



## **IMPORTANT INFORMATION REGARDING THE DISCONTINUATION OF COMMERCIAL DISTRIBUTION OF NOLVADEX® (tamoxifen citrate)**

March 15, 2006

Dear Health Care Professional,

This letter is to notify you that AstraZeneca Pharmaceuticals LP intends to discontinue the commercial manufacture of NOLVADEX® (tamoxifen citrate) Tablets in the United States by the end of June 2006. Therefore, once commercial supplies are exhausted, your patients will no longer be able to obtain brand name NOLVADEX Tablets. This applies to both new prescriptions and refills.

As you know, currently there are numerous companies that manufacture generic tamoxifen in the United States, and, as a result, the requests for brand name NOLVADEX have dwindled steadily over the last year. It is solely for this reason that AstraZeneca has voluntarily decided to cease manufacturing NOLVADEX.

With the wide availability of generic tamoxifen, the discontinuation of NOLVADEX should in no way affect patient access to this medication.

### Patient Assistance Program

When the manufacture and commercial distribution of NOLVADEX Tablets is discontinued, NOLVADEX will no longer be available within the AstraZeneca Foundation Patient Assistance Program after June 30, 2006. As a result, any new refill requests must be dated no later than June 16, 2006. The AstraZeneca Foundation must receive all refill requests on or before Monday, June 19, 2006 at 5:00 PM CST. Prescription refills received after Monday, June 19 will not be filled. Additionally, no new patients will be accepted into the program after February 28, 2006.

We are encouraging health care providers to speak with their patients as soon as possible about their therapy alternatives and to research drug assistance programs that may be available for these therapies. The Partnership for Prescription Assistance is a resource that may be able to help your patients identify alternate drug assistance programs for which they may qualify. For more information, they can visit [www.pparx.org](http://www.pparx.org) or, to speak with an educator, call 1-888-477-2669.

Should you have any questions, please contact the AstraZeneca Cancer Support Network at 1-866-992-9276.

Sincerely,

*Kenneth A. Kern*

Kenneth A. Kern, MD, MPH  
Director, Clinical Research

Please see reverse side for Important Information about NOLVADEX

NOLVADEX® (tamoxifen citrate) is a hormonal medication that has been approved for

- Treatment of metastatic breast cancer in women and men
- Adjuvant treatment of node-negative breast cancer following breast surgery and radiation
- Adjuvant treatment of node-positive breast cancer in postmenopausal women following breast surgery and radiation
- Reduction in incidence of contralateral breast cancer (in the other breast) in the adjuvant setting
- Reduction in incidence of invasive breast cancer in women with DCIS following breast surgery and radiation (see BOXED WARNING below)
- Reduction in incidence of breast cancer in women at high risk for breast cancer (see BOXED WARNING below)

### **Important Safety Information**

**WARNING—For Women with Ductal Carcinoma in Situ (DCIS) and Women at High Risk for Breast Cancer:** Serious and life-threatening events associated with NOLVADEX in the risk reduction setting (women at high risk for cancer and women with DCIS) include uterine malignancies, stroke, and pulmonary embolism.

P-1 trial (see CLINICAL PHARMACOLOGY-Clinical Studies-Reduction in Breast Cancer Incidence in High-Risk Women). Uterine malignancies consist of both endometrial adenocarcinoma (incidence rate per 1,000 women-years of 2.20 for NOLVADEX vs 0.71 for placebo) and uterine sarcoma (incidence rate per 1,000 women-years of 0.17 for NOLVADEX vs 0.0 for placebo\*). For stroke, the incidence rate per 1,000 women-years was 1.43 for NOLVADEX vs 1.00 for placebo.\*\* For pulmonary embolism, the incidence rate per 1,000 women-years was 0.75 for NOLVADEX vs 0.25 for placebo.\*\*

Some of the strokes, pulmonary emboli, and uterine malignancies were fatal.

Health care providers should discuss the potential benefits versus the potential risks of these serious events with women at high risk of breast cancer and women with DCIS considering NOLVADEX to reduce their risk of developing cancer.

\*Updated long-term follow-up data (median length of follow-up is 6.9 years) from NSABP P-1 study.  
See WARNINGS: Effects of the Uterus-Endometrial Cancer and Uterine Sarcoma.

\*\*See Table 3 under CLINICAL PHARMACOLOGY-Clinical Studies.

Women who are pregnant or who plan to become pregnant should not take NOLVADEX.

When used to reduce the incidence of breast cancer in high-risk women or in women with DCIS, NOLVADEX is contraindicated in women who require anticoagulant therapy or have a history of deep vein thrombosis or pulmonary emboli. Cataracts and cataract surgery also occurred more frequently in clinical trials with NOLVADEX than placebo. The most frequently reported adverse reactions with NOLVADEX were hot flashes and vaginal discharge.

**Please see accompanying full Prescribing Information.**