ASTRAZENECA PLC
Form 6-K
October 26, 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 October 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-_____

FDA ADVISORY COMMITTEE RECOMMENDS THE APPROVAL OF LESINURAD FOR GOUT PATIENTS

AstraZeneca has announced that the US Food and Drug Administration's (FDA) Arthritis Advisory Committee (AAC) voted 10 to 4 to recommend the approval of lesinurad 200mg tablets for the treatment of hyperuricemia associated with gout, in combination with a xanthine oxidase inhibitor (XOI). The AAC reviewed safety and efficacy data from the pivotal Phase III combination therapy programme trials, representing the largest clinical trial data set of gout patients treated with combination urate lowering therapy.

The FDA is not bound by the Advisory Committee's recommendation but takes its advice into consideration when reviewing the application for a potential medicine. The Prescription Drug User Fee Act (PDUFA) target goal date for lesinurad is 29 December 2015.

If approved, lesinurad will be the first selective uric acid reabsorption inhibitor, or SURI, in the US. It inhibits the urate transporter, URAT1, which is responsible for the majority of the renal reabsorption of uric acid.

Sean Bohen, Executive Vice President of Global Medicines Development and Chief Medical Officer, AstraZeneca, said: "The Committee's positive recommendation for lesinurad is an encouraging step for patients suffering from the debilitating effects of gout. We look forward to the outcome of the FDA's review and the opportunity to provide a new treatment option that, when combined with a xanthine oxidase inhibitor, addresses both the under-excretion and over-production of uric acid, the underlying causes of gout."

Gout is a serious and debilitating form of inflammatory arthritis caused by hyperuricemia (elevated serum uric acid (sUA)). Gout affects millions of Americans, 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 is also under regulatory review in the European Union and other territories.

About Lesinurad
If approved, lesinurad will be the first selective uric acid reabsorption inhibitor, or SURI, in the US. 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 (OAT4) a uric acid transporter involved in diuretic-induced hyperuricemia. In addition, in patients, lesinurad does not inhibit OAT1 and OAT3, which are drug transporters in the kidney associated with drug-drug interactions.

If approved, lesinurad in combination with an XOI would provide a dual mechanism of action to increase excretion and decrease production of uric acid enabling more patients with inadequately controlled gout to achieve target treatment goals.

About Hyperuricemia and Gout
Gout is a serious, chronic, progressive, and debilitating form of inflammatory arthritis. Currently, there are more than 8.3 million patients suffering from gout in the US. The underlying cause of gout is hyperuricemia (elevated serum uric acid (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). To improve signs and symptoms such as tophaceous gout, the ACR guidelines state that achieving and

maintaining sUA levels <5.0mg/dL (300 µmol/L) may be required.

Among patients treated in clinical trials, less than 50% of patients on allopurinol 300mg reached sUA target levels <6.0mg/dL (360 µmol/L). This suggests approximately two million gout patients in the US on urate lowering therapy remain inadequately controlled. For patients who cannot reach target on an XOI alone, the current ACR guidelines recommend adding an agent that increases uric acid excretion.

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, also intended for use as a combination urate lowering therapy with xanthine oxidase inhibitors. RDEA3170 is our lead investigational urate lowering therapy (ULT) in Asia and is currently entering a Phase IIb trial in the US.

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

CONTACTS

Media Enquiries

Esra Erkal-Paler		UK/Global	+44 20 7604 8030
Vanessa Rhodes		UK/Global	+44 20 7604 8037
Ayesha Bharmal		UK/Global	+44 20 7604 8034
Karen Birmingham		UK/Global	+44 20 7604 8120
Jacob Lund		Sweden	+46 8 553 260 20
Michele Meixell		US	+1 302 885 2677
Investor Enquiries	irteam@astrazeneca.com		
UK			
Thomas Kudsk Larsen	Oncology	+44 20 7604 8199	+44 7818 524185
Eugenia Litz	RIA	+44 20 7604 8233	+44 7884 735627
Nick Stone	CVMD	+44 20 7604 8236	+44 7717 618834
Craig Marks	Finance	+44 20 7604 8591	+44 7881 615764
Christer Gruvris		+44 20 7604 8126	+44 7827 836825
US			
Lindsey Trickett	Oncology, ING	+1 301 398 5118	+1 240 543 7970
Mitch Chan	Oncology	+1 301 398 1849	+1 240 477 3771
Dial / Toll-Free		+1 301 398 3251	+1 866 381 7277

Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

26 October 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: 26 October 2015

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