Autolus Therapeutics Presents Clinical Data Updates at the European Hematology Association Congress

June 10, 2022 at 3:01 AM EDT

- AUTO4 shows high level of clinical activity with a novel targeting approach for patients with T Cell Lymphoma
- AUTO1/22 demonstrates encouraging and durable responses in children ineligible for commercial CAR T product
- Obe-cel shows high level of sustained clinical activity in B-NHL patients and first activity in Primary CNS Lymphoma

Conference call to be held on Monday June 13, 2022 at 7:30 am EST/12:30 pm BST

LONDON, June 10, 2022 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces the publication of clinical data across multiple programs at the European Hematology Association (EHA) Congress, being held June 9-12, 2022.

Autolus will hold a conference call on Monday June 13 2022 at 7:30 am EST / 12:30 pm BST, which will include participation from; Dr. Steven Horwitz, M.D., Department of Medicine, Lymphoma Service, Memorial Sloan Kettering Cancer Center; Dr. Kate Cwynarski, Chair UK T cell Lymphoma Group, Consultant Hematologist, University College London Hospital; and Autolus' management team.

"We are excited to be presenting this first clinical data for two new product candidates, AUTO4 with its unique targeting approach for T cell lymphoma and AUTO1/22 a dual targeting CAR T product for the treatment of children with ALL," **said Dr. Christian Itin, CEO of Autolus.** "With obe-cel progressing towards pivotal data in the FELIX trial in adult patients with ALL, we are pleased to show obe-cel's broader utility in B-NHL patients, mirroring the high level of activity and well manageable safety profile we have seen in previous trials."

"This year's EHA is an important meeting for Autolus with four presentations providing updates from ongoing clinical studies," **said Dr. Martin Pule, Chief Scientific Officer of Autolus.** "In an oral presentation we will present AUTO4 clinical data for the first time. These data suggest that AUTO4 has the potential to become an important therapeutic option for patients with T cell lymphoma. In a second presentation, we will present our finding from clinical testing of AUTO1/22. These data show that AUTO1/22 can induce remission in children with B-ALL, including in those whose disease was not successfully treated with commercial CAR T product. Further, data suggest that AUTO1/22 can prevent antigen escape. In two additional presentations, we demonstrate incremental obe-cel data in B-NHL and B-CLL, as well as some early data in PCNSL. Obe-cel continues to have consistent safety and efficacy data across these indications."

"As clinicians, we are always searching for new strategies to address unmet needs in aggressive blood cancers," **said Dr. Steven Horwitz, M.D., Department of Medicine, Lymphoma Service, Memorial Sloan Kettering Cancer Center, New York**. "T Cell Lymphomas are particularly challenging, and I've been following Dr. Pule's strategy of CAR T targeting based on the mutually exclusive expressions of TRBC1 or TRBC2 with great interest. Any advance in bringing new effective therapies to patients with T cell lymphomas is of great importance."

Data presentations:

1. **Title: Safety and preliminary efficacy findings of AUTO4, a TRBC1-targetting CAR, in relapsed/refractory TRBC1 positive selected T Cell Non-Hodgkin Lymphoma**
   Session Title: Gene therapy and cellular immunotherapy - Clinical 2
   Session date and time: Saturday, June 11, 2022 16:30 - 17:45 CEST
   Session room: Hall Strauss 1-2
   Final Abstract Code: S261
   Presenting Author: Kate Cwynarski
   Conclusions: As of April 26 2022, 10 patients with TRBC1-positive r/r T-cell lymphoma (Peripheral T-cell lymphoma Not Otherwise Specified (PTCL-NOS), Angioimmunoblastic T-cell lymphoma (AITL), Anaplastic Large cell lymphoma (ALCL)) have been treated with AUTO4 in a Phase I dose escalation trial. Three patients had prior stem cell transplantation. After lymphodepletion with Flu/Cy, patients received either 25, 75, 225 or 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) and no Grade 3 or higher infections. CRS was only seen at the highest dose level of 450 x 10^6 CAR T cells (Grade 3 in 1 patient; Grade 1-2 in 3 patients). As of 26 April 2022, 9 patients were evaluable for efficacy. At the highest dose level 3 of the 3 patients dosed achieved a complete metabolic remission (CMR) at 1 month. 2 of these patients remain in ongoing CMR by PET-CT at Month 3 and 6 respectively, whilst the 3rd relapsed at 3 months.
2. **Title:Dual antigen targeting with co-transduced CD19/22 CAR T cells for relapsed/refractory ALL (AUTO1/22)**
   Session Title: Gene therapy and cellular immunotherapy - Clinical 1
   Session date and time: Saturday, June 11, 2022 11:30 - 12:45 CEST
   Session room: Hall Strauss 1-2

