

Adaptimmune Announces Initiation of Biologics License Application (BLA) Submission for Afami-cel, Its First-Gen Engineered TCR T-cell Therapy targeting MAGE-A4, For the Treatment of Synovial Sarcoma

- Afami-cel has the potential to be the first approved engineered TCR T-cell therapy for a solid tumor -

-Synovial sarcoma has a high unmet medical need and the pivotal trial met its primary endpoint with an overall response rate of ~39% after a single dose of afami-cel -

- Adaptimmune plans to complete its rolling BLA submission for afami-cel in mid-2023; and with RMAT status for synovial sarcoma, the application will be eligible for priority review by the FDA -

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - December 23, 2022) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a leader in cell therapy to treat cancer, today reports that it has initiated the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for afami-cel for use as a single-dose regimen for the treatment of advanced synovial sarcoma.

"Adaptimmune's goal is to design and deliver cell therapies to transform the lives of people with cancer," said Dennis Williams, PharmD, Senior VP of Late-Stage Development.

"Initiation of this rolling BLA submission is an important milestone toward achieving this goal - bringing to market a new therapeutic option for people with advanced synovial sarcoma. This also marks an important milestone for the treatment of solid tumors with autologous T-cell products."

The BLA submission for afami-cel is supported by positive clinical data from Adaptimmune's SPEARHEAD-1 clinical trial in patients with advanced synovial sarcoma. The Company plans to complete its rolling submission by mid-2023 and the application will be eligible for priority review under the FDA's regenerative medicine advanced therapy (RMAT) program.

About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products for people with cancer. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer across multiple solid tumors.

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 December 31, 2021, 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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