Autolus Therapeutics Announces FDA Acceptance of IND Application for AUTO1 for Adult Acute Lymphoblastic Leukemia

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LONDON, April 16, 2020 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer, announces that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for AUTO1, its lead CAR T product candidate for the treatment of adults with acute lymphoblastic leukemia (ALL). The active IND allows initiation of the US sites in the company's first pivotal study, AUTO1-AL1. The AUTO1-AL1 study clinical trial application was approved by the MHRA in January 2020 and the first site opened in the UK in March of this year.

The COVID-19 situation has had varying degrees of impact on the ability of clinical sites to operate normally; however, based on current expectations, the company anticipates that the impact on the AUTO1-AL1 clinical study will be minimal. The AUTO1-AL1 study has a run in phase, with a small number of patients scheduled to be enrolled into the study in Q2, limiting the impact from the COVID-19 situation at this stage. The company has continued to manufacture, without interruption, from its operations at the Cell and Gene Therapy Catapult located in Stevenage, UK, including supply to the US of clinical products for the treatment of DLBCL patients in its AUTO3-ALEXANDER study.

"We are looking forward to starting the treatment of patients at US clinical study sites in an indication where currently no CAR T therapy is approved," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "Our AL1 clinical trial is already open in the UK and this milestone enables us to build on the encouraging data published to date, which suggests AUTO1 has a high level of clinical activity combined with a manageable safety profile."

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.

About AUTO1-AL1 clinical study
The AUTO1-AL1 study will enroll patients with relapsed / refractory ALL. The study will have a short Phase1b component prior to proceeding to a single arm Phase 2 study. The primary end point is overall response rate and the key secondary end point is duration of response and MRD negative CR rate. The study will enroll approximately 100 patients across 30 of the leading academic and non-academic centers in US, UK and Europe.

About AUTO1
AUTO1 is a novel investigational CD19-targeting CAR T cell therapy designed to overcome the limitations in safety - while maintaining similar levels of efficacy - compared to current CD19 CAR T cell therapies. AUTO1 has a fast target binding off-rate designed to minimize excessive activation and associated cytokine release, which may reduce toxicity. In addition, the fast off-rate may reduce T cell exhaustion, enhance persistence, and improve the programmed T cells' ability to engage in serial killing of target cancer cells. AUTO1 is currently being evaluated in two Phase 1 studies, one in pediatric ALL and one in adult ALL.

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' financial condition and results of operations, including its expected cash runway; the development of Autolus' product candidates, including statements regarding the timing of initiation, completion and the outcome of pre-clinical studies or clinical trials and related preparatory work, and the periods during which the results of the studies and trials will become available; Autolus' plans to research, develop, manufacture and commercialize its product candidates; the potential for Autolus' product candidates to be alternatives in the therapeutic areas investigated; and Autolus' manufacturing capabilities and strategy. 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. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our 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 well as discussions of potential risks, uncertainties, and other important factors in Autolus' future filings with the Securities and Exchange Commission from time to time. All information in this press release is as of the date of the release, and the company 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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