Autolus Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Operational Progress

March 10, 2022

- Conference call to be held on March 10, 2022 at 8:30 am ET/1:30 pm GMT -

LONDON, March 10, 2022 (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, 2021.

“We rounded off the 2021 financial year announcing a collaboration with Blackstone Life Sciences, adding $150M in capital with an additional $100M in potential milestone payments triggered by future development progress of obe-cel, as well as positive clinical data from our pipeline, notably data from the Phase 1b portion of the FELIX study of obe-cel in adult ALL patients. Recruitment is ongoing in the Phase 2 portion of this pivotal study and we look forward to announcing initial Phase 2 data this year, as well as starting preparations for submitting a BLA in 2023,” said Dr. Christian Itin, Chief Executive Officer of Autolus. “We are excited about Autolus’ outlook and look forward to updating you on progress with obe-cel, as well as AUTO4 and AUTO1/22 over the coming months.”

Key Clinical and Pipeline Updates during 2021:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL*
  - *FELIX Study* – Autolus continues to enroll patients in the Phase 2 portion of the FELIX study. As presented at ASH in December 2021, the data from the Phase 1b portion of the FELIX study show a favorable safety and efficacy profile consistent with our experience in the ALLCAR19 study in adult r/r B-ALL and the CARPALL study in pediatric r/r ALL patients treated with obe-cel. No patient experienced high grade (≥ Grade 3) cytokine release syndrome (CRS) and neurotoxicity (ICANS) of any grade was limited to 13% of patients and only 6% experienced a Grade 3 event.
  - *ALLCAR19 Study* - Data were published in the Journal of Clinical Oncology (JCO)[(1)] in September 2021 from the ALLCAR19 trial in r/r adult ALL patients. Obe-cel demonstrated a manageable adverse events profile, with no patients experiencing high grade CRS, despite the majority of patients enrolled in the study having a high disease burden prior to lymphodepletion. As presented at ASH in December 2021, duration of response remains highly encouraging with morphological EFS for obe-cel of 46% at 24 months with a median follow-up of 29.3 months and patients approaching up to 42 months of durability, as of the cut-off date of October 15, 2021.

- *Obe-cel in r/r B-NHL – ALLCAR19 extension*
  - The latest data of obe-cel in relapsed/refractory B-Cell Non-Hodgkin's Lymphoma (B-NHL) and Chronic Lymphocytic Leukaemia (CLL) were presented by Autolus at ASH in December 2021. As of the data cut-off date of October 15, 2021, 15 patients with r/r B-NHL and 1 patient with B-CLL had received obe-cel, with 14 patients evaluable for response. 14 of 14 patients responded to obe-cel, of which 13 of 14 patients achieved complete metabolic response per Lugano 2014, with 1 B-CLL patient achieving a partial response. 15 of 16 patients had no disease progression at last follow-up, with 1 of 16 patients having died in CR from COVID-19. Furthermore, long term persistence was demonstrated by quantitative PCR. Across all evaluable patients, obe-cel demonstrated a favorable safety profile with no ICANS or severe Grade ≥ 3 CRS events.

- *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, which is being investigated in the ongoing FELIX trial in ALL.
  - Autolus also received PRIority MEdicines (PRIME) designation from the EMA.

- *AUTO1/22 in pediatric ALL*
  - Pre-clinical data presented at ASH in December 2021 demonstrated a high level of in vitro and in vivo activity of AUTO1/22 against leukemia cells. AUTO1/22 was shown to control leukemia in a mouse model of CD19 negative escape. AUTO1/22 is currently being tested in a study of r/r pediatric B-ALL. As of the cut-off date of October 21, 2021, 6 patients had received AUTO1/22. All patients showed engraftment of single and double CAR positive populations, pointing to early CAR T cell persistence.

- *AUTO4 in Peripheral T Cell Lymphoma*
    - Autolus received ILAP designation from the MHRA. The AUTO4 Phase 1 clinical trial is progressing through dose escalation.

Key Operational Updates during 2021

- In November 2021, Autolus announced that it had entered into a strategic collaboration and financing agreement under which Blackstone Life Sciences will provide up to $250 million in equity and milestones to support obe-cel, as well as next generation product therapies of obe-cel in B-cell malignancies.

- In November 2021, Dr. William D. Young, a Senior Advisor to Blackstone Life Sciences, was appointed as a Non-Executive Director to the Autolus Board of Directors.

- In September 2021, Autolus gave an update on its manufacturing strategy, announcing that planning approval had been granted to build the Company's new 70,000 square foot manufacturing facility in Stevenage, UK. This commercial facility is designed for a capacity of 2,000 batches a year, with an opportunity to expand.

- Also in September 2021, Autolus announced the appointment of John H. Johnson as Non-Executive Chairman of the Board of Directors.

- In July 2021, Autolus announced its entry into an agreement with Moderna, Inc., granting Moderna an exclusive license to develop and commercialize mRNA-based therapeutics incorporating Autolus' proprietary binders for up to four immuno-oncology targets.

