# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of April 2019

Commission File Number: 001-38547

### **Autolus Therapeutics plc**

(Translation of registrant's name into English)							
Forest House 58 Wood Lane White City London W12 7RZ United Kingdom (Address of principal executive office)							
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:							
☑ Form 20-F ☐ Form 40-F							
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): $\Box$							
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): $\Box$							

#### Other Events

#### AACR Press Release and Conference Call

On April 1, 2019, Autolus Therapeutics plc (the "Company") issued a press release providing initial data from its ongoing Phase 1/2 ALLCAR19 trial of AUTO1 in adult acute lymphoblastic leukemia which was presented at the American Association for Cancer Research (AACR) Annual Meeting 2019 in Atlanta, Georgia. The press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

In addition, on April 2, 2019, members of management of the Company will hold a conference call to discuss the initial data from the Phase 1/2 ALLCAR19 trial of AUTO1 as well as the AACR poster presentation. A copy of the presentation that will accompany the conference call will be available immediately preceding the call on the Company's website at <a href="https://www.autolus.com">www.autolus.com</a> and select slides from the presentation are furnished herewith as Exhibit 99.2 to this Report on Form 6-K.

Information in the attached Exhibits 99.1 and 99.2 are being furnished and these exhibits shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall they be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

### EXHIBIT LIST

Exhibit	Description				
99.1	Press Release dated April 1, 2019, "Initial Results from Autolus Therapeutics' ALLCAR19 Phase 1/2 Trial in Adult Acute Lymphoblastic Leukemia Presented at the AACR Annual Meeting."				
99.2	Select Slides from the Conference Call to Discuss AUTO1 ALLCAR19 Data Presentation at the AACR Annual Meeting 2019				

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Autolus Therapeutics plc

Date: April 2, 2019

By: /s/ Christian Itin

Name Christian Itin, Ph.D.

Title: Chief Executive Officer



#### Initial Results from Autolus Therapeutics' ALLCAR19 Phase 1/2 Trial in Adult

#### Acute Lymphoblastic Leukemia Presented at the AACR Annual Meeting

Initial results from the trial show 88% molecular complete response at one month with well-tolerated safety profile

Management to Hold Conference Call on April 2, 2019 at 8:00am ET / 1:00pm BST

LONDON, UK, April 1, 2019 — Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer, announced that Claire Roddie MB, PhD, FRCPath, honorary senior lecturer, Cancer Institute, University College London (UCL), presented today initial data from the ongoing Phase 1/2 ALLCAR19 trial of AUTO1 in adult acute lymphoblastic B cell leukemia (ALL) as a late-breaking poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2019 in Atlanta, Georgia.

Relapsed / refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) in adults is an area of significant unmet clinical need. Notably, no CD19 CAR T cell therapeutic has been approved to date for adults with r/r B-ALL. The key challenges identified in clinical studies testing standard CD19 CAR T-cells therapies in this setting are considerable toxicity associated with severe cytokine release syndrome (CRS) and high-grade neurological toxicity.

AUTO1 uses a novel CD19 binder that allows the CAR T cells to disengage rapidly after target cell encounter and kill. Preliminary data from the ongoing Phase 1/2 CARPALL trial of AUTO1 in pediatric ALL presented at the 1st European CAR T Meeting organized by European Hematology Association (EHA) in February 2019 indicated that AUTO1 has a well-tolerated safety profile and did not induce high grade CRS in pediatric patients.

As of the data cutoff date of March 18, 2019 in the ongoing Phase 1/2 ALLCAR19 trial of AUTO1 in adult ALL patients, 13 patients were leukapheresed, and products for 12 patients were manufactured, including 7 with Autolus' semi-automated, fully enclosed manufacturing process. Two patients are pending infusion. Among the 10 infused patients to date, the median age is 41 and 70% were male, with median lines of treatment of 4 (the range is 2-7). Five of the ten treated patients had 3 50% BM blasts and were considered to be high-risk for severe CRS. Patients received a split dose based on disease burden for a total dose of up to 410 million cells.

#### Safety results

Using the Lee criteria, there were no patients with severe CRS (<sup>3</sup> Grade 3), and 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 was quickly reversed with steroids. Four patients died while enrolled in the trial, two due to progression of leukemia and two due to sepsis, a common complication of advanced ALL.

#### Efficacy results

Nine patients were evaluable for response at 1 month and 8 (88%) had 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. There continues to be evidence of ongoing B cell aplasia and CAR T persistence.

"AUTO1 delivered promising early remission rates, CAR T cell expansion and persistence in this adult ALL trial cohort," said Dr. Roddie. "Despite enrolling patients with high tumor burden, we believe the safety profile in the trial appears to compare very favorably to other CD19 CARs and is consistent with the safety profile of AUTO1 observed in pediatric patients in the CARPALL trial."

