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Adaptimmune Granted Access to PRIority MEdicines (PRIME) Regulatory Support by the European Medicines Agency for ADP-A2M4 for the Treatment of Synovial Sarcoma

PHILADELPHIA and OXFORDSHIRE, United Kingdom, July 23, 2020 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in cell therapy to treat cancer, announced that the European Medicines Agency (EMA) has granted access to the PRIME initiative to the Company for ADP-A2M4 for the treatment of synovial sarcoma. PRIME access provides enhanced scientific and regulatory support by the EMA to developers of medicines with the potential to significantly address unmet medical needs.

“We are thrilled that the EMA has acknowledged the potential of ADP-A2M4 to address an unmet medical need for more effective treatment options for patients with advanced synovial sarcoma,” said Dennis Williams, PharmD, Adaptimmune’s Senior Vice President, Late Stage Development. “Access to the enhanced EMA support and guidance offered in the PRIME scheme will facilitate the development of ADP-A2M4 to ensure this important medicine reaches patients with sarcoma as early as possible.”

Access to the PRIME initiative for ADP-A2M4 was granted based on clinical data from the Phase 1 trial demonstrating compelling efficacy and early promising durability, with tolerable safety in patients with synovial sarcoma. Based on these data the Company initiated the SPEARHEAD-1 trial with ADP-A2M4, enrolling people with advanced synovial sarcoma and myxoid/ round cell liposarcoma (MRCLS) at clinical sites in Canada, France, Spain, the United Kingdom, and the United States (US). The SPEARHEAD-1 trial is intended to support the registration of ADP-A2M4 for the treatment of advanced synovial sarcoma and MRCLS.

In recent months, the US Food and Drug Administration granted Orphan Drug Designation (ODD) to SPEAR T-cells targeting MAGE-A4 for the treatment of soft tissue sarcomas and Regenerative Medicine Advanced Therapy designation for the treatment of synovial sarcoma. In addition, The EMA’s Committee for Orphan Medicinal Products adopted a positive opinion for ODD for ADP-A2M4 for the treatment of soft tissue sarcomas.

The PRIME program aims to optimize development plans and speed up evaluation of medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. To be eligible and accepted for PRIME, a medicine must show potential to benefit patients with unmet medical needs based on early clinical data coupled with non-clinical data. Through the PRIME program, the EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency. The program is intended to

optimize development plans and expedite the review and approval process so that these medicines may reach patients as early as possible.

About Synovial Sarcoma
Soft tissue sarcomas can develop from soft tissues like fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. There are approximately 50 types of soft tissue sarcomas, including synovial sarcoma, which accounts for approximately 6% to 10% of all soft tissue sarcomas. There remains a large unmet medical need for synovial sarcoma, and approximately one-third of synovial sarcomas occur in childhood and the peak incidence is in the third decade of life. The most common locations for this cancer are the hip, knee, ankle, and shoulder.

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 Quarterly Report on Form 10-Q filed with the SEC on May 14, 2020, and our other SEC filings. 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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