- Updates to Autolus' executive team over the course of the year:
    - In July 2021, Autolus announced the appointment of Edgar Braendle M.D., Ph.D., as Chief Development Officer.
    - In October 2021, Alexander Swan was promoted to Senior Vice President, Human Resources and Dr. Chris Williams was promoted to Senior Vice President, Corporate Development.

Post Period Updates:

- In January 2022 Autolus announced the retirement of Andrew J. Oakley as its Chief Financial Officer, effective March 31, 2022. Dr. Lucinda Crabtree, Senior Vice President of Business Strategy & Planning at Autolus, will succeed Mr. Oakley as Autolus' Chief Financial Officer. Brent Rice was also promoted to Senior Vice President, Chief Commercial Officer.

Key Anticipated Clinical Milestones:

- Updates on the FELIX trial, where Autolus is evaluating obe-cel in r/r adult ALL patients. The trial is currently enrolling patients into the Phase 2 portion. The Company expects to report initial clinical data from the Phase 2 study in H2 2022 and full data in H1 2023.

- Updates from the ALLCAR19 extension trial in patients with r/r B-NHL and CLL and longer-term follow-up of the fully enrolled r/r adult ALL cohort expected in H1 2022.

- Updates on the obe-cel Phase 1 trial, CAROUSEL, in Primary CNS Lymphoma in H1 2022.

- Initial clinical data from the AUTO1/22 CARPALL extension trial in pediatric ALL expected to be reported in H1 2022 and with longer follow up in H2 2022.

- Initial clinical data from AUTO4 LibraT1 Phase 1 trial in TRBC1+ Peripheral TCL expected to be reported in H1 2022.

- AUTO8 in Multiple Myeloma Phase 1 trial expected to be initiated in H1 2022.

- AUTO6NG – Neuroblastoma Phase 1 trial expected to start mid 2022.

(1)Roddie et al. "Durable responses and low toxicity after fast off-rate CD19 CAR-T therapy in adults with relapsed/ refractory B-ALL." *DOI: 10.1200/JCO.21.00917 Journal of Clinical Oncology - published online before print August 31, 2021*

Financial Results for the Quarter and Year Ended December 31, 2021

Cash at December 31, 2021, totaled $310.3 million, as compared to $153.3 million at December 31, 2020. Net total operating expenses for the twelve months ended December 31, 2021 were $165.0 million, net of grant income and license revenue of $2.3 million, as compared to net operating expenses of $168.1 million, net of grant income and license revenue of $1.7 million, for the same period in 2020.

Research and development expenses remained relatively flat at $134.8 million for the year ended December 31, 2021 when compared to $134.9 million for the year ended December 31, 2020. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to $121.4 million from $116.9 million. The increase in research and development cash costs of $4.5 million consisted primarily of (i) an increase in compensation and employment related costs of $3.8 million due to a combination of an increase in employee headcount, to support the advancement of our product candidates in clinical development, and to severance payments related to the reduction in workforce that was initiated during the first quarter of 2021, (ii) an increase of $2.5 million in facilities costs related to the continued scaling of manufacturing operations, (iii) an increase of $2.4 million in purchased consumables used in the manufacturing of obe-cel in the FELIX study, (iv) an increase of $0.9 million in IT infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations, and (v) an increase of $0.1 million related to cell logistics, which is offset by a reduction in clinical trial costs of $5.2 million.

Non-cash costs decreased to $13.4 million for the year ended December 31, 2021 from $18.1 million for the year ended December 31, 2020. The $4.7 million decrease of non-cash costs is related to a decrease of $7.7 million share-based compensation expense as a result of a lower fair value of options recognized during the period and due to the reduction in workforce that was initiated during the first quarter of 2021, offset by a $3.0 million increase in depreciation expense.

General and administrative expenses decreased to $31.9 million for the year ended December 31, 2021 from $35.0 million for the year ended December 31, 2020. Cash costs, which exclude depreciation as well as share-based compensation decreased to $26.7 million from $27.4 million. There were decreases of $0.7 million of costs related to (i) $0.8 million of expenses relating to the Company's commercial preparation costs, (ii) $0.6 million of employee compensation expense due to the reduction in workforce during the first quarter of 2021 and lower retention costs, (iii) $0.5 million of facilities costs, and (iv) $0.1 million in general administration expenses, offset by increases in director and officer insurance and IT infrastructure and support for information systems of $1.0 million and $0.3 million, respectively.

Non-cash costs decreased to $5.2 million for the year ended December 31, 2021 from $7.6 million for the year ended December 31, 2020. The $2.4 million decrease of non-cash costs is mainly attributed to lower share-based compensation expenses as a result of the lower fair value of options recognized during the period and due to the reduction in workforce that was initiated during the first quarter of 2021.

Interest income decreased to $0.3 million for the year ended December 31, 2021 from $0.5 million for the year ended December 31, 2020. This decrease is due to the lower cash balances held during the year combined with lower interest rates for cash held on deposit.

Interest expense increased to $1.1 million for the year ended December 31, 2021 and relates to the liability relating to the sale of future revenue which arose upon entering into the Collaboration and Financing Agreement with Blackstone.

