Autolus Therapeutics Announces Promising Innovative Medicine (PIM) designation for obe-cel for the treatment of relapsed/refractory adult B-cell ALL

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LONDON, Aug. 09, 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 Promising Innovative Medicine (PIM) designation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for AUTO1 (obecabtagene autoleucel, obe-cel), the company's CAR T cell therapy being investigated in the ongoing FELIX Phase 1b/2 study in relapsed/refractory (r/r) adult B-cell Acute Lymphocytic Leukemia (ALL) in patients 18 years and older.

"PIM designation is a recognition of obe-cel as a promising candidate for the Early Access to Medicines Scheme (EAMS) in the UK for the treatment of adult patients with r/r ALL, a life-threatening condition with high unmet need," said Dr. Christian Itin, chief executive officer of Autolus.

About PIM
PIM designations are given to medicinal products that are likely to offer a major advantage for patients. For the MHRA to grant a PIM Designation, the product must meet each of the following three criteria:*

- **Criterion 1**: The conditions should be life-threatening or seriously debilitating with high unmet need, meaning there is no method of treatment, diagnosis or prevention available, or existing methods have serious limitations
- **Criterion 2**: The medicinal product is likely to offer major advantage over methods currently used in the UK. Preliminary evidence should be submitted based on both non-clinical and clinical data
- **Criterion 3**: The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance

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

About Obe-cel FELIX trial
The FELIX clinical trial 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 the future clinical development, efficacy, safety, and therapeutic potential of obe-cel, 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. 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 4, 2021, 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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