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Health-related quality of life (HRQoL) changes with veliparib in patients (pts) with metastatic or locally advanced breast cancer in the phase III BROCADE 3 study

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Background

Veliparib, a poly (ADP-ribose) polymerase 1/2 inhibitor, was evaluated in the phase III BROCADE 3 study (NCT02163694) for efficacy and safety in combination with paclitaxel/carboplatin (VPC) in pts with HER2-negative metastatic or locally advanced unresectable gBRCA-associated breast cancer, in which VPC significantly prolonged progression-free survival (hazard ratio=0.71 [95% CI 0.57, 0.88], *P*=.002) compared with placebo plus paclitaxel/carboplatin (PPC) (Dieras VC et al. *Ann Oncol*. 2019:30[suppl 5]:LBA9). In this analysis we investigated the impact of veliparib on HRQoL.

Methods

This double-blind study examined the effect of veliparib (120 mg oral twice daily for 7 days out of each 21-day cycle) added to paclitaxel/carboplatin vs. PPC. HRQoL measures were EORTC-QLQ -C30 and breast cancer (BR23), EQ-5D-5L, and Brief Pain Inventory-Short Form (BPI-SF). Responses were obtained on Day 2 Cycle 1, Day 1 Cycle 2, and every other cycle thereafter starting from Cycle 4 plus final and follow-up visit. Data were analyzed only through Day 1 Cycle 30 due to attrition. For each HRQoL domain, mean change in baseline scores, % responders (improved, stable, declined), and median time to symptom worsening were analyzed across study arms.

Results

504 pts (VPC 334, PPC 170) were included in the analysis. Improvement from baseline in function, disease and treatment symptom burden, and health state was observed for both study arms, with greater benefits for VPC vs. PPC for pain, pain interference, and breast symptoms. Greater proportion of PPC vs. VPC pts declined in global health status, pain, arm symptoms, breast symptoms and pain interference, but here differences were not significant. Median time (months) to symptom worsening was significantly longer *(P*<0.05) for VPC vs. PPC pts for role functioning (8.2 vs. 6.5), physical functioning (8.8 vs. 7.1), constipation (7.7 vs. 6.2), and future perspectives (10.2 vs. 9.0).

Conclusions

Overall, addition of veliparib to paclitaxel/carboplatin has no detrimental effect on quality of life in pts with gBRCA mutation-associated advanced breast cancer and may be beneficial in some areas of functioning and symptom experience.

Clinical trial identification

NCT02163694.

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Legal entity responsible for the study

AbbVie Inc.

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