

Faslodex CHMP positive opinion in 1L breast cancer

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FASLODEX (FULVESTRANT) RECEIVES POSITIVE CHMP OPINION FOR USE IN 1st-LINE HORMONE RECEPTOR-POSITIVE ADVANCED BREAST CANCER

CHMP positive recommendation is based on Phase III data demonstrating a 20% reduction in risk of disease worsening or death over anastrozole

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending the marketing authorisation of Faslodex (fulvestrant) for the treatment of hormone receptor-positive (HR+), 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.

The CHMP recommendation is based on pivotal data from the Phase III FALCON trial, where Faslodex 500mg demonstrated superiority over anastrozole 1mg in the treatment of locally-advanced or metastatic breast cancer in post-menopausal women who had not received prior hormonal-based medicine for HR+ breast cancer.

The FALCON data show that the delay in disease worsening or death (median progression-free survival, PFS) was 2.8 months longer with Faslodex than anastrozole. The median PFS was 16.6 months in the Faslodex arm compared with 13.8 months in the anastrozole arm. Aromatase inhibitors such as anastrozole are the current standard of care for the 1st-line treatment for postmenopausal women with HR+ advanced breast cancer.

Sean Bohan, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "Faslodex has long been an effective medicine for women with advanced breast cancer in later lines of treatment and we are pleased that the CHMP has recognised its potential as a first-line option. Faslodex is also being tested in combination with over 19 different medicines, which is testament to its well-established safety and efficacy profile with over 15 years of patient evidence since its first launch in 2002."

The safety and tolerability profile was in line with current experience with Faslodex and anastrozole. 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 hormone 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.

The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union (EU). The final decision will be applicable to all 28 EU member countries plus Iceland, Norway and Liechtenstein.

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 postmenopausal women with oestrogen receptor-positive (ER+), locally-advanced or metastatic breast cancer with disease relapse on or after adjuvant anti-oestrogen treatment, or disease progression on treatment with an antioestrogen.

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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