



## **FDA Grants Regenerative Medicine Advanced Therapy (RMAT) designation to Autolus' CAR T cell therapy, obe-cel, for the treatment of adult B-ALL**

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LONDON, April 25, 2022 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to its lead gene therapy obecabatagene autoleucel (obe-cel), a CD19-directed autologous chimeric antigen receptor (CAR) T therapy that is being investigated in the ongoing FELIX Phase 2 study of adult relapsed / refractory B-Acute Lymphocytic Leukemia (ALL).

The FDA grants RMAT designation to drug candidates in recognition of the therapy's potential to address significant unmet medical needs in patients with serious or life-threatening conditions. RMAT designation provides important benefits in the drug development process, designed to facilitate and expedite development and regulatory review.

"RMAT designation is an important regulatory milestone for obe-cel and highlights its potential to address the unmet medical need for adult patients with relapsed and refractory B-ALL," said **Dr. Christian Itin, Chief Executive Officer of Autolus**. "RMAT designation from FDA, PRIME designation from EMA and ILAP designation from MHRA facilitate regulatory interactions with key health authorities and supports our drive to bring this innovative therapy to patients as quickly as possible."

obe-cel has previously been granted **Priority Medicines (PRIME)** designation by the European Medicines Agency (EMA) and Innovative Licensing and Access Pathway (ILAP) by the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom.

### **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](http://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' FELIX 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 140 patients across 34 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

### **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; 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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