Abstract

BCIRG 007: First overall survival analysis of randomized phase III trial of trastuzumab plus docetaxel with or without carboplatin as first line therapy in HER2 amplified metastatic breast cancer (MBC)

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LBA1008

Background: Based on preclinical synergism between docetaxel (T), carboplatin (C) and trastuzumab (H), BCIRG conducted a phase III trial in HER2-positive MBC to evaluate efficacy and safety of H in combination with T or TC. **Methods:** 263 patients (pts) with HER2 FISH+ MBC were randomized to TH (H with T 100mg/m^2) or TCH (H with T 75mg/m^2 and C AUC=6). Chemotherapy was given every 3 weeks (q3w) for 8 cycles with weekly H at 2mg/kg (loading dose of 4 mg/kg) followed by H q3w at 6 mg/kg until progression. Pts were stratified by centre and prior (neo) adjuvant taxane chemotherapy. Primary endpoint was Time To disease Progression (TTP). Secondary endpoints include overall survival, response rate, duration of response (DR), clinical benefit (CB) and safety. **Results:** 131 pts were treated in each arm Pt characteristics were well balanced in both groups. A first efficacy analysis was conducted at 204 events. There was no significant difference between TH and TCH in median TTP (11.1 vs 10.4 mos, p=0.57), ORR (73% in both arms), DR (10.7 vs 9.4 mos) and CB (67% in both arms). At 39 months of median follow-up, median overall survival was 36.40 and 36.57 months in TH and TCH arms respectively. More patients on TCH received the max number of chemotherapy cycles, and numerically fewer patients on TCH discontinued treatment as a result of non hematological toxicity. The most common gr 3/4 toxicities were: Neutropenic infection that was 16.8% vs 9.2% respectively for TH and TCH, thrombocytopenia (2% vs 15%), asthenia (5% vs 12%), anemia (5% vs 11%), and diarrhea (2% vs 10%). Two pts died (1.5%) due to sepsis in TCH. Absolute LVEF decline > 15 % were seen in 5.5 % vs 6.7 % of pts. One pt (0.8%) had a symptomatic CHF in TH arm. **Conclusion:** Both TH (T 100) and TCH (T 75) were highly effective treatment regimens in women having HER2-positive MBC, demonstrating high response rates, median TTP > 10 months, and median overall survival > 36 months in both TH and TCH. Cardiac toxicity was no significant problem with either treatment.