Autolus Therapeutics announces 2022 priorities

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- obe-cel has the potential to transform outcomes for adult ALL patients

- Phase 2 FELIX study data expected in 2022

LONDON, Jan. 10, 2022 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its 2022 corporate priorities and provided guidance.

“We are on track to complete patient recruitment in the FELIX study of obe-cel in adult ALL patients with the first data expected around the middle of the year,” said Dr. Christian Itin, chief executive officer of Autolus. “This study is the key driver for the Company over the coming months and we are working diligently to shape the product profile and the commercial strategy of obe-cel, whilst laying the foundation for progressing our other differentiated CAR T cell products. We are very excited about the year ahead, which could be a transformational year for Autolus.”

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. Autolus expects data from the Phase 2 trial to be available in 2022
- 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 Q1 2022
- Clinical data from the AUTO1/22 CARPALL extension trial in pediatric ALL expected in H1 2022 with longer follow up in H2 2022
- Updates on the AUTO4 Phase 1 trial in TRBC1+ Peripheral TCL expected in H1 2022
- Phase 1 trials are expected to be initiated in H1 2022 with AUTO6NG in Neuroblastoma and AUTO8 in Multiple Myeloma

Recent Key Updates:

- *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. The multi-center study is progressing well. 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. The Company reiterates its expectation of pivotal data in 2022.
  - *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 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.

- *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 r/r B-NHL and 1 B-CLL patient 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 in PR. 15 of 16 patients were without 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 qPCR. Across all patients, obe-cel demonstrated a favorable safety profile with no ICANS or severe Grade ≥ 3 CRS events.

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

- In September 2021, Autolus gave an update on its manufacturing strategy, announcing that planning approval had been granted to build the Company's new manufacturing facility in Stevenage, UK. The 70,000 square foot facility is being built by Merit Holdings Limited as general contractor for the Reef Group, who will lease the facility to Autolus. Global commercial launch capacity for obe-cel will initially be provided by the existing clinical trial manufacturing facility at The Cell and Gene Therapy Catapult facility, and will then move to the new Autolus facility, which will allow for approximately 2,000 batches a year initially, with scope to expand.

- 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.

(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

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]

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; and expectations regarding the initiation, design and reporting of data from clinical trials. 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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