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 X Form 40-F __

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Yes __ No X

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ASTRAZENECA ANNOUNCES MEDIMMUNE'S MAVRILIMUMAB AND SIFALIMUMAB BOTH MET PRIMARY ENDPOINTS IN

PHASE IIB STUDIES

Mavrilimumab produces rapid improvement in signs and symptoms of rheumatoid arthritis, measures of disability and patient-reported outcomes

Sifalimumab meets primary endpoint of reduction in global disease activity score (SRI-4), and shows clinically important improvement in skin and joint symptoms, patient reported outcomes in patients with moderate/severe systemic lupus erythematosus

AstraZeneca today announced that two key molecules in MedImmune's Respiratory, Inflammation and Autoimmune (RIA) portfolio - mavrilimumab and sifalimumab - met their primary endpoints in respective Phase II studies, demonstrating further pipeline progress in core therapeutic areas.

Top-line results from the Phase IIb study of mavrilimumab, an investigational monoclonal antibody that inhibits a key pathway in the development of rheumatoid arthritis (RA), achieved its primary endpoints. In the Phase llb study of a methotrexate inadequate responder RA population (EARTH EXPLORER-1), 326 patients with moderate and severe RA were treated for six months with either mavrilimumab (low, medium or high dose) or placebo in addition to standard methotrexate background therapy. The co-primary endpoints of the American College of Rheumatology (ACR) response of ACR20 and Disease Activity Score (DAS28) were met with all mavrilimumab doses confirming the efficacy demonstrated in the previous Phase IIa study (EARTH).

The high dose was the most effective with an ACR20 response at week 24 of 73.4 percent vs 24.7 percent for placebo ($p<0.001$) and a reduction in mean DAS28 score at day 85 of -1.9 vs -0.68 for placebo ($p<0.001$). Additionally, all secondary endpoints including ACR50, ACR70 response and DAS28 remission score achieved statistical significance for the high dose. Mavrilimumab also produced rapid improvement in the multiple symptoms of rheumatoid arthritis and significant improvements in patient reported outcomes including disability, pain and fatigue. The safety findings observed were consistent with those previously reported for the Phase IIa study. The most commonly-reported adverse events (>3 percent) included headache, nasopharyngitis (common cold), hypertension, bronchitis and worsening of RA.

"Through innovative, novel research, MedImmune has built a diverse emerging pipeline in Respiratory, Inflammation and Autoimmune disease, covering a broad set of patients.
We are focused on advancing data and drug discovery to improve treatment options and clinical outcomes for patients," said Dr. Bahija Jallal, Executive Vice President, MedImmune. "Compelling Phase II data from two of our molecules - mavrilimumab for rheumatoid arthritis and sifalimumab for systemic lupus - further confirm our commitment to bringing new medicines to patients as quickly as possible."

MedImmune also announced top-line results from the Phase II study of sifalimumab (MEDI-545), a novel monoclonal antibody being investigated as a treatment for patients with moderate/severe systemic lupus erythematosus (SLE or lupus). The study met its primary endpoint of percentage of subjects that responded by the SLE Responder Index (SRI-4) at Day 365. Clinically important improvements in organ-specific outcome measures (joint, skin) and patient reported outcomes were also observed.

In the study, three doses of sifalimumab were evaluated against placebo when added to stable standard of care therapy in patients with moderately to severely active lupus despite standard of care therapy. In addition to efficacy in the primary endpoint, there is a broad-based body of clinical evidence supporting the efficacy of sifalimumab. The study achieved two secondary endpoints at specific doses - improvement in skin (rashes) as measured by CLASI (Cutaneous Lupus Erythematosus Disease Area and Severity Index) and improvement in fatigue. Sifalimumab demonstrated an overall acceptable safety profile, with a numerical increase in the incidence of Herpes Zoster reactivations.

"Patients with lupus have severely limited options for control of their symptoms, as only one new treatment has been approved in more than 50 years," said Dr. Bing Yao, Senior Vice President and Head of MedImmune's Respiratory, Inflammation and Autoimmunity Innovative Medicines Unit. "There is clearly a sense of urgency to deliver new treatments for patients suffering from this debilitating, chronic disease, and we are hopeful that we will be able to offer a new option."

The company anticipates presenting additional study results for both molecules at a future medical conference later this year. The Phase II programme in lupus with anifrolumab (MEDI-546), which targets the type 1 interferon receptor, is also ongoing.

About Rheumatoid Arthritis (RA)
Rheumatoid arthritis is a painful, systemic, chronic inflammatory autoimmune disease which causes damage to the joints and vital organs. The disease affects approximately one in 100 people worldwide. If not adequately treated, RA is a major cause of disability leading to diminished work capacity and is associated with reduced life expectancy.

The American College of Rheumatology (ACR) response represents a percentage improvement in symptoms. To achieve an ACR20 score, a person with RA must have at least 20 percent fewer tender joints and at least 20 percent fewer swollen joints. In addition the patient must also have a 20 percent improvement in at least three of the following five areas: 1) the patients overall (global) assessment of their RA 2) the patient assessment of their pain 3) the patients assessment of their physical functioning 4) the physician's global assessment of their patients RA, and 5) the results of a C-reactive protein and erythrocyte sedimentation rate blood test as key indicators of inflammation.

The Disease Activity Score (DAS) represents an assessment of disease symptoms. The DAS score consists of a numerical assessment of a set of 28 joints for swelling and tenderness, plus the patients overall (global) assessment of their RA and the results of a C-reactive protein and erythrocyte sedimentation rate blood test as key indicators of inflammation.

About Lupus
Lupus is an autoimmune disease in which the immune system produces antibodies that, instead of targeting viruses or other foreign invaders, attacks healthy tissue in the body, including skin, joints, the brain, and blood vessels. Lupus can cause a range of symptoms, including pain, rashes, fatigue, swelling in joints, and fevers, and is associated with a higher risk of death from causes such as infection and cardiovascular disease.

The SLE Responder Index-4 represents a clinically significant improvement in lupus disease activity. To achieve SRI-4 response, a person with lupus must have at least a 4 point improvement on the SLE Disease Activity - 2K (SLEDAI-2K) score, a validated measure of disease activity and have no worsening on the Physician Global Assessment of disease activity and the BILAG (British Isles Lupus Assessment Group) disease activity index.

About Mavrilimumab
Mavrilimumab (formerly CAM-3001) is a first in class human monoclonal antibody that targets the alpha receptor for the cytokine granulocyte-macrophage colony-stimulating factor (GM-CSF). Through the targeted blockade of the receptor on the macrophage, a key cell in the pathogenesis of rheumatoid arthritis, mavrilimumab could add a significant new treatment option for RA patients.

About Sifalimumab
Sifalimumab (formerly MEDI-545) is an investigational human monoclonal antibody that targets IFN- , a type of inflammatory cytokine in the body known to play a role in the development of SLE. Previous studies have shown that high levels of type I IFN- are correlated with more severe disease activity in SLE patients, and early studies of sifalimumab have demonstrated that this agent blocks
signaling of all interferon alpha subtypes.

About MedImmune
MedImmune is the global biologics research and development arm of AstraZeneca. 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 centres. 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 commercialisation 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

-ENDS-

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