ASTRAZENECA PLC
Form 6-K
July 26, 2017

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 July 2017

Commission File Number: 001-11960

AstraZeneca PLC

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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 __

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Yes __ No X

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26 July 2017 16:45 BST

FASLODEX RECEIVES EU APPROVAL AS FIRST-
LINE THERAPY FOR ADVANCED BREAST CANCER

Faslodex reduced risk of disease progression by 20%
vs anastrozole, the current standard treatment option

Potential new first-line standard of care for postmenopausal women with
oestrogen-receptor positive locally-advanced or metastatic disease

AstraZeneca today announced that the European Commission (EC) has approved Faslodex (fulvestrant) for the treatment of oestrogen-receptor positive, locally-advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy.

The EU approval is based on pivotal data from the Phase III FALCON trial, which demonstrated the superiority of Faslodex 500mg over anastrozole 1mg as a first-line treatment for postmenopausal women with locally-advanced or HR+ metastatic breast cancer who had not received prior hormone-based therapy.

In the FALCON trial, median progression-free survival (PFS) was significantly longer with Faslodex than with the aromatase inhibitor, anastrozole - 16.6 months versus 13.8 months (HR: 0.797; 95% CI: 0.637-0.999; p=0.0486). Aromatase inhibitors such as anastrozole are the current standard of care for the first-line treatment for postmenopausal women with HR+ advanced breast cancer.

Jamie Freedman, Executive Vice-President and Head of AstraZeneca's Oncology Business Unit, said: "This new EU approval shows the scientific strength of Faslodex with more than 15 years of clinical experience. Postmenopausal women with hormone receptor-positive advanced breast cancer can now benefit from Faslodex at an earlier stage in their disease. We continue to explore the full potential of this important medicine as monotherapy and in combination with other medicines."

Matthew Ellis, MD, PhD, study investigator, and director of the Lester and Sue Smith Breast Center in the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine in Houston, said: "A 20% reduction in disease progression or death observed with fulvestrant compared to the current standard therapy is an advance in the management of postmenopausal women diagnosed with previously untreated hormone receptor-positive advanced breast cancer. The study provides evidence that the earlier use of fulvestrant in these patients will prolong the time before the disease progresses, which requires a change to a second line drug."

The safety and tolerability profiles for Faslodex and anastrozole reported in the FALCON trial were in line with current experience. The most-commonly reported adverse events (AEs) in the Faslodex and anastrozole arms were arthralgia (16.7% vs. 10.3%), hot flush (11.4% vs. 10.3%) and nausea (10.5% vs. 10.3%).

Faslodex is the only hormonal medicine for advanced breast cancer that slows tumour growth by binding to and degrading the oestrogen receptor - a key driver of breast cancer progression in some women. It is widely approved for the treatment of HR+ advanced breast cancer in postmenopausal women with disease progression following

anti-oestrogen medicine.

Faslodex was first approved in 2002 and is currently being tested in combination with over 19 different medicines for the treatment of women with advanced HR+ breast cancer.

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 comparing the antitumour effects and tolerability profile of a 500mg dose of Faslodex plus placebo with a 1mg dose of anastrozole plus placebo, in postmenopausal women with HR+, locally-advanced or metastatic breast cancer who have not been treated previously with any hormonal medicine.

The FALCON trial was designed on the basis of positive results from the Phase II FIRST trial, which demonstrated a median overall survival nearly six months longer with Faslodex compared to anastrozole.

About Advanced Breast Cancer
Advanced/metastatic breast cancer refers to Stage III and IV breast cancer. Stage III disease may also be referred to as locally-advanced breast cancer, while metastatic disease is the most-advanced stage of breast cancer (Stage IV), and occurs when cancer cells have spread beyond the initial tumour site to other organs of the body outside the breast. Since there is no cure for the disease, the goal of current treatment is to delay disease worsening or death.

About Faslodex
Faslodex (fulvestrant) is indicated for the treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy, or with disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on anti-oestrogen therapy.

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

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 six 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 five 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, Tumour Drivers 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, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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 and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

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 July 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary