ASTRAZENECA PLC
Form 6-K
December 18, 2015

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 2015

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-_____

CHMP ISSUES POSITIVE OPINION ON LESINURAD FOR GOUT

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the marketing authorisation of lesinurad 200mg tablets. Lesinurad, in combination with a xanthine oxidase inhibitor (XOI), is recommended for the adjunctive

treatment of hyperuricaemia in adult gout patients (with or without tophi) who have not achieved target serum uric acid levels (sUA) with an adequate dose of a XOI alone.

The CHMP's positive opinion on lesinurad will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The final decision will be applicable to all 28 EU member countries plus Iceland, Norway and Liechtenstein. AstraZeneca anticipates a final decision by the EC in the first quarter of 2016. If approved, lesinurad will be the first selective uric acid reabsorption inhibitor (SURI) to treat patients with inadequately controlled gout in Europe.

Lesinurad is also under review in the United States. On 23 October 2015, the US Food and Drug Administration's Arthritis Advisory Committee recommended the approval of lesinurad 200mg tablets for the treatment of hyperuricemia associated with gout, in combination with an XOI. The Prescription Drug User Fee Act (PDUFA) target goal date is 29 December 2015.

Gout is a serious and debilitating form of inflammatory arthritis caused by hyperuricemia (elevated sUA). It affects millions of patients, many of whom do not reach recommended sUA treatment goals on the current standard of care (XOIs), which decrease production of uric acid. For those inadequately controlled patients, the addition of a urate lowering therapy to increase excretion of uric acid, may help them achieve treatment goals.

Lesinurad, developed by Ardea Biosciences, a member of the AstraZeneca Group, is a SURI that inhibits the urate transporter, URAT1, which is responsible for the majority of the renal reabsorption of uric acid. By inhibiting URAT1, lesinurad increases uric acid excretion and thereby lowers sUA.

About Lesinurad
If approved, lesinurad will be the first selective uric acid reabsorption inhibitor (SURI) in the EU. It inhibits the urate transporter, URAT1, which is responsible for the majority of the renal reabsorption of uric acid. By inhibiting URAT1, lesinurad increases uric acid excretion and thereby lowers serum uric acid (sUA). Lesinurad also inhibits organic anion transporter (OAT) 4 a uric acid transporter involved in diuretic-induced hyperuricemia. In addition, in people, lesinurad does not inhibit OAT1 and OAT3, which are drug transporters in the kidney associated with drug-drug interactions.

About Hyperuricemia and Gout
Gout is a serious, chronic, progressive, and debilitating form of inflammatory arthritis that affects more than 15.8 million people in major markets.* The underlying cause of gout is hyperuricemia (elevated sUA), which leads to the deposition of crystals primarily in the joints and in other tissues. This can result in recurrent attacks of inflammatory arthritis and, if left uncontrolled, could lead to chronic, progressive arthritis, and tophus (visible deposits of urate crystals) formation.

The goal of sUA lowering treatment is to reduce sUA levels to the target level of <6.0mg/dL (360 µmol/L) as recommended by both the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR). In those with greater disease severity and urate burden, such as those with tophi, guidelines recommend lowering sUA to <5.0 mg/dL (300 µmol/L) to achieve better disease control.

Among patients treated in clinical trials, less than 50% of patients on allopurinol 300mg reached sUA target levels <6.0mg/dL (360 µmol/L). For patients who cannot reach target on an XOI alone, the current ACR and EULAR guidelines recommend adding an agent that increases uric acid excretion.

*Major markets include the United States, France, Germany, Italy, Spain, the United Kingdom and Japan

About Ardea Biosciences

Ardea Biosciences, Inc. was acquired by AstraZeneca in June 2012. It is located in San Diego, California and is a member of the AstraZeneca Group. Ardea is leading the development of AstraZeneca's gout portfolio, including lesinurad and RDEA3170. RDEA3170 is a potent selective uric acid reabsorption inhibitor (SURI), also intended for use as a combination urate lowering therapy (ULT) with xanthine oxidase inhibitors. RDEA3170 is our lead investigational ULT in Asia and is currently entering a Phase IIb trial worldwide.

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

18 December 2015

-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: 18 December 2015

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