



Autolus Therapeutics provides business outlook for 2021 & 2022

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- *Company prioritizes AUTO1, a potentially transformational treatment for Adult Acute Lymphoblastic Leukemia (ALL), with full data from the AUTO1-AL1 study expected in 2022*
- *Company intends to partner AUTO3, ahead of progressing into the next phase of development*
- *Company adjusting its workforce and infrastructure footprint to align with AUTO1 prioritization*
- *Company continues to develop its pipeline of next generation programs, specifically tailored for oncology indications with high unmet need*

LONDON, Jan. 06, 2021 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, updated its business outlook, strengthening its focus on its potentially transformational CAR T cell therapy candidate, AUTO1, which is being investigated in relapsed / refractory adult B-Acute Lymphoblastic Leukemia (ALL).

"We are very excited about the unique characteristics of AUTO1 that we reported at ASH in December 2020, with some patients continuing in molecular complete remission at 24 months without a subsequent transplant, an event-free survival of 52% at 12 months and a well-tolerated safety profile. Taking into consideration the high unmet need in adult ALL and the commercial opportunity this represents, we are prioritizing this program with potential pivotal data expected in 2022," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "We also plan to capitalize on the differentiated profile of AUTO1 by exploring activity in additional B-cell malignancies, including Primary CNS Lymphoma (PCNSL) where no adequate standard of care currently exists. We expect to see first data from these additional indications in 2021."

Additional clinical data points in 2021 are expected from AUTO1/22, a novel dual targeting CAR T cell based therapy candidate based on AUTO1, with the first pediatric ALL patient dosed in December 2020, and AUTO4 in Peripheral T Cell Lymphoma (PTCL), which will continue in 2021 through a dose escalation phase. Furthermore, the company continues to progress its pipeline of next generation programs, including for solid tumor indications, in collaboration with its academic partners.

With the prioritization of the AUTO1 program, the company plans to seek a partner for the AUTO3 program, its CD19 and CD22 dual targeting CAR T product candidate being investigated in relapsed/refractory diffuse large B cell lymphoma (DLBCL), before progressing the program into the next phase of development. In addition, through Q1 2021, the company will adjust its workforce and infrastructure footprint, which will involve an overall reduction in headcount of approximately 20%. The company expects to realize cash savings, on an annualized basis, of approximately \$15 million per annum once the operational changes are fully implemented. Additionally, the company announced a reorganization of its management team. David Brochu was promoted to Chief Technical Officer (CTO) with expanded responsibilities from Senior Vice President, Product Delivery. Senior Vice Presidents Dr. Adam Hacker and Dr. Nushmia Khokhar will be leaving the company in Q1 2021. A search for a new Chief Medical Officer is ongoing.

"Building on its differentiated clinical profile, we believe AUTO1 is well positioned to deliver fundamental value for patients and shareholders. Our organizational focus will position us well to realize the potential of AUTO1 and lay the foundation for the next opportunities in our pipeline with several clinical proof of concepts targeted during 2021 and 2022," said Dr. Christian Itin, chairman and chief executive officer of Autolus.

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 AUTO1

AUTO1 is a CD19 CAR T cell investigational therapy designed to overcome the limitations in safety - while maintaining similar levels of efficacy - 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, AUTO1 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. AUTO1 is currently being evaluated in two Phase 1 trials, one in pediatric ALL and one in adult ALL. The company has also now progressed the program to a potential pivotal trial, AUTO1-AL1.

About AUTO1-AL1 pivotal trial

The AUTO1-AL1 trial will enroll patients with relapsed / refractory ALL. The trial will have a short Phase1b component prior to proceeding to a single arm Phase 2 trial. The primary endpoint is overall response rate and the key secondary endpoints include duration of response, MRD negative CR rate and safety. The trial will enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe.

About AUTO3

AUTO3 is a programmed T cell investigational therapy containing two independent chimeric antigen receptors targeting CD19 and CD22 that have each been independently optimized for single target activity. By simultaneously targeting two B cell antigens, AUTO3 is designed to minimize relapse due to single antigen loss in patients with B cell malignancies. AUTO3 is currently being tested in diffuse large B cell lymphoma in the ALEXANDER clinical trial, including a 20-patient cohort to assess feasibility of treatment in an outpatient setting.

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' refocus in business strategy; the efficacy, safety and therapeutic potential of AUTO1 and the future clinical development of AUTO1, including progress, expectations as to the reporting of data, conduct and timing and potential future activity in additional B-cell malignancies; expectations regarding the initiation, design and reporting of data from the AUTO1-AL1 trial and other clinical trials; the development of Autolus' pipeline of next generation programs, including for solid tumor indications, in collaboration with its academic partners, including expectations as to the reporting of data, conduct and timing; the efficacy, safety and therapeutic potential of AUTO3 and ability for Autolus to obtain a partner for next stages of clinical development; needs for additional funding and ability to raise additional capital; Autolus' ability to attract and retain qualified employees and key personnel; the restructuring program and Autolus' expected cash savings as a result of the restructuring program and operational changes. 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 3, 2020, as amended, 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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