ASTRAZENECA PLC
Form 6-K
August 31, 2018

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of August 2018

Commission File Number: 001-11960

AstraZeneca PLC

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
AstraZeneca Update on Anifrolumab in SLE

This announcement contains inside information

31 August 2018 07:00 BST

Update on TULIP 1 Phase III trial for
anifrolumab in systemic lupus erythematosus

Trial did not meet the primary endpoint of a reduction of
disease activity as measured by the SLE Responder Index

AstraZeneca and MedImmune, its global biologics research and development arm, today announced top-line results from the TULIP 1 Phase III trial for anifrolumab in adult patients with moderate-to-severe systemic lupus erythematosus (SLE).

The trial did not meet the primary endpoint of a statistically-significant reduction in disease activity in patients with SLE as measured by the SLE Responder Index 4 (SRI4) at 12 months.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "SLE is a debilitating autoimmune disease with significant unmet need among patients who struggle to achieve meaningful disease control. The result of this trial is disappointing for patients and the lupus community."

The pivotal Phase III TULIP 1 trial was a randomised, double-blinded, 52-week placebo-controlled, multi-centre trial assessing the safety and efficacy of anifrolumab as a treatment for adult patients with moderate-to-severe SLE. A full evaluation of the data will be conducted when TULIP 2 data are available later this year. TULIP 1 data will be presented at a future medical meeting.

About Anifrolumab
Anifrolumab (formerly MEDI-546) is a fully human monoclonal antibody and potential new medicine that binds to subunit 1 of the type I interferon receptor, blocking the activity of all type I interferons including IFN-a, IFN-b and IFN-y.1 Type I interferons are cytokines involved in the inflammatory pathways.2 60% - 80% of adult lupus patients have an increased type I interferon gene signature, which has been shown to correlate with disease activity.2, 3

About the Phase III TULIP Programme
The pivotal TULIP (Treatment of Uncontrolled Lupus via the Interferon Pathway) programme includes two Phase III clinical trials, TULIP 1 and TULIP 2, that are evaluating the efficacy and safety of anifrolumab versus placebo in patients with moderately-to-severely active autoantibody-positive SLE who are receiving standard of care treatment. TULIP 1 randomised 460 eligible patients (1:2:2) to receive a fixed-dose intravenous infusion of 150mg anifrolumab, 300mg anifrolumab, or placebo every 4 weeks. TULIP 2 randomised 373 eligible patients (1:1) to receive a fixed-dose intravenous infusion of 300mg anifrolumab or placebo every 4 weeks.

The programme assesses the effect of anifrolumab in reducing disease activity, as measured by the SRI4, decreasing use of oral corticosteroids, improving skin manifestations, as measured by Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI)4, and reducing flares. In addition to the pivotal trials, anifrolumab is also being tested in a Phase III SLE long-term extension trial, a Phase II trial using subcutaneous delivery in SLE and a Phase II trial for lupus nephritis.

About SLE
SLE is an autoimmune disease in which the immune system attacks healthy tissue in the body instead of primarily targeting viruses or other foreign invaders.5 Lupus can cause a range of symptoms, including pain, rashes, fatigue, swelling in joints and fevers.6 It is associated with a greater risk of death from causes such as infection and cardiovascular disease.7 There has been only one new medicine approved for lupus in the last 60 years.8

About MedImmune
MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular, Renal and Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and South San Francisco, Calif. For more information, please visit www.medimmune.com.

About AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

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2. Lauwerys, Bernard R, et al. Type I interferon blockade in systemic lupus erythematosus: where do we stand?. Rheumatology. 2013;53(8);1369-1376.
3. Crow, M. K, Type I Interferon in the Pathogenesis of Lupus, J Immunol. 2014;192(12);5459-5468.
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5. The Lupus Foundation of America. Available at https://resources.lupus.org/entry/what-is-lupus?utm_source=lupusorg&utm_medium=answersFAQ. [Accessed August 2018]
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7. Nossent, J., et al. Current causes of death in systemic lupus erythematosus in Europe, 2000-2004: relation to disease activity and damage accrual. Lupus. 2007;16(5);309-317.
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SIGNATURES

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

AstraZeneca PLC

Date: 31 August 2018

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary