

Adaptimmune Therapeutics PLC
Form 8-K
February 16, 2016

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

Current Report

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **February 16, 2016**

ADAPTIMMUNE THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction of
incorporation)

1-37368
(Commission File Number)

Not Applicable
(IRS Employer Identification No.)

**101 Park Drive, Milton Park
Abingdon, Oxfordshire OX14 4RY**

United Kingdom

(Address of principal executive offices, including zip code)

(44) 1235 430000

Edgar Filing: Adaptimmune Therapeutics PLC - Form 8-K

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 8.01. Other Events.

Adaptimmune Therapeutics plc (Adaptimmune or the Company) has received notification that the independent Data Monitoring Committee (DMC) of an international Phase II study in gastro-esophageal cancer being led by investigators at The Christie NHS Foundation Trust, Manchester, UK (The Christie) as part of an EU FP7 project, has recommended that recruitment in the trial can resume. The study evaluates Adaptimmune s affinity enhanced T-cell therapy targeting the NY-ESO-1 cancer antigen in patients with advanced cancer of the esophagus and stomach.

The Christie s investigators had voluntarily paused enrollment in this investigator-initiated study following the death of one patient forty six days after cell infusion. Adaptimmune shared details of this event with the FDA. The enrollment of patients into Adaptimmune s own clinical trials using its NY-ESO TCR therapy was not affected by this event.

The Company has worked closely with The Christie s investigators to support their review of the case. The independent DMC made the recommendation after a review of safety data from the patient and the overall Adaptimmune NY-ESO program, as well as correlative studies, including molecular analyses of patient samples. Investigators will present results of safety and molecular analysis in a peer reviewed scientific journal.

The Christie study protocol is being amended and will incorporate changes that include reduction in intensity of the pre-conditioning chemotherapy regimen, removal of IL-2 therapy and changes in management of safety events. The study is expected to reinitiate recruitment after approval of the amended protocol by local regulatory authorities and ethics committees. The revised protocol will align more closely with those in the ongoing Adaptimmune program.

This investigator-initiated trial is coordinated by the Manchester Academic Health Science Centre Trials Coordination Unit, and is part of a European Framework collaboration program known as ATTACK 2 (Adoptive engineered T cell Targeting to Achieve Cancer Killing) (www.attack-cancer.eu).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ADAPTIMMUNE THERAPEUTICS PLC

Date: February 16, 2016

By: /s/ Margaret Henry
Name: Margaret Henry
Title: Corporate Secretary