

# NSABP B-42

## For Postmenopausal Women Who Have Completed 5 Years of Adjuvant Hormonal Therapy After Surgery for Breast Cancer

### NSABP B-42 Available Through the CTSU

A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer

#### Patient Population

See Section 4.0 for Complete Eligibility Details

- Female patients with primary tumor that was pathologic or clinical stage I, II, or IIIA invasive carcinoma of the breast documented by core needle or open biopsy.
- Primary tumor was ER- and/or PgR-positive.
- Patients must have undergone either lumpectomy with axillary nodal staging followed by breast RT or a total mastectomy with axillary nodal staging. SN biopsy alone is acceptable if SNs were negative on H&E staining.
- Patients must be postmenopausal at time of randomization (see Section 4.2.4).
- Patients must have remained disease-free from the time of initial breast cancer diagnosis until the time of randomization.
- Patients must have received hormonal therapy following diagnosis for a duration of 57-63 months from the first dose regardless of number of missed doses. Hormonal therapy must have consisted of an AI or a combination of up to 3 years of tamoxifen followed by an AI.
- Patients must be randomized within 6 months of completing initial adjuvant hormonal therapy.
- Patients must not be taking sex hormonal therapy, e.g., HRT or oral contraceptives, or hormonal agents such as raloxifene for management of osteoporosis. Patients are eligible if these treatments are discontinued prior to randomization.

**Number of Participants: 3,840**

#### Treatment Plan

##### Double-Blind Randomization

- Letrozole 2.5 mg/placebo PO QD x 5 years (5 years from the date of the first dose regardless of any missed doses)
- Osteoporosis Management
  - Calcium supplement 500-600 mg PO BID recommended for all patients.
  - Vitamin D 400 IU PO QD recommended for all patients.
  - Bisphosphonate therapy recommended for all patients meeting criteria in Section 7.2.2.

**NSABP  
Protocol Chair:**  
Eleftherios Mamounas,  
MD

#### Patient Enrollment

Non-NSABP Members: CTSU Patient Registrar 1-888-462-3009

#### Protocol Information

CTSU Help Desk 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

## Please Enroll Your Eligible Patients!

# Schema

## NSABP B-42

A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer

