December 3, 2019

Regenerative Medicine Advanced Therapy Designation Granted by FDA to ADP-A2M4 for the Treatment of Synovial Sarcoma

Will enable expedited development and review of ADP-A2M4 with the goal of commercialization in 2022 for patients with few other treatment options

PHILADELPHIA and OXFORDSHIRE, United Kingdom, Dec. 03, 2019 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced that it has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for ADP-A2M4 for the treatment of synovial sarcoma. Earlier this year, FDA granted Orphan Drug Designation (ODD) to ADP-A2M4 for the treatment of soft tissue sarcomas.

“RMAT designation is another important step in bringing our ADP-A2M4 therapy to market in 2022 for patients with synovial sarcoma,” said Elliot Norry, Adaptimmune’s acting Chief Medical Officer. “We have compelling data with ADP-A2M4 for the treatment of synovial sarcoma and are eager to make this therapy available to patients who have few other treatment options. We are screening and enrolling patients with sarcoma in our Phase 2 SPEARHEAD-1 trial.”

Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the drug development and review processes for promising pipeline products. A product is eligible for RMAT designation if it is a regenerative medicine therapy, such as a T-cell therapy, and is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

RMAT designation includes the incentives of Breakthrough Therapy designation including additional FDA interaction and guidance, potential ways to support accelerated approval and satisfy post-approval requirements, potential priority review of the biologics license application (BLA) and other opportunities to expedite development and review.

Data from patients with synovial sarcoma treated in the expansion phase of Adaptimmune’s Phase 1 trial with ADP-A2M4 were recently presented at CTOS. There was an overall response rate of 50%, and a disease control rate of 93% with 13 out of 14 patients showing clinical benefit with best overall responses of partial responses (confirmed or unconfirmed; n=7) or stable disease (n=6).

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. For more information, please visit http://www.adaptimmune.com.

Adaptimmune 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 Securities and Exchange Commission (SEC) on November 6, 2019, 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.

Adaptimmune Contacts:

Media Relations:
Sébastien Desprez – VP, Communications and Investor Relations
T: +44 1235 430 583
M: +44 7718 453 176
Sebastien.Desprez@adaptimmune.com

Investor Relations:
Juli P. Miller, Ph.D. – Senior Director, Investor Relations
T: +1 215 825 9310
M: +1 215 460 8920
Juli.Miller@adaptimmune.com

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