ASTRAZENECA PLC
Form 6-K
December 12, 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-_____

FDA Advisory Committee votes on Investigational Medicine Metreleptin

Advisory Committee recommends metreleptin for the treatment of paediatric and adult patients with generalised lipodystrophy; does not recommend for the treatment of partial lipodystrophy for the indication currently proposed

AstraZeneca and Bristol-Myers Squibb Company today announced the US Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) recommends the investigational medicine metreleptin for the treatment of paediatric and adult patients with generalised lipodystrophy (LD). Specifically, EMDAC determined by a vote of 11 to 1 that there is substantial evidence that the benefits of metreleptin exceed the risks for the treatment of paediatric and adult patients with generalised lipodystrophy.

EMDAC did not recommend metreleptin in patients with partial LD for the indication currently proposed, by a vote of 2 to 10. AstraZeneca and BMS remain committed to pursuing metreleptin for treatment in patients with metabolic disorders associated with partial LD. The Companies acknowledge the committee's feedback and will continue to work with the FDA to identify the appropriate patients with partial LD who may benefit from metreleptin.

The FDA is not bound by the EMDAC's recommendation but will take it into consideration when reviewing the Biologics License Application (BLA) for metreleptin

LD is a group of rare syndromes often associated with severe metabolic abnormalities and significant morbidity and mortality. Metreleptin is being reviewed by the FDA as a treatment of paediatric and adult patients with generalised lipodystrophy (LD) or metabolic disorders associated with partial LD, including hypertriglyceridemia and/or diabetes mellitus inadequately controlled on a current therapy, and/or evidence of hepatic steatosis (fatty liver disease).

The Prescription Drug User Fee Act (PDUFA) goal date for metreleptin is 24 February 2014. There are no therapies approved by the FDA to treat patients with rare forms of LD (not including HIV-associated LD).

The EMDAC based its recommendations on a review of data from the metreleptin clinical development programme for LD that supported the BLA submission, including pivotal efficacy and safety data from two open-label, investigator-sponsored National Institutes of Health (NIH) studies, as well as important supplemental efficacy and safety data on investigational metreleptin from an additional open-label expanded access study, FHA101.

About the NIH Metreleptin Studies
The first clinical study of investigational metreleptin was initiated in 2000 by investigators at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of NIH. The open-label, investigator-sponsored pilot study was designed to evaluate the safety and efficacy of investigational metreleptin administration in patients with rare forms of generalised or partial LD and did not include patients with HIV-associated LD. Based on the efficacy data in the pilot study, a long-term, open-label clinical trial was initiated to determine the safety and efficacy of investigational metreleptin for improving metabolic abnormalities in patients with LD, and is currently ongoing.

About Metreleptin
Metreleptin, an investigational recombinant analog of the human hormone leptin, has received orphan designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Metreleptin is being evaluated for the treatment of paediatric and adult patients with generalised LD or metabolic disorders associated with partial LD, including hypertriglyceridemia and/or diabetes mellitus inadequately controlled on a

current therapy, and/or evidence of hepatic steatosis (fatty liver disease).

About Lipodystrophy

LD is a group of rare syndromes often associated with severe metabolic abnormalities and significant morbidity and mortality. It is estimated to affect only a few thousand people worldwide. LD is heterogeneous in presentation and often occurs at an early age - during childhood or in early adulthood. There are several reasons for developing LD. In some patients, it is genetic, and in others it may be acquired for different reasons, including cases in which the immune system may attack and destroy existing fat tissue. Sometimes, clearly defined reasons for the development of the condition are unknown.

Whether genetic or acquired in origin, all forms of LD share a common pathophysiology: loss of fat tissue, especially fat under the skin. This loss of fat tissue, which causes a deficit in the hormone leptin, can vary from complete loss, or "generalised," to loss of fat in only some parts of the body, or "partial." Without enough fat tissue or leptin, the body's system for regulating energy use and storage falls out of balance. The resulting serious imbalance causes lipid to accumulate where it should not be found-such as in the liver and muscle-which may lead to severe metabolic abnormalities, primarily hypertriglyceridemia, severe insulin resistance with resultant hyperglycaemia and type 2 diabetes, and hepatic steatosis (fatty liver disease).

The metabolic abnormalities in patients with LD are often difficult to control even with high doses of currently available diabetes and lipid-lowering therapies. These therapies are rendered less effective by the profound insulin resistance associated with LD. Moreover, these therapies are not designed to correct the underlying deficiency of leptin. Patients with LD are left with the burden of these chronic and uncontrolled metabolic abnormalities, which can be associated with premature mortality often due to acute pancreatitis, renal failure, severe cardiac disease, or liver failure. Therefore, there is a significant unmet medical need for a therapy that improves the metabolic disorders found in these patients.

About the AstraZeneca / Bristol-Myers Squibb Diabetes Alliance

Dedicated to addressing the global burden of diabetes by advancing individualised patient care, AstraZeneca and Bristol-Myers Squibb are working in collaboration to develop and commercialise a versatile portfolio of innovative treatment options for diabetes and related metabolic disorders that aim to provide treatment effects beyond glucose control. Find out more about the Alliance and our commitment to meeting the needs of health care professionals and people with diabetes at www.astrazeneca.com or www.bms.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.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit http://www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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12 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: 12 December 2013 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary