Autolus Therapeutics Announces FDA RMAT Designation Granted to Obe-cel for the Treatment of Systemic Lupus Erythematosus and Lupus Nephritis

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Enrollment in LUMINA, the pivotal Phase 2 study of obe-cel in refractory lupus nephritis, is ongoing

LONDON and GAITHERSBURG, Md., Sept. 09, 2026 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation programmed T cell therapies and candidates, today announced that the U.S. Food and Drug Administration (FDA) has granted regenerative medicine advanced therapy (RMAT) designation to obecabtagene autoleucel (obe-cel) for the treatment of systemic lupus erythematosus (SLE) and lupus nephritis (LN).

RMAT designation is a program created under the 21st Century Cures Act to accelerate the development and regulatory review of regenerative medicine therapies, including cell therapies, intended to treat serious or life-threatening diseases.

Dr. Matthias Will, Chief Development Officer of Autolus, said: “SLE and LN are serious autoimmune diseases with a critical unmet need for new therapeutic options, particularly for patients with severe refractory disease. We are grateful to have received the RMAT designation for obe-cel based on the Phase 1b data reported from the CARLYSLE trial and believe it provides an important framework to facilitate efficient development within the LUMINA trial. We look forward to continuing to work closely with the FDA as we advance obe-cel through clinical development.”

The next data update from the Phase 1 CARLYSLE trial in patients with SLE has been submitted for presentation at the American College of Rheumatology (ACR) Annual Meeting in the fourth quarter of 2026. LUMINA, the pivotal Phase 2 study of obe-cel in patients with refractory LN, continues enrolling in five countries and Autolus expects to report data in 2028.

About Autolus Therapeutics plc
Autolus Therapeutics plc (Nasdaq: AUTL) is a commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation T cell therapies and candidates 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 and controlled T cell therapies that are designed to better recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has a marketed therapy, AUCATZYL®, and 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.

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’ future expectations, plans and prospects, including the therapeutic potential and expected clinical benefits of obe-cel; in SLE and LN; the development of obe-cel in autoimmune indications and of additional product candidates, including statements regarding the initiation, timing, progress and results of clinical studies or trials and related preparatory work; expectations regarding regulatory interactions, regulatory pathways and potential accelerated approval pathways; and the period during which the results of clinical studies or trials will become available. 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 identified in the section titled “Risk Factors” in Autolus’ Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC), on March 26, 2026 and its subsequent Quarterly Reports on Form 10-Q, 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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