Autolus Therapeutics presents positive obe-cel data at the 63rd ASH Annual Meeting & Exposition

December 13, 2021 at 7:01 AM EST

- Obe-cel shows sustained durability of response with morphological EFS of 46% at 24 months in the ALLCAR19 study

- Obe-cel response and safety data from the Phase 1b portion of the FELIX study consistent with the Phase 1 ALLCAR19 study

- Obe-cel achieves a metabolic CR in 100% patients with FL, MCL and DLBCL, with long term persistence evident and without ICANS or high grade CRS

- Dual targeting AUTO1/22 shows data consistent with high level of activity and good engraftment

Conference Call and Webcast to be held Monday, Dec 13, 2021 at 8:00 am ET / 1:00 pm GMT

LONDON, Dec. 13, 2021 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, presented further progress on obecabtagene autoleucel (obe-cel) in an oral presentation [Abstract 477] entitled “Industrialization of an Academic Miltenyi Prodigy-Based CAR T Process” at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, being held between December 11-14, 2021. The Company also presented an update of obe-cel in relapsed/refractory aggressive and indolent B-Cell Non-Hodgkin's Lymphoma (B-NHL) and Chronic Lymphocytic Leukaemia (CLL) patients from the ALLCAR19 extension study, as well as preclinical and initial engraftment data with AUTO1/22 in Pediatric ALL in two separate poster presentations [Abstracts 3823 and 1710, respectively].

“We continue to observe sustained responses with obe-cel, with an EFS of 46% at 24 months and patients approaching up to 42 months of durability in the ALLCAR-19 study, supporting the curative potential of obe-cel as a standalone therapy in r/r B-ALL patients. Furthermore, we were encouraged to observe comparable safety and high complete response data between patients treated in the academic ALLCAR19 study and those in the Phase 1b portion of the Autolus sponsored FELIX study,” said Dr. Christian Itin, chief executive officer of Autolus. “In addition, we are excited to observe further positive data for obe-cel in r/r B-NHL and B-CLL patients, as well as compelling initial data for AUTO1/22, pointing to the potential for indication expansion and life cycle management opportunities longer term.”

Obe-cel in Adult Acute Lymphoblastic Leukemia patients (FELIX study)
Oral Presentation Title: Industrialization of an Academic Miltenyi Prodigy-Based CAR T process
Session Name: 711. Cell Collection and Processing: Advances in Mobilization, Collection, Manipulation and Engineering of HSCs and T Cells
Abstract: #477
Date: Sunday, December 12, 2021
Session Time: 12:00 PM - 1:30 PM ET; Presentation Time: 12:30 PM ET
Location: Georgia World Congress Center, Hall A1
Presenter: Dr. Claire Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

Initial experience in the phase 1b portion of the FELIX 1b/2 study (NCT04404660) resulted comparable results as seen in the Phase 1 ALLCAR19 study. As of the cut-off date of 13 September, 16 patients in the Phase 1b part of the FELIX study had received obe-cel. Patient characteristics in the FELIX 1b portion were broadly comparable to those observed in the ALLCAR19 study in r/r adult B-ALL.

- As of the data cut off date of 15 October 2021, ALLCAR19 data shows morphological EFS for obe-cel is 46% at 24 months with a median follow-up of 29.3 months and patients approaching up to 42 months of durability.
- Baseline characteristics between FELIX Phase 1b and ALLCAR19 studies are similar. 75% patients in the FELIX Phase 1b had >20% blasts at pre-conditioning, compared with 60% patients in ALLCAR19. 56.3% patients received prior blinatumomab in the FELIX Phase 1b study compared with 25% in ALLCAR19[1].
- High level of CR/CRi response rate at 1 month observed across both studies, with 12/16 patients in the FELIX Phase 1b study, consistent with 17/20[1] patients in the ALLCAR19 study.
- Safety consistent between the ALLCAR19 study and FELIX Phase 1b study, with no patient having high grade (≥Grade 3) cytokine release syndrome (CRS). 1 of 16 patients experienced a Grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) in the FELIX Phase 1b study, as compared with 3 of 20 patients in ALLCAR-19 study[1].

The company expects to present data from the Phase 2 portion of the FELIX study in 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

Obe-cel (AUTO1) in Adult Acute Lymphoblastic Leukemia patients (ALLCAR study)
Poster Presentation Title: Safety and Efficacy of AUTO1, a Fast-Off Rate CD19 CAR in Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma (B-NHL) and Chronic Lymphocytic Leukaemia (CLL)
Session Title: 704. Cellular Immunotherapies: Clinical: Poster III

Abstract: #3823
Date: Monday, December 13, 2021
Presentation Time: 6:00 PM - 8:00 PM ET
Location: Georgia World Congress Center, Hall B5
Presenter: Dr. Claire Roddie, MD, PhD, FRCPath, Consultant Haematologist and Honorary Senior Lecturer, Cancer Institute, University College London (UCL)

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.
- Median follow up time for Follicular Lymphoma (FL) and DLBCL patients was 11.8 months (range 2-14.2m).
- Median follow up time for Chronic Lymphocytic Leukemia (CLL) and Mantle Cell Lymphoma patients was 7.4 months (range 1.1-14.8m).
- Across all patients, obe-cel demonstrated a favorable safety profile with no ICANS or severe Grade ≥ 3 CRS events.

The company expects to present further data from more B-NHL and CLL patients in H1 2022.

AUTO1/22 in Pediatric Acute Lymphoblastic Leukemia patients (CARPALL)
Poster Presentation Title: A high sensitivity aCD22 CAR combined with aCD19 CAR to generate dual targeting CAR T cells for the treatment of r/r B-ALL
Session Title: 703. Cellular Immunotherapies: Basic and Translational: Poster I
Abstract: #1710
Date: Saturday, December 11, 2021
Presentation Time: 5:30 PM - 7:30 PM ET
Location: Georgia World Congress Center, Hall B5
Presenter: Dr. Sara Ghorashian, MD, PhD, Hon clinical senior lecturer, UCL Great Ormond Street Institute of Child Health

Obe-cel had previously been tested in r/r pediatric B-ALL[2] in the CARPALL Study. Whilst obe-cel was safe and effective, similar to other studies in pediatric B-ALL, antigen escape was a common cause of treatment failure. AUTO1/22 has been designed to address antigen escape by the co-expression of a CD22 CAR with the CD19 CAR in obe-cel. Pre-clinical data 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. We expect to present clinical data from the full cohort of patients in H1 2022.

2 Ghorashian et al. “Enhanced CAR T cell expansion and prolonged persistence in pediatric patients with ALL treated with a low-affinity CD19 CAR.” Nature Medicine volume 25, pages1408–1414(2019) (Sept 25, 2019)

Investor call details
Management will host a conference call and webcast on Monday, December 13, 2021 at 8:00 am ET/1:00 pm GMT to discuss the ASH data. 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 9036269. 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 9036269.

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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