Abstract # 804
PD09–03
Impact of BRCA1/2 mutation status in TBCRC009: A multicenter phase II study
of cisplatin or carboplatin for metastatic triple negative breast cancer

1. Background
Triple-negative breast cancer (TNBC) accounts for 15% of all breast cancers and has a poor prognosis. 
TNBC, which describes tumors that are negative for estrogen receptor and/or progesterone receptor or HER2 overexpression or amplification. No specific therapeutic targets have been validated for TNBC.
The majority of BRCA-associated breast cancer is triple-negative, suggesting TNBC and BRCA1/2-associated breast cancer may share biologic features.

2. Methods (1)

2.1. Study Design
TBCRC09 was a single arm, multi-center phase II study to evaluate cisplatin or carboplatin chemotherapy for metastatic TNBC. The study enrolled patients from May 2010 to June 2012. Activity was halted on June 10, 2012, at which time active patients were censored. The primary endpoint was the Overall Response Rate (ORR) defined as the proportion of patients achieving a partial response (PR) or complete response (CR). We recently reported a 30.2% ORR of 30.2% in this study.

2.2. Population
BRCA1/2 mutation testing was performed on 86 patients. 10 patients were not tested due to failed reactions or missing blood samples. 11 (14.5%) BRCA1/2 mutation carriers and 76 (85.5%) BRCA1/2-WT was identified in this cohort of 86 patients. 7% of patients were long term survivors with durable responses but this did not correlate with improved Progression Free Survival (PFS) in BRCA1/2 carriers compared to BRCA1/2-WT patients. There was no evidence of improved Progression Free Survival in BRCA1/2 carriers, but the study was underpowered for this analysis.

2.3. Secondary Objectives

3. Methods (2)

3.1. Study Design

3.2. Population

4. Results – Patient Characteristics

4.1. Number of patients
86

4.2. Enrollment Period
6/07/10 - 10/15/10

4.3. Baseline characteristics

5. Results - Response Data

5.1. Primary Response Rate

5.2. Secondary and Exploratory Endpoints

6. Results – Progression Free Survival

6.1. Kaplan-Meier analysis shows survival in BRCA1/2 carriers vs non-Carriers

7. Results – BRCA1/2 Carrier Characteristics

8. Results – Long Term Survivors

9. Summary and Discussion

Acknowledgements

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