breast cancer, metastatic

HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND DISEASE SYMPTOMS IN PATIENTS (PTS) WITH LOWLY ADVANCED OR METASTATIC BREAST CANCER (MBC) TREATED WITH ERIBULIN (ERI) OR CAPECITABINE (CAP) IN A POST ANTHRACYCLINE AND TAXANE SETTING

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Aim: In a phase 3, open-label, randomized study, ERI demonstrated numerically longer survival compared with CAP (median overall survival: 15.9 vs 14.5 months; hazard ratio [HR] 0.88; p = 0.056) in 1102 MBC pts previously treated with anthracyclines and taxanes. To assess the impact of ERI and CAP on pts, we conducted post hoc analyses of HRQOL.

Methods: HRQOL was assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire 30 (EORTC QLQ-C30) at baseline, 6 weeks and 3, 6, 12, 18 and 24 months (or disease progression/treatment change), and at unscheduled visits. Between-treatment differences in change from baseline were assessed by linear-mixed and pattern-mixture models with covariates. The proportion of pts with improvement or deterioration equal to or greater than the minimally important difference (MID) was assessed by Chi-squared or Fisher’s exact test and established MID thresholds. Time to symptom worsening was defined as time to a clinically meaningful deterioration.

Results: HRQOL scores were similar for ERI and CAP pts for global health status, physical, emotional, cognitive and social functioning, and fatigue, pain, dyspnea and constipation. In all, 74–96% of pts maintained or improved their global health status throughout the study, with no significant differences between groups. HRQOL scores were significantly different, in favor of ERI, for nausea/vomiting and diarrhea (both p ≤ 0.001); a significantly greater proportion of CAP than ERI pts had clinically meaningful worsening of nausea/vomiting (HR = 1.177, p = 0.033) and diarrhea (HR = 1.189, p = 0.027). Time to symptom worsening was significantly longer with ERI than CAP for nausea/vomiting (10.2 vs 7.6 months; p = 0.024) and diarrhea (11.5 vs 8.4 months; p = 0.014). The QLQ-C30 revealed no consistent HRQOL benefits for CAP vs ERI.

Conclusions: ERI and CAP provide clinical benefits without adversely impacting HRQOL (assessed by EORTC QLQ-C30) in MBC pts previously treated with anthracyclines and taxanes; ERI has a more favorable gastro-intestinal adverse event profile.

Disclosure: G. Velikova: has acted as a consultant to Eisai in 2013 advising them on the methodology for QoL analysis. She has prepared and presented one training session in 2013, and was paid for consultancy time and the travel from Leeds, UK to Chicago, IL, USA; S. Hudgens: Clinical Outcomes Solutions conducted the Eisai sponsored quality of life post hoc analysis through funding by Eisai; A. Forsythe: is an employee of Eisai Inc.; S. McCutcheon: is an employee of Eisai Inc.; J. Cortes: has disclosed a consultant or advisory relationship with Novartis, Celgene and Roche for which he has been compensated. He has also received honoraria from Novartis, Celgene, Roche and Eisai.