Income tax benefit decreased to $23.9 million for the year ended December 31, 2021 from $24.2 million for the year ended December 31, 2020 due to small decrease in the research and development expenditures which were qualifying for tax credits for the year. As research and development credits fell at a faster rate than the Company's 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 the Company's qualifying research and development expenses, and the decrease in the net credit was primarily attributable to a decrease in its eligible research and development expenses.

Net loss attributable to ordinary shareholders was $142.1 million for the twelve months ended December 31, 2021, compared to $142.1 million for the same period in 2020. The basic and diluted net loss per ordinary share for the twelve months ended December 31, 2021, totaled $(1.97) compared to a basic and diluted net loss per ordinary share of $(2.76) for the twelve months ended December 31, 2020.

Autolus estimates that its current cash on hand and anticipated milestone payments from Blackstone, extends the Company's runway into 2024.

Financial Results for the Year Ended December 31, 2021

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 310,338	$ 153,299
Restricted cash	338	786
Prepaid expenses and other current assets	36,276	42,899
Total current assets	346,952	196,984
Non-current assets:		
Property and equipment, net	33,541	38,046
Prepaid expenses and other non-current assets	2,362	3,033
Operating lease right-of-use assets, net	18,775	51,637
Long-term deposits	2,039	2,625
Deferred tax asset	1,826	1,754
Intangible assets, net	65	158
Total assets	$ 405,560	$ 294,237
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	431	2,263

Accrued expenses and other liabilities	23,667	27,781
Operating lease liabilities, current	4,453	3,590
Total current liabilities	28,551	33,634
Non-current liabilities:		
Operating lease liabilities, non-current	16,545	50,571
Liability related to sale of future revenue, net	47,016	—
Other long term payables	128	—
Total liabilities	92,240	84,205
Commitments and contingencies (Note 15)		
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized at December 31, 2021 and 2020, 90,907,830 and 52,346,231 shares issued and outstanding at December 31, 2021 and 2020	4	3
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2021 and 2020	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2021 and 2020	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at December 31, 2021 and 2020	—	—
Additional paid-in capital	843,108	595,016
Accumulated other comprehensive loss	(8,570)	(5,861)
Accumulated deficit	(521,340)	(379,244)
Total stockholders' equity	313,320	210,032
Total liabilities and stockholders' equity	$ 405,560	$ 294,237

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	December 31,		
	2021	**2020**	**2019**
Grant income	$ 823	$ 1,473	$ 2,908
License revenue	1,507	242	—
Operating expenses:			
Research and development	(134,789)	(134,888)	(105,418)
General and administrative	(31,865)	(34,972)	(39,452)
Loss on impairment of leasehold improvements	—	—	(4,102)
Loss on disposal of leasehold improvements	(676)	—	—
Total operating expenses, net	(165,000)	(168,145)	(146,064)
Other (expense) income:			
Interest income	262	536	2,542
Other (expense) income	(145)	1,352	4,514
Interest expense	(1,105)	—	—
Total other (expense) income, net	(988)	1,888	7,056
Net loss before income tax	(165,988)	(166,257)	(139,008)
Income tax benefit	23,892	24,163	15,159
Net loss attributable to ordinary shareholders	(142,096)	(142,094)	(123,849)
Other comprehensive (loss) income:			
Foreign currency exchange translation adjustment	(2,709)	2,830	6,797
Total comprehensive loss	(144,805)	(139,264)	(117,052)
Basic and diluted net loss per ordinary share	$ (1.97)	$ (2.76)	$ (2.88)
Weighted-average basic and diluted ordinary shares	72,034,803	51,558,075	43,065,542

Conference Call

Management will host a conference call and webcast today 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**:** 2794888. 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**:** 2794888.

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 Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL. Autolus has progressed obe-cel to the FELIX trial, a potential pivotal trial for adult ALL.

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel is enrolling adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase 1b component prior to proceeding to the single arm, Phase 2 clinical trial. The primary endpoint is overall response rate, and the secondary endpoints include duration of response, MRD negative CR rate and safety. The trial is designed to enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

About AUTO1/22
AUTO1/22 is a novel dual targeting CAR T cell based therapy candidate based on obe-cel. It is designed to combine the enhanced safety, robust expansion & persistence seen with the fast off rate CD19 CAR from obe-cel with a high sensitivity CD22 CAR to reduce antigen negative relapses. This product candidate is currently in a Phase 1 clinical trial for patients with r/r pediatric ALL. [NCT02443831]

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.

About AUTO8
AUTO8 is our next-generation product candidate for multiple myeloma which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other BCMA CARs currently in 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 Autolus' development of the obe-cel 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; expectations regarding regulatory approval process for any product candidates; the collaboration between Autolus and Blackstone; the discovery, development and potential commercialization of potential product candidates including obe-cel using Autolus' technology and under the collaboration agreement; the therapeutic potential for Autolus in next generation product developments of obe-cel in B-cell malignancies; the potential and timing to receive milestone payments and pay royalties under the strategic collaboration; and the Company's anticipated 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 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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