SWOG
Leading cancer research. **Together.**

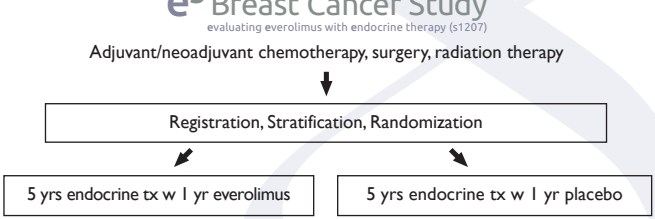
e3 • S1207

+/- 1 yr everolimus w adjuvant endocrine tx for high-risk br ca

ver 8/13/13

INELIGIBILITY • Patient must *not* have: *(refer to protocol for details)*

- metastatic disease
- grade III/IV cardiac disease (NYHA criteria), unstable angina, MI within last 6 months, or serious uncontrolled arrhythmia
- GI impairment or disease that may alter drug absorption
- hepatitis, uncontrolled diabetes, uncontrolled pulmonary disease, or organ allograft or other history of immune compromise
- chronic systemic corticosteroid use (topical or inhaled are allowed)
- live attenuated vaccine ≤ 7 days prior to registration
- strong CYP3A4 inhibitors or inducers ≤ 14 days prior to registration
- prior mTOR inhibitors (rapamycin, everolimus, temsirolimus, or deforolimus)
- other investigational drug ≤ 28 days prior to registration (concurrent bisphosphonate *is* allowed; concurrent trastuzumab is *not*)
- prior malignancy, *except:*
  - » adequately treated basal or squamous cell skin cancer
  - » in situ cervical cancer
  - » other cancer from which patient has been disease-free for 5 years
- be pregnant or nursing; women and men of reproductive potential must agree to use effective, non-hormonal contraceptive method



THIS PROTOCOL CARD IS A SCREENING TOOL *ONLY* AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL

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"Phase III, Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer"

Patients at CCOPs must also be offered the opportunity to take part in correlative behavioral and health outcomes (BAHO) study S1207-E01, led by NSABP.

ELIGIBILITY • Patient must have:

- histologically confirmed diagnosis of invasive breast carcinoma (multifocal, multicentric, synchronous bilateral, or inflammatory br ca is allowed)
- positive estrogen and/or progesterone receptor (by ASCO/CAP guidelines)
- negative HER2 status (by IHC or gene amplification)
- completed neoadjuvant or adjuvant taxane or anthracycline based chemotherapy
- fit in one of four high-risk groups:
  - A. completed adjuvant chemotherapy, node-negative, tumor greatest diameter ≥ 2 cm, *and* Oncotype DX® Recurrence Score (RS) > 25
  - B. completed adjuvant chemo, 1 – 3 positive nodes, *and* RS > 25
  - C. completed adjuvant chemo and ≥ 4 positive nodes
  - D. completed *neo*adjuvant chemo and ≥ 4 positive nodes
- had either breast-conserving surgery with whole-breast radiation, or total mastectomy; must have negative margins
- had axillary staging by sentinel node biopsy or axillary lymph node dissection (ALND)
- if ≥ 4 positive nodes, must have breast/chest wall & nodal basin radiation & ALND
- if 1 – 3 positive nodes, sentinal node biopsy alone is allowed *if* patient had whole breast or chest wall radiation *and* primary tumor < 2 cm
- all radiation therapy completed ≥ 21 days prior to registration and radiation toxicites > grade 1 resolved
- all chemotherapy completed ≤ 21 weeks prior to registration
- adequate bone marrow, hepatic, and renal function; fasting cholesterol ≤ 300 mg/dL; triglycerides ≤ 2.5 x IULN; Zubrod PS of 0 – 2

*See back of card for **INELIGIBILITY** factors.*