Autolus Therapeutics Announces Innovation Licensing and Access Pathway (ILAP) designation for obe-cel for the treatment of relapsed/refractory adult B-cell ALL

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LONDON, June 15, 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 innovative licensing and access pathway (ILAP) 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.

"The ILAP designation for obe-cel, alongside the recent PRIority MEdicines (PRIME) designation from the European Medicines Agency (EMA), is another step forward in accelerating the review process of this promising therapy," said Dr. Christian Itin, chief executive officer of Autolus. "Obe-cel continues to show the potential to be differentiated on efficacy, durability and safety from other CAR T cell products and could change standard of care by offering a potentially curative therapy for r/r ALL."

About ILAP
ILAP was announced in December 2020 and launched at the start of 2021 in order to accelerate the development and access to promising medicines and is geared toward medicines that are in the early stages of development. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with MHRA and other stakeholders including the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC). (RELATED: *MHRA sheds light on pathway to accelerate R&D*, Regulatory Focus 24 December 2020).

The innovation passport designation is the first step in the ILAP process and triggers the MHRA and its partner agencies to chart a roadmap for regulatory and development milestones with the goal of early patient access in the UK. Other benefits of ILAP include access to range of development tools, such as the potential for a 150-day accelerated Marketing Authorization Application (MAA) assessment, rolling review and a continuous benefit risk assessment.

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 (obecabtagene autoleucel, obe-cel)
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 into the FELIX study, a potential pivotal study.

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 and the 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; and the potential for an accelerated regulatory approval pathway for obe-cel. 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 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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