

ASTRAZENECA PLC

Form 6-K

November 01, 2017

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 November 2017

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 ☒ Form 40-F ☐

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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 ☒

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82- \_\_\_\_\_

This announcement contains inside information

1 November 2017 07:00 GMT

ASTRAZENECA PROVIDES UPDATE ON TRALOKINUMAB PHASE III PROGRAMME IN SEVERE, UNCONTROLLED ASTHMA

AstraZeneca and its global biologics research and development arm, MedImmune, today announced the top-line results of the Phase III STRATOS 2 and TROPOS trials for tralokinumab, an anti-interleukin-13 (IL-13) human monoclonal antibody, in severe, uncontrolled asthma.

In STRATOS 2, tralokinumab did not achieve a statistically-significant reduction in the annual asthma exacerbation rate (AAER), the primary endpoint, in patients with severe, uncontrolled asthma and elevated levels of a biomarker, Fractional exhaled Nitric Oxide (FeNO), compared to placebo.

In TROPOS, tralokinumab did not achieve a statistically-significant reduction in oral corticosteroid (OCS) use, the primary endpoint, when added to the standard of care, in patients dependent on OCS.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "The results are disappointing as we had hoped that tralokinumab would benefit patients with severe asthma, which is a complex disease with limited treatment options today."

FeNO is a well-established biomarker for airway inflammation and was identified in the previous pivotal trial (STRATOS 1) as most likely to predict an enhanced response to tralokinumab.

The safety and tolerability findings in STRATOS 2 and TROPOS were consistent with those observed in previous trials with tralokinumab.

Full data from STRATOS 1, STRATOS 2 and TROPOS will be presented at a forthcoming medical meeting.

#### About Severe Asthma

Asthma affects 315 million individuals worldwide, and up to 10% of asthma patients have severe asthma, which may be uncontrolled despite high doses of standard-of-care asthma controller medicines and can require the use of chronic OCS.

Severe, uncontrolled asthma is debilitating and potentially fatal with patients experiencing frequent exacerbations and significant limitations on lung function and quality of life.

Severe, uncontrolled asthma can lead to a dependence on OCS, with systemic steroid exposure potentially leading to serious short- and long-term adverse effects, including weight gain, diabetes, osteoporosis, glaucoma, anxiety, depression, cardiovascular disease and immunosuppression. There is also a significant physical and socio-economic burden of severe, uncontrolled asthma with these patients accounting for 50% of asthma-related costs.

#### About Tralokinumab

Tralokinumab is an anti-IL-13 human immunoglobulin-G4 monoclonal antibody that blocks binding and signalling of IL-13 to IL-13 receptors. IL-13 is an important signalling protein that is a key driver in asthma. When IL-13 binds to receptors (IL-13Ra1 and IL-13Ra2) found on cells in the airways, it can lead to inflammation, hypersensitivity and structural changes.

#### About FeNO

In asthma, FeNO (fractional exhaled nitric oxide) is a well-established biomarker for T2 airway inflammation driven by T-helper cells type 2 (Th2). IL-13 and IL-4 are two inflammatory cytokines produced by Th2 cells. These cytokines induce the release of nitric oxide (NO) from airway epithelial cells which can be measured in expired breath (FeNO).

#### About the ATMOSPHERE Programme

The ATMOSPHERE programme is comprised of 2,298 patients at 571 sites across 27 countries including the pivotal efficacy trials, STRATOS 1 and STRATOS 2, along with the TROPOS, MESOS and Japan Long-Term Safety (LTS) trials.

STRATOS 1 and 2 are Phase III multicentre, randomised, double-blinded, parallel-group, placebo-controlled trials designed to evaluate the efficacy and safety of a regular, subcutaneous administration of tralokinumab for 52-weeks in adult and adolescent patients with severe asthma inadequately controlled despite treatment with inhaled corticosteroids (ICS) plus LABA. STRATOS 1 also explored potential biomarkers to identify patients with an enhanced response to tralokinumab and identified FeNO as the lead biomarker. STRATOS 2 sought to validate this.

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TROPOS is a Phase III multicentre, randomised, double-blinded, parallel-group, placebo-controlled trial for 40-weeks in adult and adolescent patients with severe asthma who require continuous treatment with ICS plus LABA, and chronic treatment with maintenance oral corticosteroid (OCS) therapy.

MESOS is a Phase II multicentre, randomised, double-blinded, parallel group, placebo-controlled trial for 12-weeks designed to evaluate the effect of tralokinumab administered subcutaneously every 2-weeks on airway inflammation in adults with uncontrolled asthma requiring continuous treatment with ICS, with or without other asthma controllers.

Japan LTS is an open-label, multicentre trial to evaluate the safety of tralokinumab for 52-weeks in Japanese adults and adolescents with asthma inadequately controlled on ICS plus LABA.

### About AstraZeneca in Respiratory Disease

Respiratory disease is one of AstraZeneca's main therapy areas, and the Company has a growing portfolio of medicines that reached more than 18 million patients in 2016. AstraZeneca's aim is to transform asthma and COPD treatment through inhaled combinations at the core of care, biologics for the unmet needs of specific patient populations, and scientific advancements in disease modification.

The Company is building on a 40-year heritage in respiratory disease and AstraZeneca's capability in inhalation technology spans both pMDIs and dry powder inhalers, as well as the innovative Aerosphere Delivery Technology. The company's biologics include benralizumab (anti-eosinophil, anti-IL-5 $\alpha$ ), which has been accepted for regulatory review in the US, EU and Japan, and tezepelumab (anti-TSLP), which successfully achieved its Phase IIb primary and secondary endpoints. AstraZeneca's research is focused on addressing underlying disease drivers focusing on the lung epithelium, lung immunity and lung regeneration.

### 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 & Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is in Gaithersburg, Md., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and Mountain View, CA. For more information, please visit [www.medimmune.com](http://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 & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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](http://www.astrazeneca.com) and follow us on Twitter @AstraZeneca.

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Adrian Kemp  
Company Secretary  
AstraZeneca PLC

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: 1 November 2017  
By: /s/ Adrian Kemp  
Name: Adrian Kemp  
Title: Company Secretary