**INTRODUCTION**

Triplet-negative metastatic breast cancer (mTNBC) has a poor prognosis and an aggressive clinical course. nab-Paclitaxel (nab-P) is a novel formulation of nab-Paclitaxel (nab-P) and carboplatin (nab-P/C) is a standard chemotherapy regimen for patients with mTNBC. This study aims to evaluate the efficacy and safety of nab-P/C in a phase II/III study designed to evaluate the efficacy and safety of nab-P/C in the treatment of patients with mTNBC who are refractory to nab-P/G or G/C as first-line treatment of patients with mTNBC. This study is supported by Celgene Corporation, Summit, NJ. The authors received editorial and production support in the preparation of this poster from MediTech disclosure; H.A.: nothing to disclose; J.E.: nothing to disclose; A.S.: nothing to disclose; L.D.L.C.M.: nothing to disclose; S.W.: speakers bureau and honoraria, Genentech.

**METHODS**

An algorithm ranking 5 key efficacy and safety endpoint parameters was used to identify the "best" nab-P/C experimental arm based on the relative risk (RR) of PFS (nab-P/G/C vs nab-P/C) for each endpoint: PFS, ORR, OS, safety vs placebo. RANKING ALGORITHM: The most common AEs leading to discontinuation of any study drug included neutropenia, or red blood cell/platelet transfusion.

**RESULTS**

**TREATMENT EXPOSURE AND SAFETY (TABLES 3, 4; FIGURE 4)**

In the treatment exposure, neutropenia was the most common AE leading to dose reduction (RR 0.54). The combination of nab-P/G demonstrated a significantly longer PFS and a better risk-benefit profile than nab-P/C in this phase II/III study designed to evaluate the efficacy and safety of nab-P/C in the treatment of patients with mTNBC who are refractory to nab-P/G or G/C as first-line treatment of patients with mTNBC.

**DISCLOSURES**

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**CONCLUSIONS**

- nab-P/C demonstrated a significantly longer PFS and a better risk-benefit profile than nab-P/G as first-line treatment of patients with mTNBC.
- Treatment duration and exposure were greater with nab-P/G than with nab-P/C or G/C in this phase II/III study designed to evaluate the efficacy and safety of nab-P/C in the treatment of patients with mTNBC.
- Due to the overlapping landscape involving ongoing phase III trials with immunotherapy and other novel agents, this trial is not progressing to phase II. However, nab-P/ was being used as a backbone chemotherapy with novel agents in both nab-P/C and the combination setting (NCCTG N0539, NCT01302039, NCT01302039).