ASTRAZENECA PLC
Form 6-K
May 27, 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 May 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'S FASLODEX MET PRIMARY ENDPOINT IN FIRST-LINE TREATMENT OF ADVANCED BREAST CANCER

AstraZeneca today announced positive results from the Phase III FALCON trial comparing Faslodex 500mg (fulvestrant) to Arimidex 1mg (anastrozole) for the treatment of locally-advanced or metastatic breast cancer, in post-menopausal women who have not had prior hormonal treatment for hormone-receptor-positive (HR+) breast cancer.

Faslodex 500mg demonstrated superiority compared with Arimidex 1mg in FALCON, and met its primary endpoint of extended progression-free survival. The trial showed an adverse event profile generally consistent with current knowledge of the safety profile of the medicines.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The FALCON results bring us closer to offering more and earlier treatment options to postmenopausal women with HR+ locally-advanced or metastatic breast cancer; the potential to delay disease progression is important for these patients as there is currently no cure. Faslodex has over 10 years of clinical evidence and we are committed to exploring its potential along with the rest of our outstanding oncology portfolio."

A full evaluation of the data is ongoing and the results are expected to be presented at a medical meeting in 2016.

Aromatase inhibitors (such as Arimidex) are the current standard of care in first-line treatment for postmenopausal women with advanced HR+ breast cancer.i

Faslodex 500mg is approved for the treatment of postmenopausal women with oestrogen-receptor (ER)-positive locally-advanced or metastatic breast cancer whose cancer has progressed following anti-oestrogen therapy.ii Most recently, on 2 March 2016, the US Food and Drug Administration approved Faslodex 500mg, in combination with palbociclib, for the treatment of women with hormone-receptor-positive, human-epidermal-growth-factor-receptor 2-negative (HER2-) advanced or metastatic breast cancer (MBC), whose cancer has progressed after endocrine therapy.iii

About FALCON
The FALCON (Fulvestrant and AnastrozoLe COmpared in hormonal therapy Naïve advanced breast cancer) trial is a Phase III, randomised, double-blind, multicentre trial. The trial compared the anti-tumour effects and tolerability profile of a 500mg dose of Faslodex plus placebo with a 1mg dose of Arimidex plus placebo, in postmenopausal women with hormone-receptor-positive, locally-advanced or metastatic breast cancer who have not been treated previously with any hormonal therapy.

About Advanced breast cancer (ABC)
ABC is the most advanced stage of breast cancer (stage IV), and occurs when cancer cells have spread beyond the initial tumour site to other parts of the body outside of the breast. Since there is no cure for ABC, the goal of current treatment is to delay disease progression.iv

About Faslodex 500mg (fulvestrant)
Faslodex 500mg is indicated for the treatment of postmenopausal women with ER+, locally-advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.2

In the US, Faslodex 500mg is also approved, in combination with palbociclib, for the treatment of US women with HR+, human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer (MBC), whose cancer has progressed after endocrine therapy. Faslodex 500mg represents a hormonal therapy approach that helps to slow tumour growth by blocking and degrading the oestrogen receptor - a key driver of disease progression.v

About AstraZeneca in Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least 6 new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advance New Oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms -- immuno-oncology, the genetic drivers of cancer and resistance, DNA damage response and antibody drug conjugates -- and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

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

References

i Journal of Clinical Oncology. Endocrine Therapy for Hormone Receptor-Positive Metastatic Breast Cancer: American Society of Clinical Oncology Guideline. Available at: http://jco.ascopubs.org/content/early/2016/05/19/JCO.2016.67.1487.full.pdf+html. Last accessed 25.05.2016
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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

27 May 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: 27 May 2016

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