ASTRAZENECA PLC
Form 6-K
February 25, 2014

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 February 2014

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-_____

US FDA APPROVES ORPHAN DRUG MYALEPT™ (METRELEPTIN FOR INJECTION)

AstraZeneca today announced the US Food and Drug Administration (FDA) approved orphan drug MYALEPT™ (metreleptin for injection), which is indicated as an adjunct to diet as replacement therapy for the treatment of complications of leptin deficiency in patients with congenital or acquired generalised lipodystrophy. MYALEPT, a recombinant analogue (laboratory-created form) of human leptin, is the first and only treatment approved by the FDA for these patients.

AstraZeneca is working to complete the transfer of the Biologics License Application (BLA) for MYALEPT from Bristol-Myers Squibb Company to AstraZeneca as part of the acquisition of the diabetes alliance assets, including MYALEPT and Amylin Pharmaceuticals, which was completed on 1 February 2014.

Lipodystrophy is a group of rare syndromes characterised by loss of fat tissue. In some patients it is genetic, while in others it may be acquired for different pathophysiological, and in some cases unknown, reasons. Generalised lipodystrophy is characterised by widespread loss of fat tissue under the skin. This loss of fat tissue causes a deficit in the hormone leptin leading to multiple metabolic complications.

The safety and effectiveness of MYALEPT for the treatment of complications of partial lipodystrophy or for the treatment of liver disease, including non-alcoholic steatohepatitis (NASH), have not been established. MYALEPT is not indicated for use in patients with HIV-related lipodystrophy or for use in patients with metabolic disease, including diabetes mellitus and hypertriglyceridaemia, without concurrent evidence of congenital or acquired generalised lipodystrophy.

MYALEPT has boxed warnings regarding the risk of anti-metreleptin antibodies with neutralising activity and risk of lymphoma. Because of these risks associated with the development of anti-metreleptin antibodies that neutralise endogenous leptin and/or MYALEPT and the risk for lymphoma, MYALEPT is available only through a restricted distribution programme under a Risk Evaluation and Mitigation Strategy (REMS).

"We are pleased that MYALEPT will be available to patients in the US. MYALEPT is the first approved therapy, as an adjunct to diet, to help treat the complications of leptin deficiency affecting the lives of children and adults with generalised lipodystrophy," said Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer, AstraZeneca. "MYALEPT represents a significant treatment advancement for people living with this serious and rare disorder. We are committed to supporting this patient community and are dedicated to ensuring the appropriate patients who are prescribed MYALEPT will also have a comprehensive patient support programme available to them."

MYALEPT is for subcutaneous injection only and is available in an 11.3 mg vial that requires reconstitution.

MYALEPT is contraindicated in patients with general obesity not associated with congenital leptin deficiency. MYALEPT has not been shown to be effective in treating general obesity, and the development of anti-metreleptin antibodies with neutralising activity has been reported in obese patients treated with MYALEPT. MYALEPT is also contraindicated in patients with prior severe hypersensitivity reactions to metreleptin or any of the product components.

AstraZeneca is working to make MYALEPT available to patients as soon as possible 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

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25 February 2014

-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: 25 February 2014

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