Autolus Therapeutics to Present Four Clinical Data Updates at the European Hematology Association Congress

May 12, 2022 at 10:52 AM EDT

- AUTO4: oral presentation on initial clinical experience in peripheral T cell lymphoma
- AUTO1/22: oral presentation on initial experience in r/r pediatric B-cell acute lymphoblastic leukemia
- obe-cel: poster presentation in r/r primary CNS lymphoma
- obe-cel: poster presentation in r/r B-non-Hodgkins lymphoma and chronic lymphoblastic leukemia
- Conference call to be held on June 13, 2022 at 7:30 am EST/12:30 pm BST

LONDON, May 12, 2022 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces the online publication of four abstracts submitted to the European Hematology Association (EHA) Congress to be held June 9-12, 2022. Autolus plans to present more detail on these programs and the next steps in a conference call following the EHA presentations, on June 13, 2022, details below.

"We are delighted to be presenting encouraging early clinical data from four of our pipeline programs, including important additive safety and efficacy data from our lead asset obe-cel in indications beyond adult r/r B-ALL. These data demonstrate the inherent value in both our pipeline and our technology base from which it originates," **said Dr. Christian Itin, Chief Executive Officer of Autolus**. "With oral presentations on the early safety, tolerability, feasibility and preliminary efficacy of AUTO4 and AUTO1/22, we're in a great place to evaluate the next strategic steps for these candidates and further build on the data presented here."

Abstracts to be presented:

1. **Title: Safety and preliminary efficacy findings of AUTO4, a TRBC1-targetting CAR, in relapsed/refractory TRBC1 positive selected T Cell Non-Hodgkin Lymphoma LINK**
   Session Title: Gene therapy and cellular immunotherapy - Clinical 2
   Session date and time: Saturday, June 11 - 16:30 - 17:45 CEST
   Session room: Hall Strauss 1-2
   Final Abstract Code: S261
   Presenting Author: Kate Cwynarski
   Summary: Peripheral T cell lymphomas (PTCL) are typically aggressive, treatment resistant, and associated with poor prognosis. Finding the right target is challenging because there is a lack of tumor-specific antigens, and pan-T cell depletion leads to immunosuppression. T cell lymphoma is clonal, and tumor cells express either TRBC1 or TRBC2. AUTO4 targets TRBC1+ cells, which allows part of the T cell compartment to be retained. As of 9 February 2022, 9 patients screened for r/r TRBC1+ peripheral T-cell lymphoma have been treated with AUTO4. Two patients had prior stem cell transplantation. After lymphodepletion with Flu/Cy, 3 patients received 25 x 10^6 CAR T cells, 2 patients received 75 x 10^6 CAR T cells, 1 patient received 225 x 10^6 CAR T cells and 3 patients received 450 x 10^6 CAR T cells. AUTO4 demonstrated a tolerable safety profile, with no patient experiencing any dose limiting toxicities, and no neurotoxicity/immune effector cell-associated neurotoxicity (ICANS). Three patients experienced cytokine release syndrome (CRS) (1 patient with Grade 1, 1 patient with Grade 2 and 1 patient with Grade 3). Of the 9 patients treated, 5 patients had achieved complete metabolic responses (CMR) by PET-CT at Month 1, 1 patient remains with a partial response (PR) 6 months post AUTO4 infusion, and 3 patients did not respond. All 3 patients at the highest dose level achieved a CMR at Month 1.

2. **Title: Dual antigen targeting with co-transduced CD19/22 CAR T cells for relapsed/refractory ALL (AUTO1/22) LINK**
   Session Title: Gene therapy and cellular immunotherapy - Clinical 1
   Session date and time: Saturday, June 11 - 11:30 - 12:45 CEST
   Session room: Hall Strauss 1-2
   Final Abstract Code: S259
   Presenting Author: Sara Ghorashian
   Summary: CD19 negative escape is a major cause of relapse after CD19 CAR T cell therapy for relapsed/refractory (r/r) pediatric ALL. To overcome this challenge, AUTO1/22 builds on the favorable safety profile and excellent persistence of obe-cel by combining it with an additional CD22 targeting CAR. As of 8 February 2022, 10 pediatric ALL patients have been treated with AUTO1/22 and 8 are evaluable with >1 month follow-up. 5 of 8 patients had relapsed post allogeneic stem cell transplant (SCT), 4 had received prior Blincyto and 3 had relapsed after prior Kymriah. CRS occurred in 7/8 patients (grade 1 n=2, grade 2 n=5), but severe CRS was not seen. 7 of 8 evaluable patients achieved MRD negative