"These data from the ALLCAR19 study of AUTO1 in relapsed refractory ALL, while early, are encouraging, with a high response rate we now associate with CAR T cell therapies, but with a potentially improved safety profile. If AUTO1 continues to be associated with a lower incidence of adverse events with additional patients treated, this could represent an important advance for more vulnerable adult patients, as side effects of these therapies, including serious cytokine release syndrome and neurotoxicity, limit our ability to treat these individuals." said Krishna Komanduri, M.D., Kalish Family Chair in Stem Cell Transplantation and Director, Adult Stem Cell Transplant Program at the Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine.

"The strong persistence of the CAR T cells over time, coupled with the low frequency of severe CRS events seen in these patients, represent encouraging initial data for AUTO1 in relapsed/refractory adult ALL," said Dr. Christian Itin, chairman and chief executive officer of Autolus Therapeutics. "We expect AUTO1 in adult ALL to move into a registration trial towards the end of this year."

For information about the ALLCAR19 trial, visit https://clinicaltrials.gov/ct2/show/NCT02935257?term=ALLCAR19&rank=1

#### Conference Call Information

Autolus management will host a conference call featuring Dr. Roddie on Tuesday, April 2, 2019 at 8:00 am ET/ 1:00 pm BST to discuss the ALLCAR19 data presented at AACR. To listen to the webcast and view the accompanying slide presentation, please go to <a href="https://www.autolus.com/investor-relations/news-events/events">https://www.autolus.com/investor-relations/news-events/events</a>.

The call may also be accessed by dialing 866-679-5407 (U.S.) or 409-217-8320 (international) and referencing conference ID 7679666. After the conference call, a replay will be available for one week. To access the replay, please dial 855-859-2056 (U.S.) or 404-537-3406 (international) and enter conference ID 7679666.

#### About AUTO1

AUTO1 is a CD19 CAR T cell investigational therapy designed to overcome the limitations in safety—while maintaining similar levels of efficacy—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, Autolus believes AUTO1 may reduce toxicity and be less prone to T cell exhaustion, which could enhance persistence and improve the T cells' abilities to engage in serial killing of target cancer cells. In 2018, Autolus signed a license agreement under which Autolus acquired global rights from UCL Business plc (UCLB), the technology-transfer company of UCL, to develop and commercialize AUTO1 for the treatment of B cell malignancies. AUTO1 is currently being evaluated in two Phase 1/2 trials, one in pediatric ALL and one in adult ALL.

#### About Adult Acute Lymphoblastic Leukemia

According to the American Cancer Society, acute lymphoblastic leukemia (ALL) is predicted to affect approximately 5,960 adults in the United States in 2018. Combination chemotherapy enables 90% of adult patients to experience CR (complete response). Despite this, the prognosis of adult ALL is still poor and has not changed significantly during the last two to three decades, with long-term remission rates limited to 30–40%. Approximately 50% of all adult ALL patients will relapse.

#### 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.

#### 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 company's product candidates and research programs including the company's ongoing and planned clinical developments of AUTO1 including its timeline to move into a registration trial. 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 the company's Annual

Report on Form 20-F filed on November 23, 2018 as well as discussions of potential risks, uncertainties, and other important factors in the company's 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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# **Autolus AACR Investor and Analyst Call**

April 2<sup>nd</sup>, 2019



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### **Disclaimer**

These slides and the accompanying oral presentation made by Autolus Therapeutics plc ("Autolus" or the "Company") contain forward-looking statements within the meaning of the "safe harbor" provisions of The Private Securities Litigation Reform Act of 1995, including statements about the Company's ongoing and planned clinical trials, including its clinical development of AUTO1, the anticipated benefits of the Company's product candidates, the timing and availability of data from clinical trials, the timing and ability to obtain and maintain regulatory approvals for the Company's product candidates and the size and growth potential of the markets for its product candidates. All statements other than statements of historical fact contained in this presentation, including statements regarding the Company's future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward- looking statements by terms such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These statements involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward looking statements include the risks described in the "Risk Factors" section of the Company's Annual Report on Form 20-F for the year ended September 30, 2018 filed with the SEC on November 23, 2018, as well as those set forth from time to time in the Company's other SEC filings, available at www.sec.gov. The forward-looking statements contained in this presentation reflect the Company's views as of the date of this presentation regarding future events, except as required by law, and the Company does not assume any obligation to update any forwardlooking statements. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this presentation.

