

January 13, 2025



Adaptimmune Announces U.S. FDA Breakthrough Therapy Designation Granted to Letetresgene Autoleucel (lete-cel) for Treatment of Myxoid/Round Cell Liposarcoma (MRCLS)

The Company will present at the Annual J.P. Morgan Healthcare Conference, providing business updates on its sarcoma franchise and other cell therapy pipeline assets

Adaptimmune Allo-T program to be featured at the [Biotech Showcase](#)^(TM) and the Wuxi Global Forum 2025

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - January 13, 2025) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a company working to redefine the treatment of solid tumor cancers with cell therapy, today announced that letetresgene autoleucel (lete-cel), has been granted breakthrough therapy designation by the U.S. FDA for the treatment of patients with unresectable or metastatic myxoid/round cell liposarcoma (MRCLS) who have received prior anthracycline-based chemotherapy, are positive for HLA-A*02:01, HLA-A*02:05, or HLA-A*02:06, and whose tumor expresses the NY-ESO-1 antigen.

More details about the Company's sarcoma franchise, including the lete-cel clinical program and launch progress for TECELRA[®] (afamitresgene autoleucel), the Company's first commercial product and the first FDA approved engineered cell therapy for a solid tumor, will be provided during the Company's presentation at the Annual J.P. Morgan Healthcare Conference, taking place in San Francisco, California, on **Tuesday, January 14th, 2025, 4:30-5:10 PM PST** ([Webcast access here](#)).

Breakthrough therapy designation for lete-cel in MRCLS was based on the results in this indication from the Phase II IGNYTE-ESO trial. The Company previously received breakthrough therapy designation for lete-cel for the treatment of synovial sarcoma in 2016. In the Phase II analysis, 27/64 (42%) people with synovial sarcoma or MRCLS had RECISTv1.1 responses by independent review, with 6 complete responses and 21 partial responses. The response rate was 14/34 (41%) for people with synovial sarcoma and 13/30 (43%) for people with MRCLS. The median duration of response (DoR) was 12.2 months (95% CI 6.8, 19.5). In synovial sarcoma, the median duration of response was 18.3 months (95% CI 3.3, -). In MRCLS, the median duration of response was 12.2 months (95%, CI 5.3, -). Safety findings were consistent with the known profile of lete-cel from previous data. All patients experienced treatment-emergent adverse events: cytopenias, cytokine release syndrome (CRS) and rash were the most common adverse events. Overall, toxicities were

manageable, and consistent with an acceptable benefit to risk profile. Data from this trial were presented at the Connective Tissue Oncology Society (CTOS) 2024 annual meeting (Link to press release [HERE](#); Presentation [HERE](#)).

Adrian Rawcliffe, Adaptimmune's Chief Executive Office: "This designation by the FDA highlights the potential of lete-cel to address a critical need for new treatment options for patients with MRCLS. This is another important milestone in building out our sarcoma franchise, as we aim to bring lete-cel to market in 2026 for the treatment of synovial sarcoma and MRCLS. We look forward to initiating a rolling Biologics License Application for lete-cel later this year for the treatment of both sarcoma indications."

The breakthrough therapy designation is designed to expedite drug development and review processes. The criteria for this designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. With the designation, lete-cel will receive incentives, such as additional interaction and guidance from the FDA, the potential for a rolling submission, and potential priority review of the biologics license application, as well as other opportunities to expedite the development.

In addition to the Company's presentation at J.P. Morgan, Adaptimmune will present the Company's Allo-T program as a spin-out opportunity at the Biotech ShowCase™ and the Wuxi Global Forum 2025 Investor Roundtable. Details can be found below:

[Biotech Showcase™ | Investor conference | Co-produced by Demy-Colton and EBD Group](#)

Presentation at 2 p.m. PST on Tuesday, January 14th, Yosemite C, Hilton Hotel, Union Square.

[WuXi Global Forum 2025 - WXPRESS: for WuXi news and R&D insights](#)

Round Table Presentation at 5 p.m. PST on Tuesday, January 14th, Tower 3, Hilton Hotel, Union Square

About Adaptimmune

Adaptimmune is a fully integrated cell therapy company working to redefine how cancer is treated. With its unique engineered T cell receptor (TCR) platform, the Company is developing personalized medicines designed to target and destroy difficult-to-treat solid tumor cancers and to radically improve the patient's cancer treatment experience.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended 31 December, 2023, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the Securities and Exchange

Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

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