discounts but before estimated offering expenses, were $108.9 million. Proceeds from this public offering are not included in the March 31, 2019 financial statements.

Anticipated Milestones

- Presentation of a data update from the ALEXANDER Phase 1/2 trial of AUTO3 in adult relapsed/refractory diffuse large B cell lymphoma (DLBCL) in the third quarter of 2019.

- Initiation of the Phase 2 portion of the AMELIA trial of AUTO3 in pediatric ALL in the second half of 2019.

- Initiation of a Phase 2/registration trial of AUTO1 in adult ALL in the second half of 2019 (pending regulatory feedback).

- Presentation by the end of 2019 of data updates from the following trials: AUTO1 in adult ALL and pediatric ALL; AUTO3 in DLBCL and pALL and AUTO2 in multiple myeloma.

"In the first quarter of 2019, we made good progress in all aspects of the business. Important was the first presentation of clinical data from AUTO1 in adult patients with acute lymphoblastic leukemia, which points to a differentiated profile for AUTO1," stated Dr. Christian Itin, chairman and chief executive officer of Autolus. "For the remainder of 2019, we are placing particular focus on advancing our clinical programs, specifically AUTO3 in DLBCL and AUTO1 in adult ALL, towards registrational trials."

Financial results for first quarter 2019:

- Cash and equivalents at March 31, 2019 totaled $187.7 million, compared with $217.5 million at December 31, 2018.

- Net total operating expenses for the three months ended March 31, 2019 were $30.2 million, net of grant income of $2.0 million, as compared to net operating expenses of $15.5 million, net of grant income of $0.4 million, for the same period in 2018. The increase was due, in general, to the increase in clinical trial activity, which is expected to deliver on key milestones throughout the rest of 2019; increased headcount; and the cost of being a public company.

- Research and development expenses increased to $22.6 million for the three months ended March 31, 2019 from $11.6 million for the three months ended March 31, 2018. Cash costs, which exclude depreciation as well as share-based compensation, increased to $17.5 million from $10.6 million. The increase in research and development cash costs of $6.9 million consisted primarily of an increase of compensation-related costs of $5.6 million primarily due to an increase in headcount to support the advancement of our product candidates in clinical development, an increase of $2.7 million in facilities costs supporting the expansion of our research and translational science capability and investment in manufacturing facilities and equipment, and an increase of $0.8 million in research and development program expenses related to the activities necessary to prepare, activate, and monitor clinical trial programs, offset by a decrease of $1.9 million in professional fees primarily related to the UCL license fees expensed for the three months ended March 31, 2018, and other reductions of $0.3 million.

- General and administrative expenses increased to $9.6 million for the three months ended March 31, 2019 from $4.3 million for the three months ended March 31, 2018. Cash costs, which exclude depreciation as well as share-based compensation, increased to $6.3 million from $3.5 million. The increase of $2.8 million consisted primarily of an increase in compensation-related expense of $1.2 million due to an overall increase in headcount, and an increase in legal and professional fees of $0.9 million related to insurance and patent costs.

- Net loss attributable to ordinary shareholders was $27.2 million for the three months ended March 31, 2019, compared to $16.7 million for the same period in 2018.

- The basic and diluted net loss per ordinary share for the three months ended March 31, 2019 totaled $(0.69) compared to a basic and diluted net loss per ordinary share of $(0.58) for the three months ended March 31, 2018.

- Autolus anticipates that cash on hand provides a runway into the second half of 2021.

Conference Call and Presentation Information

Autolus management will host a conference call today, May 14, at 8:30 a.m. EST/ 1:30pm BST, 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-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 7358198. 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 7358198.

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 Statement

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, as well as statements regarding the anticipated development of Autolus' product candidates, including its intentions regarding the timing for providing further updates on the development of its product candidates, and the sufficiency of its cash resources. 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 on November 23, 2018 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.

# # #

Autolus Therapeutics PLC

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Grant income	$ 1,964	$ 426
Operating expenses:		
Research and development	(22,565)	(11,627)
General and administrative	(9,556)	(4,330)
Total operating expenses, net	(30,157)	(15,531)
Other income (expense):		
Interest income	541	289
Other expense	(984)	(2,941)
Total other expense, net	(443)	(2,652)
Net loss before income tax	(30,600)	(18,183)
Income tax benefit	3,421	1,466
Net loss attributable to ordinary shareholders	(27,179)	(16,717)
Other comprehensive income:		
Foreign currency exchange translation adjustment	5,051	4,964
Total comprehensive loss	$ (22,128)	$ (11,753)
Basic and diluted net loss per ordinary share	$ (0.69)	$ (0.58)
Weighted-average basic and diluted ordinary shares	39,471,029	28,833,465

Autolus Therapeutics PLC
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash	$ 187,733	$ 217,450
Restricted cash	681	105
Prepaid expenses and other current assets	22,574	15,411
Total current assets	210,988	232,966
Non-current assets:		
Property and equipment, net	24,554	19,968
Right of use asset, net	26,804	—
Long-term deposits	2,010	1,276
Total assets	$ 264,356	$ 254,210
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	1,833	2,022
Accrued expenses and other liabilities	16,248	19,054
Lease liability	1,703	—
Total current liabilities	19,784	21,076
Non-current liabilities:		
Lease liability	26,448	—
Long-term lease incentive obligation	—	207
Other long-term payables	241	285
Total liabilities	46,473	21,568
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 40,147,441 and 40,145,617, shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	2	2
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2019 and December 31, 2018	118	118
Deferred C shares, £0.000001 par value; 1 share authorized, issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Additional paid-in capital	368,680	361,311
Accumulated other comprehensive loss	(10,437)	(15,488)
Accumulated deficit	(140,480)	(113,301)
Total shareholders' equity	217,883	232,642
Total liabilities and shareholders' equity	$ 264,356	$ 254,210

Investor contact:
Susan A. Noonan
S.A. Noonan Communications
+1-212-966-3650
susan@sanoonan.com

Media contact:
Silvia Taylor
Vice President, Corporate Affairs and Communications, Autolus
+1-240-801-3850
s.taylor@autolus.com

Julia Wilson
JW Communications
+44 (0) 7818 430877
j.wilson@autolus.com