Certain data in this presentation was obtained from various external sources. Such data speak only as of the date referenced in this presentation and neither the Company nor its affiliates, advisors or representatives make any representation as to the accuracy or completeness of that data or undertake to update such data after the date of this presentation. Such data involve risks and uncertainties and are subject to change based on various factors.



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### **AUTO1**

CAR T cell therapy designed to reduce the risk of severe CRS and improve the safety profile of the CD19 binder

- CD19-targeting programmed T cell therapy with a new binder (CAT19) with fastoff kinetics
- Similar structure to Kymriah®, 41BB endo-domain, lentivial vector
  - · Key difference is the binder
- In pre-clinical studies, AUTO1 has shown better proliferation, cytotoxicity, less exhaustion and cytokine production

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- AUTO1 behaves more like a natural T cell
- Currently in ongoing Phase 1 clinical trial at University College London



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### **AUTO1** and Kymriah®: Pediatric ALL¹

AUTO1* Data Summary - 2018						
Patient Numbers	14					
CRR (at 3 months)	86%					
EFS (at 12 months)	46%					
	(95% CI, 16 to 72)					
CD19-neg relapse	83%					
CRS ≥ Grade 3	0%					
Neurotox ≥ Grade 3	7%					
Tocilizumab use	No					
Grade ≥ 4 Cytopenia > 1 month	57%					

AUTO1 - one patient died due to a serious adverse event (sepsis)

Kymriah (Maude et al., NEJM 2018)						
Patient Numbers	75					
CRR (at 3 months)	81%					
EFS (at 12 months)	50%					
	(95% CI, 35 to 64)					
CD19-neg relapse	~60%					
CRS ≥ Grade 3#	47%					
Neurotox ≥ Grade 3	13%					
Tocilizumab use	Yes					
Grade ≥ 3 Cytopenia > 1 month	32%					

Kymriah\* - eleven patients died, including four due to adverse events (encephalitis, cerebral hemorrhage, systemic mycosis and hepatobiliary disorders relating to allo transplant)

25% on ventilator and 10% on dialysis

### AUTO1 has 0% ≥Grade 3 CRS & may need lower intensity of care



<sup>1</sup>Although the Company believes these observations from the CARPALL trial are promising, no definitive conclusions regarding safety or effectiveness can be drawn between these two studies given the investigational stage of AUTO1, the small study size, differing study designs between the CARPALL and ELIANA trials, and other factors

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<sup>\*</sup> All data as of the November 16, 2018 data cut off

## **AUTO1** and Kymriah®: Pediatric ALL

- AUTO1 Dose 1mil/kg vs 2-5mil/kg Kymriah
- Peak expansion: 10x higher than Kymriah
- AUC: 10x of Kymriah
- We believe AUTO 1 may have lower toxicity
- We believe the safety profile may enable AUTO1 to be well-suited for the treatment of adult ALL: older patients, more co-morbidities and less likely to tolerate toxicity



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# **Next Steps for AUTO1**

April 2<sup>nd</sup>, 2019



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# **Key Outcomes of CD19 CARs and BiTEs in ALL**

AUTO1 shows potential for low rate of severe CRS

	Pediatric ALL		Adult ALL		
	<sup>1</sup> Kymriah- pALL	<sup>2</sup> AUTO1 - pALL	<sup>3</sup> AUTO1 aALL	4YESCARTA	<sup>5</sup> Blinatumomab
Patient Numbers	75	14	10	14	271
CR Rate	81%	86%	88%	93%	42%
EFS	EFS 12m: 50% (95% CI, 35 to 64)	EFS 12m: 46% (95% CI, 16 to 72)	tbd	tbd	EFS 6m: 30%
CRS ≥ Grade 3	47%	0%	0%*	18%	3%
Neurotox ≥ Grade 3	13%	7%	11%	45%	13%

<sup>\*</sup>One patient had Grade 3 CRS by UPenn criteria

- 1. Maude et al., NEJM 2018
- 2. Ghorashian et al., European CAR T Cell Meeting 2019
- 3. Roddie et al., AACR 2019 4. Wierda et al., ASH 2018
- 5. Blinatumomab FDA label



Although the Company believes these observations from the CARPALL and ALLCAR trials are promising, no definitive conclusions regarding Although the Company believes these observations from the Canada and Although the Indianal stage of AUTO1, the small study size, differing study designs between the various trials, as well as other factors.

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## **AUTO1 Outlook and Next Steps**

- This initial data set for AUTO1 from the Phase 1/2 ALLCAR19 trial in adult r/r B-ALL patients indicates a potential attractive safety profile
- Further follow up will provide information on durability of treatment effect
- Level of CD19-negative relapse rate is too early to call
- Full update of ALLCAR19 trial planned for ASH 2019
- Planned transition to Phase 2 in Q4 2019



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