



Autolus Therapeutics Receives PRIME designation for AUTO1 for the treatment of adult ALL

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LONDON, April 01, 2021 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced that it has received PRiority MEdicines (PRIME) designation from the European Medicines Agency (EMA) for AUTO1, the company's CAR T cell therapy being investigated in the ongoing FELIX Phase 1b/2 study in relapsed / refractory (r/r) adult B-Acute Lymphocytic Leukemia (ALL).

"We are pleased to have received PRIME designation for AUTO1 as it will accelerate the review of a promising therapy targeting unmet medical need," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "The designation comes soon after we presented compelling activity and safety data from the ALLCAR Phase 1 clinical trial at the 62nd American Society of Hematology (ASH) Annual Meeting. We believe AUTO1 could change standard of care by offering a potentially curative therapy for r/r ALL."

About PRIME

The PRIME program aims to optimize development plans and speed up evaluation of medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. To be eligible and accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data coupled with non-clinical data. Through the PRIME program, the EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency. The program is intended to optimize development plans and expedite the review and approval process so that these medicines may reach patients as early as possible.

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 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, 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. In collaboration with our academic partner, UCL, AUTO1 is currently being evaluated in a Phase 1 clinical trial in adult ALL and B-NHL. The company has also progressed AUTO1 to the FELIX study, a potential pivotal study.

About AUTO1 FELIX study

The FELIX study is enrolling adult patients with relapsed / refractory ALL. The trial has a short Phase 1b component prior to proceeding to a single arm Phase 2 clinical 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.

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' refocused business strategy, including specifically on the development of the AUTO1 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; 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; and Autolus' expected 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 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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