BCIRG 006: Quality of life of patients treated with docetaxel and trastuzumab-based regimens in node positive and high risk node negative HER2 positive early breast cancer.

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Background

- BCIRG 006, a large international randomized controlled trial, randomized three different regimens to patients (pts) with node positive or high risk node negative HER2 positive early breast cancer.

Objective

A comparison of the health-related quality of life (QoL) of patients between 3 different treatment arms and a secondary objective of the 006 study. The QoL results are presented here.

Methods

• Primary endpoint compared to pts just starting their taxane on AC-TH, but negative HER2-positive early breast cancer.

- Study Population

  - BCIRG 006, a large international randomized controlled trial, randomized three different regimens to patients (pts) with node positive or high risk node negative HER2 positive early breast cancer.
  - N=3,222 (Central FISH)
  - HER2+ risk N-
  - HER2- risk N-

- Global quality of life (Global)

- Four symptom scales (systemic therapy side effects [SE], breast pain, dyspnea, sleep, appetite loss, constipation, diarrhea, and financial impact)

- Nine symptom scales and items (fatigue, nausea / vomiting, anxiety, coughing, depression, physical functioning, role functioning, cognitive functioning, and social functioning)

- Five functional domains (physical [PF], role, cognitive, emotional, and social)

- Four symptom scales (systemic therapy side effects [SE], breast pain, dyspnea, sleep, appetite loss, constipation, diarrhea, and financial impact)

- Nine symptom scales and items (fatigue, nausea / vomiting, anxiety, coughing, depression, physical functioning, role functioning, cognitive functioning, and social functioning)

- Analysis

  - Questionnaires were completed at baseline, on and after chemotherapy at:
    - Cycle 4 (Mid), 18 weeks (Cycle 7/end of chemotherapy)
  - Changes from baseline to mid, EOC, and 12 months using a two-way ANOVA

- Study sponsored by Sanofi-Aventis with support from Genentech

Results

Table 1: Questionnaire Compliance

<table>
<thead>
<tr>
<th></th>
<th>Mobile</th>
<th>Semi</th>
<th>No</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>AC</td>
<td>76.3</td>
<td>62.9</td>
<td>80</td>
<td>67.0</td>
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<tr>
<td>TCH</td>
<td>87.2</td>
<td>84.3</td>
<td>85</td>
<td>85.2</td>
</tr>
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</table>

- All arms and more favorable in TCH than AC-TH

Results

- Primary endpoint compared to pts just starting their taxane on AC-TH, but negative HER2-positive early breast cancer.

Discussion & Conclusions

- QoL, symptoms and treatment scores were comparable across a balanced group of patients
- No future perspective mean change scores were affected or worsened to improve throughout treatment
- Systemic Therapy Side Effects change scores were significantly better for TCH at the EOC, supporting the response analysis, suggesting that this regimen is better tolerated.
- There was no significant effect on survival for any of the treatment arms
- OS arm had no survival benefit in PF, Global, and SB QoL scales by year.

References