Autolus Therapeutics receives Medicines and Healthcare products Regulatory Agency (MHRA) certification for Nucleus commercial manufacturing site

March 12, 2024 at 7:00 AM EDT

LONDON, March 12, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that following the most recent GMP inspection by the MHRA in February 2024, Autolus' Nucleus manufacturing facility in Stevenage has obtained a Manufacturer's Importation Authorisation (MIA) together with the accompanying GMP certificate. This authorisation enables Autolus to manufacture for global commercial and clinical product supply from the Nucleus effective as of March 18, 2024.

Following a full site inspection in February 2024, Autolus's Nucleus site has recently received the formal certification from the MHRA. The MHRA issued two new licenses to cover both clinical and commercial manufacture from the site and found no major or critical observations in their summary report.

"We are really proud of our brand-new facility for autologous cell therapies. Our manufacturing team did an outstanding job qualifying, validating and taking into operation the Nucleus in record time and establishing the foundation for high quality product supply," **commented Dave Brochu, Chief Technology Officer of Autolus**. "We look forward to continuing to work with the MHRA, EMA and FDA throughout the evaluation process of obe-cel for patients with ALL and thank the internal team at Autolus for their hard work."

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, the Company 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. Clinical trials of obe-cel have demonstrated that this "fast off-rate" profile reduces 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 action date of November 16, 2024 and a regulatory submission with the EMA is being prepared. 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 Ib/II clinical trial of obe-cel enrolled adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase Ib component prior to proceeding to the single arm, Phase II 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 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 of its product candidates. 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 20-F filed with the Securities and Exchange Commission, or the SEC, on March 7, 2023 and in Autolus' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, 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. 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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