



Lapatinib + Capecitabine vs. Capecitabine alone for ErbB2+ Metastatic Breast Cancer: Quality-of-Life Assessment

Xiaolei Zhou¹, Anthony Segreti¹, David Cella², David Cameron³, Charles Geyer⁴, Mayur Amonkar⁵, Steven Stein⁵, Mel Walker⁶

¹RTI Health Solutions, Research Triangle Park, NC, United States
²CORE, Evanston Northwestern Healthcare, Evanston, IL, United States
³Western General Hospital, Edinburgh, United Kingdom
⁴Allegheny General Hospital, Pittsburgh, PA, United States
⁵GlaxoSmithKline, Collegeville, PA, United States
⁶GlaxoSmithKline, London, United Kingdom

Presented April 18, 2008
6th European Breast Cancer Conference (EBCC-6) Berlin, Germany

X. Zhou

Lapatinib + Capecitabine vs. Capecitabine alone for ErbB2+ MBC: QOL Assessment

- A Phase 3, randomised, open-label, multicenter study
- Women with ErbB2 + and refractory metastatic breast cancer who had received prior therapy, including anthracyclines, a taxane, and trastuzumab.

- **Study treatments:**

L+C Arm

Lapatinib: 1250 mg/day, daily, continuously
Capecitabine: 2000 mg/m²/day, days 1-14, every 21 days

C Arm

Capecitabine: 2500 mg/m²/day, days 1-14, every 21 days

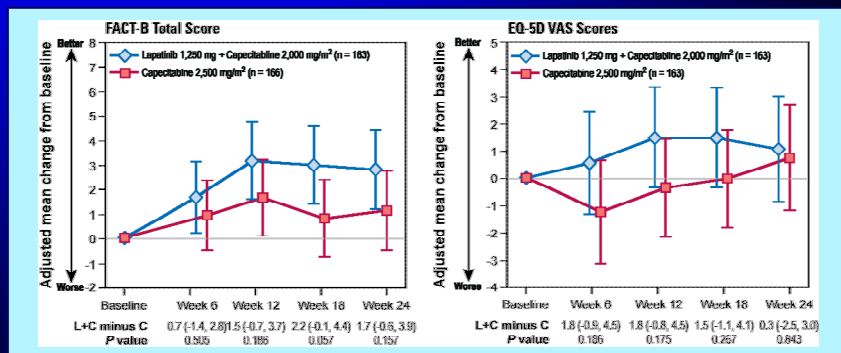
- **Outcomes:** FACT-B total, FACT-G, TOI, EQ-5D utility, and EQ-5D VAS scores measured at the screening visit (baseline), every 6 weeks for the first 24 weeks, every 12 weeks thereafter, and at study withdrawal.

X. Zhou



Adjusted* Changes from Baseline for FACT-B Total Score and EQ-5D VAS Score

- Group differences in adjusted mean change from baseline were consistently in favor of the L+C arm and ranged from 0.7 to 2.2 (FACT-B), 0.9 to 1.5 (FACT-G), 0.2 to 1.5 (TOI), 0.00 to 0.03 (EQ-5D utility), and 0.3 to 1.8 (EQ-5D VAS) over a 24-week follow-up, although not statistically significant ($P > 0.05$).



* Adjusted for baseline score using ANCOVA. The Bars indicate ± 1.96 standard errors. Missing post-baseline data were imputed using LOCF method.

X. Zhou



Conclusions

- Overall, subjects' QOL was improved after treatment with both the L+C combination arm and the C monotherapy arm. Point estimates for all QOL scores were generally higher for the L+C arm versus the C arm.
- The two treatment groups appear to be similar in QOL scores over a 24-week follow-up, suggesting that there was no detriment to QOL in patients receiving combination therapy (L+C) compared with those receiving monotherapy (C) in this heavily pretreated patient population.
- The addition of lapatinib to capecitabine significantly prolonged time to progression without any loss of quality of life, providing overall clinical benefit to the patients

X. Zhou