Final Abstract Code: S259
Presenting Author: Sara Ghorashian
Conclusions: As of May 27 2022, in 11 treated patients, we have reproducibly generated a product that is balanced in CD19 and CD22 CAR expression, with predominance of dual CAR T cells and having a mostly central memory phenotype. To date and in Kymriah-ineligible patients, AUTO1/22 has demonstrated a favorable safety profile. There have been no incidences of severe CRS, and one Grade 4 ICANS which was indistinguishable from chemotherapy-related leukoencephalopathy. We have seen excellent CAR T expansion, with only 4 patients losing CAR T persistence at the last follow up. Overall, 9 out of 11 patients achieved complete response, and there were 2 non-responders. Notably, 2 out of 3 patients with CD19-ve disease achieved complete response demonstrating the efficacy of the CD22 CAR. Two patients relapsed with CD19+CD22+ disease, a further patient had emergence of molecular MRD and all these events were associated with lack of CAR T Cell persistence. No antigen negative relapses were seen in responding patients. At a median follow up of 8.7 months, 6 of 9 responding patients were in MRD-negative complete remission (1-12 months) and the median duration of b-cell aplasia has not been reached.

3. **Title: Safety and efficacy findings of AUTO1, a fast off-rate CD19 CAR, in relapsed/refractory Primary CNS Lymphoma**
   Session Title: Poster session
   Session date and time: Friday, June 10, 2022 - 16:30 - 17:45 CEST
   Final Abstract Code: P1460
   Presenting Author: Claire Roddie
   Conclusions: Excellent AUTO1 expansion was observed in the peripheral blood by qPCR, with persistence in all treated patients at last follow-up. No grade >/=3 CRS was observed using IV or I-VEN AUTO1 administration. Two cases of grade 3 ICANS were reported following IV infusion. In the first case the patient had several neurological deficits that evolved despite ICANS treatment and were compatible with progressive PCNSL, as confirmed with the month 1 MRI scan. The second case was a patient whose neurological deficits improved with steroids/anakinra. Encouraging response rates were observed: of 6 patients evaluable for efficacy following IV AUTO1, the ORR was 4/6 (67%), with 2 CRs and 2 PRs. These four responding patients are without disease progression at last follow up. Two patients died from progressive PCNSL on study. Longer follow-up is needed and enrolment of additional patients is ongoing.
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)**
   Session Title: Poster session
   Session date and time: Friday, June 10, 2022 - 16:30 - 17:45 CEST
   Final Abstract Code: P1459
   Presenting Author: Claire Roddie
   Conclusions: AUTO1 continues to display a favorable safety profile with no ICANS or Grade ≥ 3 CRS. Long term persistence of AUTO1 in the peripheral blood was demonstrated by qPCR. Of the 20 patients evaluable for efficacy, the overall response rate was 18/20 (90%). In the B-NHL cohorts the CRR was 16/17 (94%) (FL: 7/7, MCL: 3/3, DBCL: 6/7). In the CLL cohort a best response of a PR was achieved in 2/3 patients, notably both achieved MRD-negativity in their marrow and both remain in PR at 10 and 6 months respectively. Of the responding MCL, DLBCL, FL and CLL patients, 17/18 (94%) are without disease progression at last follow-up. One MCL patient relapsed six months following treatment and 1 FL patient died in CR from COVID-19. Longer follow-up and enrolment of additional MCL, FL, DLBCL and CLL patients is ongoing.

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-celFELIX 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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