Autolus Therapeutics announces acceptance of Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for obecabtagene autoleucel (obe-cel) for Patients with Relapsed/refractory (r/r) Adult B-Cell Acute Lymphoblastic Leukemia (B-ALL)

April 2, 2024 at 7:00 AM EDT

- Submission includes results from pivotal Phase 2 FELIX study evaluating obe-cel in r/r B-ALL
- The US marketing application is under review with a Prescription Drug User Fee Act (PDUFA) target action date of November 16, 2024

LONDON, April 02, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that the European Medicines Agency (EMA) has accepted the Company's Marketing Authorization Application (MAA) for obecabtagene autoleucel (obe-cel). Obe-cel is Autolus' lead investigational chimeric antigen receptor (CAR) T cell therapy, for the treatment of patients with relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL). The MAA submission was based on data from the pivotal Phase 2 FELIX study of obe-cel in adult r/r B-ALL.

Autolus' Nucleus site has recently received the formal certification from the MHRA following a full inspection of the site in February 2024. The MHRA issued two new GMP certificates to cover both clinical and commercial manufacture from the site.

"Along with the recent acceptance of the BLA by the FDA, the acceptance of our EU marketing application is an important milestone in expanding into the European market and delivering this potentially transformative therapy to B-ALL patients," **commented Dr. Christian Itin, Chief Executive Officer of Autolus**. "We look forward to working with the EMA throughout the evaluation process of obe-cel, and thank the internal team at Autolus for their work on the submission and Nucleus site inspection."

Obe-cel has been granted Orphan Drug Designation by the FDA, Orphan Medical Product Designation by the EMA, Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA and PRIority MEdicines (PRIME) designation by the EMA for adult r/r B-ALL.

About Autolus Therapeutics plc
Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, Autolus is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target 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, solid tumors and autoimmune diseases. 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. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. In clinical trials of obe-cel, this "fast off-rate" profile reduced toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024, and a filing has also been accepted by the EMA. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL.

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel enrolled 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 was overall response rate, and the secondary endpoints included duration of response, MRD negative CR rate and safety. The trial enrolled over 100 patients across 30 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 and commercialization of its product candidates, timing of data announcements and regulatory submissions, its cash resources and the market opportunity 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; and possible safety and efficacy concerns. 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 10-K filed with the Securities and Exchange Commission, or the SEC, on March 21, 2024, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the SEC. 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. You should, therefore, not rely on these forward-looking statements as representing Autolus'

views as of any date subsequent to the date of this press release.

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