

# **Ixabepilone and cyclophosphamide as neoadjuvant therapy in HER2-negative breast cancer with exploratory Oncotype DX assessments: A Sarah Cannon Research Institute phase II trial.**

## **Sub-category:**

Cytotoxic Chemotherapy

## **Category:**

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## **Abstract Disclosures**

### **Abstract:**

**Background:** Ixabepilone (Ixa) is active in taxane-refractory metastatic breast cancer as well as in the neoadjuvant setting where Ixa yielded a pathologic complete response (pCR) rate of 18%. In this study, we evaluated Ixa in combination with cyclophosphamide (Cyc) as neoadjuvant treatment for HER2-negative breast cancer. The primary endpoint was pathologic complete response (pCR) rate, defined as no residual cancer in breast or lymph nodes. Responses were correlated with Oncotype DX recurrence scores.

**Methods:** Eligible women were HER2-negative (IHC 0-1+ or FISH negative), node positive or T > 2 cm with inflammatory and T1N0 tumors excluded. Patients (pts) received Ixa 40mg/m<sup>2</sup> with Cyc 600 mg/m<sup>2</sup> day 1 of each 21-day cycle. Following 6 cycles, pts went to surgery. Postoperative radiation and hormonal treatments were at discretion of the treating MD. Core biopsies (pretreatment and at surgery) were analyzed using the Oncotype DX RT-PCR assay; the associations between recurrence scores and clinical responses were investigated in an interim analysis.

**Results:** 156 women have been enrolled. Baseline characteristics for the first 78 pts are reported (median age 52 years; 86% invasive ductal; 50%/33% T2/T3; 41% triple negative). 50 pts have undergone surgery. 14 pts discontinued treatment early (disease progression – 6; pt/MD request – 5; toxicity – 3). Grade 3/4 toxicity

included: neutropenia (69%), leukopenia (51%), neuropathy (9%), and febrile neutropenia (6%). The pCR rate was 18%. Higher pretreatment recurrence scores (>31) were associated with higher pCR rate ( $p=0.025$ ) in 38 patients with available data. Non-significant trends were observed for ER and PR by RT-PCR, but not for HER2. None of these measures were predictive of clinical tumor responses after 3 or 6 cycles of therapy, although assessment methods varied across timepoints.

**Conclusions:** Ixabepilone with cyclophosphamide as neoadjuvant therapy is feasible and active. Tumors with higher Oncotype DX recurrence scores at baseline were more likely to achieve pCR.