ASTRAZENECA PLC
Form 6-K
June 02, 2016

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 June 2016

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 LICENSES ZURAMPIC TO
GRÜNENTHAL GMBH IN EUROPE AND LATIN AMERICA

Agreement includes rights to the fixed-dose combination of lesinurad and allopurinol in gout

AstraZeneca today announced that it has entered into a licensing agreement with Grünenthal GmbH for the exclusive rights to Zurampic (lesinurad) in Europe and Latin America. Zurampic was approved by the European Medicines Agency (EMA) in February 2016 , in combination with a xanthine oxidase inhibitor (XOI), for the adjunctive treatment of hyperuricemia (excess of uric acid in the blood) in adult patients with uncontrolled gout.

Grünenthal will acquire the exclusive rights to Zurampic in all 28 European Union member states, Switzerland, Iceland, Norway and Lichtenstein, and in all Latin-American countries including Mexico, the Dominican Republic and Cuba. In addition, Grünenthal will also obtain the exclusive rights to the fixed-dose combination of lesinurad and allopurinol in these markets. This combination is currently in clinical trials.

Under the terms or the agreement, Grünenthal will submit the fixed-dose combination programme for regulatory review and will pay AstraZeneca up to $230 million in sales and other related milestones over the lifetime of the contract. Grünenthal will also pay tiered, low double-digit royalties on annual Product Sales. AstraZeneca will initially manufacture and supply Zurampic to Grünenthal and will undertake the European post-approval commitment on Grünenthal's behalf. From 1 October 2021, Grünenthal has the option to take over manufacturing of Zurampic.

Luke Miels, Executive Vice President, Global Product and Portfolio Strategy, AstraZeneca, said: "Grünenthal has an established presence across European and Latin American markets and extensive expertise in inflammatory diseases. This agreement allows us to further focus our resources on our strategic priorities."

Prof. Dr. Eric-Paul Pâques, CEO, Grünenthal, said: "We are highly committed to the research, development and commercialisation of innovative therapies that bring true benefits to patients. Zurampic is a strong addition to our existing portfolio of innovative therapies in the areas of inflammatory diseases and chronic pain. We will thus use our capabilities to provide patients in our markets with this innovative new medicine to better control their condition."

Gout is a serious, chronic, progressive and potentially debilitating form of inflammatory arthritis that affects more than 7.8 million people in the major European and Latin American markets1.

Financial considerations
Revenue from the licensing agreement will provide AstraZeneca with future recurring Externalisation Revenue from expected milestone payments and tiered, low double-digit percent royalty payments on Product Sales. The agreement does not impact AstraZeneca¹s financial guidance for 2016.

1 Markets include France, Germany, Italy, Spain, United Kingdom, Brazil, Mexico, Colombia, and Argentina. Source: Decision Resources Group, Community Oriented Programme for Control of Rheumatic Diseases.

About Zurampic
Zurampic (lesinurad) is the first in a new class of medicines called Selective Uric Acid Reabsorption Inhibitors (SURI) that work selectively to complement xanthine oxidase inhibitors (XOIs) in the treatment of hyperuricemia associated with uncontrolled gout. Zurampic is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. XOIs reduce the production of uric acid; Zurampic increases the excretion of uric acid. Together, the combination of Zurampic and an XOI provides a dual mechanism of action that both decreases production and increases excretion of uric acid, thereby lowering serum uric acid (sUA) levels in patients who have not achieved target serum acid levels with XOI treatment alone. Zurampic selectively inhibits the function of transporter proteins urate transporter (URAT1) and organic anion transporter 4 (OAT4), involved in uric acid reabsorption in the kidney. In people, Zurampic does not inhibit OAT1 and OAT3, which are drug transporters in the kidney associated with drug-drug interactions. The efficacy of Zurampic was established in three Phase III clinical

trials that evaluated a once daily dose of Zurampic in combination with the XOI allopurinol or febuxostat compared to XOI alone.

In April 2016, AstraZeneca entered into a licensing agreement with Ironwood Pharmaceuticals for the exclusive US rights to Zurampic and the fixed-dose combination of lesinurad and allopurinol.

About Grünenthal
The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. We are an entrepreneurial specialist delivering true benefits to patients. By sustainably investing in research and development above the industrial average, we are committing to innovation in order to treat unmet medical needs and bring value adding products to markets. Grünenthal is a fully integrated research & development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. Altogether, the Grünenthal Group is present in 32 countries with affiliates in Europe, Latin America and the US. Grünenthal products are sold in more than 155 countries and approx. 5,300 employees work for the Grünenthal Group worldwide. In 2015, Grünenthal achieved revenues of €1.2 bn. More information: www.grunenthal.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 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

2 June 2016

-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: 02 June 2016

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