Phase II Feasibility Trial Incorporating Bevacizumab Into Dose Dense Doxorubicin and Cyclophosphamide Followed by Paclitaxel in Patients with Lymph Node Positive Breast Cancer

**Purpose of Study:**
1) To determine the incidence of clinically apparent cardiac dysfunction in patients with lymph node positive breast cancer treated with bevacizumab and dose dense doxorubicin/cyclophosphamide followed by paclitaxel (ddAC>T).

**Secondary Objectives:**
1) To evaluate changes in LVEF during treatment.
2) To evaluate non-cardiac toxicity.

**Study Chairs:** Edith A. Perez M.D.
Tom R. Fitch M.D.

**Statistician:**

**Nurse Resource:**

**Status:**
Activated 02/24/2006
Perm. Closed 11/06/2006

**Projected Number of Patients:** 20

**Excluded:** None

**Final Accrual:** 5

**Stratification Factors:** None

**Schema:** Register

Arm A: Doxorubicin/Cyclophosphamide/Bevacizumab followed by Paclitaxel/Bevacizumab followed by Bevacizumab
Arm B: Doxorubicin/Cyclophosphamide followed by Paclitaxel/Bevacizumab followed by Bevacizumab

**Treating Schedule:**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Agent</th>
<th>Dose</th>
<th>Route</th>
<th>Days</th>
<th>Freq</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Doxorubicin</td>
<td>60 mg/m2</td>
<td>IV push</td>
<td>1</td>
<td>Every 14 days (cycles 1-4)</td>
</tr>
<tr>
<td>1+</td>
<td>Cyclophosphamide</td>
<td>600 mg/m2</td>
<td>IV infusion</td>
<td>1</td>
<td>Every 14 days (cycle 5-8)</td>
</tr>
<tr>
<td>A</td>
<td>Bevacizumab</td>
<td>10 mg/kg</td>
<td>* IV infusion</td>
<td>1</td>
<td>Every 14 days (cycles 1-18)</td>
</tr>
<tr>
<td>A</td>
<td>Paclitaxel</td>
<td>175 mg/m2</td>
<td>IV infusion</td>
<td>1</td>
<td>Every 14 days (cycles 5-18)</td>
</tr>
<tr>
<td>B</td>
<td>Paclitaxel</td>
<td>175 mg/m2</td>
<td>IV infusion</td>
<td>1</td>
<td>Every 14 days (cycles 5-22)</td>
</tr>
</tbody>
</table>

* Bevacizumab given after AC Arm A only
+ Arms A and B
Accrual: NCCTG accrued 5 patients on this study. Accrual to Arm A was closed in July 2006 having met its accrual goal. Accrual to Arm B was closed in November 2006 having met its accrual goal.

Two abstracts have been published:
