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## *AstraZeneca's Faslodex met primary endpoint in first-line treatment of advanced breast cancer*

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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 postmenopausal 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 Bohan, 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<sup>1</sup>.

*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<sup>2</sup>. 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<sup>3</sup>.

## NOTES TO EDITORS

### 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<sup>4</sup>.

### 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.<sup>2</sup>

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<sup>5</sup>.

### 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](http://www.astrazeneca.com)

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## CONTACTS

### Media Enquiries

Neil Burrows  
UK/Global  
+44 7842 350541  
Vanessa Rhodes  
UK/Global  
+44 7880 400690  
Karen Birmingham  
UK/Global  
+44 7818 524012  
Jacob Lund  
Sweden  
+46 8 553 260 20  
Michele Meixell  
US  
+1 302 885 2677

### Investor Enquiries

UK

Thomas Kudsk Larsen  
  
+44 7818 524185  
Nick Stone

Media Enquiries

CVMD, RIA  
+44 7717 618834  
Henry Wheeler  
Oncology  
+44 7788 354619  
Craig Marks  
Finance  
+44 7881 615764  
Christer Gruvris  
ING, Consensus Forecasts  
+44 7827 836825

US

Lindsey Trickett  
CVMD, Oncology  
+1 240 543 7970  
Mitch Chan  
Oncology  
+1 240 477 3771  
Dial / Toll-Free

+1 866 381 7277

*Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease,*

*ING - Infection, Neuroscience and Gastrointestinal*