ASTRAZENECA PLC
Form 6-K
December 13, 2013

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 December 2013

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 __

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 ANNOUNCES TOP-LINE RESULTS FROM PHASE III MONOTHERAPY STUDY OF LESINURAD IN GOUT PATIENTS

AstraZeneca today announced top-line results from LIGHT, a Phase III study investigating the potential of lesinurad as a monotherapy in the small population of gout patients who are intolerant to, or otherwise cannot take, one or both xanthine oxidase inhibitors allopurinol and febuxostat. Lesinurad is an investigational agent being studied as a selective uric acid re-absorption inhibitor (SURI) that inhibits the URAT1 transporter, normalising uric acid excretion and reducing serum uric acid (sUA).

In the trial, lesinurad met the primary endpoint with a statistically significant ($p< 0.0001$) higher proportion of patients meeting the sUA goal of <6.0 mg/dL at six months compared with those patients treated with placebo.

Patients in the LIGHT study treated with lesinurad monotherapy were more likely to experience serum creatinine elevations and renal adverse events, including serious events, compared to patients on placebo. Other commonly reported adverse events in patients treated with lesinurad monotherapy were diarrhoea, nausea and constipation.

Briggs Morrison, Executive Vice President, Global Medicines Development & Chief Medical Officer said: “The top-line results from LIGHT demonstrate the efficacy of lesinurad monotherapy, while also providing important safety data, in the small population of patients who can’t take xanthine oxidase inhibitors. We await the results of the remaining three Phase III trials that are investigating lesinurad as a combination therapy with xanthine oxidase inhibitors. We believe that combination therapy, addressing both production and excretion of uric acid, may be an effective way to treat gout patients who do not achieve treatment goals on xanthine oxidase inhibitors alone.”

The other Phase III trials in the lesinurad programme are investigating lesinurad in combination with allopurinol in patients not reaching target sUA levels on allopurinol alone (CLEAR1 and CLEAR2) and as a combination therapy with febuxostat in patients with tophaceous gout (CRYSTAL). The results of these studies are expected in mid 2014, and regulatory submissions in the US (NDA) and EU (MAA) are expected in the second half of 2014.

LIGHT (Lesinurad Monotherapy in Gout Subjects Intolerant to Xanthine Oxidase Inhibitors) was a six month study conducted by AstraZeneca and Ardea Biosciences, a wholly-owned subsidiary of AstraZeneca, to assess the sUA lowering effects and safety of 400mg of lesinurad used once daily as a monotherapy compared to placebo in 214 patients with sUA levels ≥ 6.5 mg/dL (highly symptomatic population with mean sUA of 9.3mg/dL at baseline) who are intolerant, or have a contraindication, to allopurinol or febuxostat.

About Gout

Gout is the most common form of inflammatory arthritis. Currently there are an estimated 15.3 million diagnosed cases of gout in major markets, which is forecast to increase to 17.7 million in 2021. Gout is caused by high levels of uric acid in the blood known as hyperuricemia which leads to the deposition of needle-like crystals in joints and soft tissues throughout the body, causing inflammation. Hyperuricemia results when the kidneys do not efficiently remove enough uric acid, or when the body produces too much.

While diet can contribute to elevated levels of uric acid, the majority of uric acid is produced by the body’s naturally occurring processes, and gout is most often caused by the inefficient excretion of uric acid by the kidneys. A person’s genetics play a significant role in their risk of developing gout.

The most common symptom of gout is extremely painful arthritis. Over time, the deposits of uric acid crystals may lead to joint damage, visible nodules called tophi, and impaired quality of life. Additionally, gout commonly presents with other serious health problems (comorbidities) including cardiovascular disease, diabetes and kidney impaired renal function.

About Ardea Biosciences
Ardea Biosciences, Inc. was acquired by AstraZeneca in June 2012. It is located in San Diego, California and is a wholly owned subsidiary of AstraZeneca PLC.

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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13 December 2013

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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: 13 December 2013

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