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Section: Expanded Reporting

European launch of Faslodex reported  
Breast Cancer

[AstraZeneca](#) announced the first European launches of its new breast cancer drug Faslodex ( fulvestrant) in Germany and Sweden, with Austria following imminently.

The novel drug - an estrogen receptor antagonist with no agonist effects - is for the treatment of advanced breast cancer in postmenopausal women whose cancer has progressed on previous anti-estrogen treatments such as tamoxifen. Fulvestrant has been launched in the U.S. since May 2002, and more recently in Brazil in July 2003.

Fulvestrant was approved for launch in the European Union (E.U.) on 12 March 2004, making it the first new type of hormonal treatment for estrogen receptor-positive breast cancer to be approved in the E.U. since 1995. The launch of the drug in Germany, Sweden, and Austria therefore provides new hope to the thousands of women suffering from advanced disease in these countries. Further launches throughout Europe are expected during the course of this year.

Commenting on the launch, professor Kurt Possinger, head of the oncology department at Humboldt University of Berlin, Germany, explains, "The availability of 'Faslodex' in these countries is very exciting as women who have progressed on prior tamoxifen therapy now have a new additional and effective treatment option which may help extend the window of endocrine therapy and delay the use of cytotoxic chemotherapies with their well-recognized and unwanted side-effects.

In addition, unlike other endocrine therapies used in postmenopausal women, 'Faslodex' is a once-monthly injection which enables clinicians to have greater contact with their patients to review progress and free women of the worry of remembering to take a daily tablet, allowing them to focus on their life and not their illness."

Breast cancer affects one in nine women at some point in their lives and although many tumors are detected early and

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treated successfully, a large number of women still go on to be diagnosed with advanced breast cancer. The goal of treatment for these women is to achieve an effective disease response and to enable the patient to maintain good quality of life for as long as is feasibly possible.

Hormonal agents such as aromatase inhibitors and tamoxifen are standard therapy in postmenopausal women with advanced breast cancer, providing an effective and well-tolerated treatment option. However, in time tumour cells can grow resistant to treatment with these hormonal therapies and as a result there is a need for new agents to which tumors are not resistant. Fulvestrant is an exciting new type of therapy, which brings new choices for women with advanced disease, extending the sequence of 'patient-friendly' hormonal therapies that can be used to control the disease.

Fulvestrant works differently to any other treatment available, although like the other hormonal therapies it interferes with the effect of the hormone 'estrogen' on tumour growth. Many breast cancers are dependent on the presence of estrogen to grow. Of the current therapies, aromatase inhibitors (e.g. Arimidex (anastrozole)) work by reducing the amount of estrogen in a woman's body, and tamoxifen (an anti-estrogen) blocks estrogen receptors. However, tamoxifen also mimics some of the actions of estrogen, which can result in unwanted side effects. In contrast, fulvestrant works by blocking and removing the estrogen receptors in the breast cancer cells and, unlike tamoxifen, does not mimic the actions of estrogen.

Fulvestrant offers durable responses and has tolerability benefits compared with aromatase inhibitors and tamoxifen. Fulvestrant is effective following disease progression on prior anti-estrogen and aromatase inhibitor therapy in addition both therapies are effective following fulvestrant therapy. Fulvestrant therefore meets a key unmet need for women with advanced breast cancer, since it can be added in to the sequence of well-tolerated hormonal therapies and may delay the need to resort to cytotoxic chemotherapies with their well-recognized side effects.

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