complete response (CR) at 1 month post infusion. Overall, at a median follow up of 4.8 months, 5/8 patients remain in MRD negative CR at last follow up. The study results demonstrate that dual CD19/22 targeting CAR T cells generated by co-transduction show an acceptable safety profile, with robust expansion/persistence and early efficacy in a heavily pre-treated cohort. To date with limited follow-up we have not observed antigen negative relapse but longer follow up is needed.

3. **Title: Safety and efficacy findings of AUTO1, a fast off-rate CD19 CAR, in relapsed/refractory Primary CNS Lymphoma LINK**
   Session Title: Poster session
   Session date and time: Friday, June 10 - 16:30 - 17:45 CEST
   Final Abstract Code: P1460
   Presenting Author: Claire Roddie
   Summary: Relapsed/refractory primary central nervous system lymphoma (PCNSL) has a median overall survival of 2-8 months and few therapeutic options. obe-cel (AUTO1) has previously demonstrated high remission rates, low incidence of CRS/ICANS and long-term persistence, making it a viable treatment option for PCNSL. As of 14 February 2022, the CAROUSEL study enrolled 6 patients with r/r PCNSL where the median prior lines of treatment was 2. 5 patients were infused with IV AUTO1 and 1 patient with intraventricular AUTO1. Following CAR T infusion, Grade 1 and 2 CRS affected 1 and 3 patients respectively and any Grade ICANS was observed in 2 patients with 2 Grade 3 events. AUTO1 engraftment and response was evaluable in 4 patients at 1 month following iv infusion. 2 of 4 patients had no measurable disease at 2 and 6 months of follow up respectively. AUTO1 showed encouraging remission rates and excellent CAR T engraftment/expansion in the blood and CSF. Intraventricular administration was well-tolerated and showed that AUTO1 has activity via that route in a patient who failed IV therapy. Additional patients updated biological data and longer follow up will be presented.

4. **Title: Safety and efficacy findings of AUTO1, a fast off-rate CD19 CAR, in relapsed/refractory B-Cell Non-Hodgkin's Lymphoma (B-NHL), and chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL) LINK**
   Session Title: Poster session
   Session date and time: Friday, June 10 - 16:30 - 17:45 CEST
   Final Abstract Code: P1459
   Presenting Author: Claire Roddie
   Summary: obe-cel (AUTO1) has demonstrated an excellent safety profile in previous trials, with low levels of CRS/ICANS and long-term engraftment of CAR T cells, making it an ideal CAR T candidate to evaluate in B-NHL, CLL/SLL. As of 8 February 2022, 19 patients had been infused with AUTO1; 10 with low grade NHL, 6 with DLBCL and 3 with CLL. Patients treated had received a median of 3 prior lines of treatment. Grade 1 CRS was reported in 6/19 and Grade 2 CRS in 3/19. No ICANS was observed in the B-NHL and CLL cohorts. In the lg-NHL and DCBCL cohorts, 10/10 and 4/5 evaluable patients respectively were in CMR post-treatment. Responses were ongoing in 9/10 lg-NHL at 12 months and in 4/4 DLBCL at months 1,3,3 and 6. In the CLL cohort, 2/3 evaluable patients achieved MRD negative remission in the bone marrow with residual small volume lymph nodes by CT at 6 and 3 months of follow up respectively. AUTO1 demonstrated a tolerable safety profile in patients with r/r B-NHL and CLL despite high disease burden. Early data shows excellent complete remission rates and CAR engraftment/expansion. Additional patients, updated data and longer follow up will be presented.

Conference Call

Management will host a conference call and webcast on June 13, 2022 at 7:30 am ET/12:30 pm BST to discuss the EHA 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: 6594553. 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**:** 6594553.

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 called CARPALL 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. AUTO4 has been tested in a Phase 1 clinical trial, LibRA1 for patients with peripheral T cell Lymphoma.

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 10, 2022, 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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