Randomized comparison of neoadjuvant docetaxel (D), epirubicin (E) and pegfilgrastim (P) (+ trastuzumab [T] in HER2+ patients [pts]) with and without capecitabine (C) for operable breast cancer (BC): Results of a planned safety analysis of ABCSG24.

Sub-category: Adjuvant Therapy
Category: Breast Cancer - Local-Regional and Adjuvant Therapy
Meeting: 2007 ASCO Annual Meeting
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Abstract Disclosures

Abstract:

Background: ABCSG-24 is assessing the effect of adding C to DE and adding T to DE or DEC on pCR rate. Pts with operable BC (any T stage except T4d, N+/-, M0) scheduled for pre-operative chemotherapy: six 3-weekly cycles of D 75 mg/m², d1 + E 75 mg/m² d1 + P 6 mg d2, ± C 1,000 mg/m² bid d1-14. P

Methods: Pts with operable BC (any T stage except T4d, N+/-, M0) scheduled for pre-operative chemotherapy: six 3-weekly cycles of D 75 mg/m², d1 + E 75 mg/m² d1 + P 6 mg d2, ± C 1,000 mg/m² bid d1-14. P

Results: From Nov 04 to Nov 06, 262 pts were enrolled, including 29 HER2+ pts. 145 are evaluable (DE: 74 pts, 400 cycles; DEC: 74 pts, 344 cycles). The table shows grade 3/4 adverse events (AEs) in >2% of pts in either arm. Febrile neutropenia was absent. Serious AEs occurred in 22% vs 20% of pts in DE vs DEC, respectively. Fewer pts in the DE than the DEC arm required dose reduction (0.5% vs 6.6% of cycles), withdrew consent (4% vs 13%) or were withdrawn by the investigator (1% vs 17%). Reasons for withdrawal by investigator were: HFS, stomatitis, mucositis, diarrhea, vomiting, peripheral neuropathy, fatigue, asthenia, docetaxel hypersensitivity, and asymptomatic liver enzyme elevation. No serious toxicity has occurred with T. Conclusions: Despite infrequent grade 3/4 AEs in both arms, more pts withdrew consent or were withdrawn by the investigator in DEC than in DE, by either patient’s or investigator’s choice. Since May 06, no DEC pts have withdrawn consent, perhaps because of improved pt education and symptom management. This finding reinforces the need for close mor management of AEs. The addition of C to DE presents no safety concerns. Efficacy results are due

<table>
<thead>
<tr>
<th>Grade 3/4 Adverse Events in &gt;2% of Pts</th>
<th>DE (n=74)</th>
<th>DEC (n=71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>11%</td>
<td>10%</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>Condition</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>--------------------</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Nausea</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Hand-Foot Syndrome</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Pain</td>
<td>3%</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Associated Presentation(s):**

No items found.

**Other Abstracts in this Sub-Category:**

1. Tamoxifen, hot flashes, and breast cancer recurrence: Support for pharmacogenetics.
   
   Meeting: 2007 ASCO Annual Meeting  Abstract No: 500  First Author: J. Mortimer  
   Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

2. Tamoxifen-induced hot flashes are associated with estrogen receptor polymorphisms.
   
   Meeting: 2007 ASCO Annual Meeting  Abstract No: 501  First Author: V. Stearns  
   Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

3. Could treatment with tamoxifen be superior to aromatase inhibitors in early-stage breast cancer after pharmacogenomic testing? A modeling analysis.
   
   Meeting: 2007 ASCO Annual Meeting  Abstract No: 502  First Author: R. S. Punglia  
   Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

**Abstracts by G. G. Steger:**

   
   Meeting: 2011 Breast Cancer Symposium  Abstract No: 41  First Author: A. Berghoff  
   Category: Detection, Screening, and Imaging - Predictive and Prognostic Factors

2. Effect of change of body mass index (BMI) during therapy on the efficacy of endocrine therapy in premenopausal patients with breast cancer: An analysis of the ABCSG-12 trial.
   
   Meeting: 2011 ASCO Annual Meeting  Abstract No: 514  First Author: G. Pfeiler  
   Category: Breast Cancer - HER2/ER - ER+

3. Impact of HER2-targeted therapy on overall survival (OS) in patients (pts) with HER2-positive (HER2+) metastatic breast cancer (MBC).
   
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   Category: Breast Cancer - HER2/ER - HER2+

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   Meeting: 2010 ASCO Annual Meeting  
   Presenter: Guenther G. Steger  
   Session: Breast Cancer - Local-Regional and Adjuvant Therapy (Poster Discussion Session)

2. 6 vs. 3 Cycles of epirubicin/docetaxel + G-CSF in operable breast cancer: Results of ABCSG 14.

   Meeting: 2004 ASCO Annual Meeting  
   Presenter: Guenther G. Steger, MD  
   Session: Breast Cancer I (Poster Discussion Session)

3. Fulvestrant beyond the second hormonal treatment line in metastatic breast cancer

   Meeting: 2003 ASCO Annual Meeting  
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