

ASTRAZENECA PLC
Form 6-K
May 12, 2014

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 May 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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 ☐

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 ☒

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

ASTRAZENECA TO PRESENT RESPIRATORY DATA AT
ATS 2014 INTERNATIONAL CONFERENCE

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Benralizumab and tralokinumab data both show improvement in key measures of asthma control for patients with specific, severe forms of asthma

Data underscore strength and breadth of AstraZeneca's respiratory pipeline

AstraZeneca today announced that MedImmune, its global biologics research and development arm, will present Phase IIb data on two novel investigational molecules - benralizumab and tralokinumab - at the upcoming American Thoracic Society (ATS) 2014 International Conference being held in San Diego, California, 16-21 May.

In the Phase IIb data being presented, both benralizumab and tralokinumab show promising safety and efficacy outcomes, suggesting they may offer important new therapeutic options for patients with specific forms of severe, uncontrolled asthma.

"AstraZeneca is pioneering innovative research and exploring novel pathways in respiratory disease, one of our core therapeutic areas, and we have a diverse emerging pipeline covering a broad set of patients. Our approach leverages AstraZeneca and MedImmune's combined expertise in monoclonal antibody research with our broad experience in drug development," said Dr. Bahija Jallal, Executive Vice President, MedImmune. "We are applying translational approaches and generating clinical data that put us in a good position to understand the biology, disease phenotypes and new drug combinations that will help drive step-changes in clinical outcomes for asthma patients."

MedImmune is presenting Phase IIb asthma data on benralizumab, an investigational monoclonal antibody binding to the interleukin-5 receptor alpha (IL-5R α). Benralizumab has a unique mode of action as it binds to IL-5R α on eosinophils and subsequently depletes eosinophils by inducing antibody dependent cellular cytotoxicity. Eosinophils are white blood cells that are a key target in inflammatory respiratory diseases such as asthma and Chronic Obstructive Pulmonary Disease (COPD). Scientific literature supports that elevated eosinophil levels are associated with the cause and severity of asthma and asthma exacerbations, as well as COPD exacerbations.

In the Phase IIb study, subjects with uncontrolled severe asthma and elevated baseline blood eosinophil levels taking benralizumab had a statistically significant reduction in their asthma exacerbation rate (AER), as well as improvements in lung function (FEV1) and asthma control versus subjects taking placebo over a period of one year. Specifically, the study showed that benralizumab decreased blood eosinophil counts to very low levels after the first dose, and reduced asthma attacks by approximately 40-70 percent depending on dose received and baseline blood eosinophil level. (Abstract 3699, presentation 19 May at 2:00pm PDT)

The company is also presenting Phase IIb data for tralokinumab, a human monoclonal antibody which potently and selectively neutralises interleukin-13 (IL-13), a key cytokine considered to be a central mediator of asthma. The study recruited a broad (all-comer) intent-to-treat population with severe uncontrolled asthma allowing subgroup analyses of sub-populations with biomarkers indicating an IL-13 pathogenesis. The study did not meet its primary endpoint of reduction in AER in the all-comer population versus placebo. However, reversible and periostin-high subgroup AER reductions were 54 percent (-65, 87 percent) and when excluding subjects receiving oral corticosteroids, 67 percent (2, 89 percent). Improved lung function (FEV1) and improvement in patient-reported measures and health-related quality of life (AQLQ) were observed in periostin-high subgroups of patients along with high airway reversibility in patients who received treatment every two weeks versus placebo. (A6670, presentation 20 May at 8:15am PDT)

As previously communicated, benralizumab is currently in Phase III development for asthma. A personalised healthcare strategy is included in the company's trial design and a simple blood test is used to identify patients with elevated blood eosinophils who are most likely to respond to therapy.

The company intends to move tralokinumab into Phase III development for asthma and benralizumab into Phase III for COPD later this year. Further details will be communicated once the first patient is dosed in a Phase III programme.

In the benralizumab and tralokinumab trials to date, frequencies of treatment emergent serious adverse events/adverse events have been similar within treatment and placebo groups.

"It is encouraging that benralizumab is positively affecting lung function and asthma control in addition to reducing the rate of exacerbations in patients with elevated eosinophils. Tralokinumab is also showing positive effect in patients with potential biomarkers for IL-13, which helps us identify a path forward in Phase III trials," said Dr. Bing Yao, Senior Vice President and Head of MedImmune's Respiratory, Inflammation and Autoimmunity Innovative Medicines Unit. "Our scientists are using the necessary biomarkers to identify which patients are most likely to benefit from our respiratory therapies, opening doors of exploration into new and improved treatment pathways for patient care."

AstraZeneca and MedImmune will present a combined 33 abstracts at ATS. Other accepted abstracts of note include:

- Dosing studies of PT003, a combination of glycopyrronium and formoterol fumarate in a pressurised metered-dose inhaler being developed by AstraZeneca's Pearl Therapeutics. (A3758 and A3759, both presentations 19 May at 2:00pm PDT)
- Analyses of database and survey data examining the association between higher sputum and blood eosinophils and more frequent asthma attacks. (A2311, presentation 18 May at 2:00pm PDT, and A4235, presentation 20 May at 8:15am PDT)
- Benralizumab Phase IIa COPD data will be presented (A3771, presentation 19 May at 2:00pm PDT)

AstraZeneca will host a briefing for analysts and investors during the ATS conference, to be held in San Diego on 20 May 2014.

Note: data beyond what is included in the abstracts are embargoed until date and time of presentation at ATS.

About benralizumab

Benralizumab is a humanized monoclonal antibody directed at the alpha subunit of the interleukin-5 receptor (IL-5R) that depletes eosinophils, a key target cell in inflammatory respiratory disease. Scientific literature supports that eosinophil levels are associated with exacerbations and increased eosinophils are associated with frequent exacerbations. In October 2013, AstraZeneca announced the start of the Phase III Windward programme for benralizumab. The goal of CALIMA, the first study in the Windward programme, is to determine whether benralizumab reduces the number of exacerbations in patients with severe asthma that remains uncontrolled, despite receiving high doses of inhaled corticosteroids in combination with a second controller such as a long-acting beta agonist.

An estimated 5 to 10 percent of the 300 million people worldwide who suffer from asthma have a severe form, and people with eosinophilic airway inflammation represent approximately 40 to 60 percent of the severe asthmatic population.

Benralizumab is in-licensed from BioWa, Inc., a wholly-owned subsidiary of Kyowa Hakko Kirin Co., Ltd.

About tralokinumab

Tralokinumab is a human IgG4 monoclonal antibody that targets IL-13, a key cytokine that is believed to play a key role in the pathogenesis of asthma through the promotion of inflammation, airway hyper-responsiveness, mucus hyper-secretion, airway remodeling via fibrosis, increased IgE synthesis and mast cell activation.

About MedImmune

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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 key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers. For more information, please visit www.medimmune.com.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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.

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12 May 2014

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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: 12 May 2014

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