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METASTATIC BREAST CANCER

LBA2 Everolimus plus aromatase inhibitors vs aromatase inhibitors as maintenance therapy after first-line chemotherapy in HR+/HER2- metastatic breast cancer: Final results of the phase III randomized MAIN-A trial

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Background: Hormonal therapy is the mainstay of treatment for HR+/HER2- metastatic breast cancer (MBC). However, patients (pts) presenting with aggressive disease are generally offered first-line chemotherapy (CT), followed by maintenance hormonal therapy. This study is aimed to evaluate whether maintenance everolimus (EVE) combined with aromatase inhibitors (AI) can prolong progression free survival (PFS) over AI alone in pts with disease control after first-line CT.

Methods: The Main-A trial is an investigator driven, randomized Phase III study. Postmenopausal pts achieving disease control (stable disease, partial response or complete response) after first-line CT were randomly assigned to EVE 10 mg po daily plus AI or to AI alone. Primary aim is PFS. We estimated a sample size of 54 pts per arm to detect an improvement from 6 to 11 months in the median PFS (Hazard Ratio 0.55).

Results: 110 pts were randomized to EVE+AI (n = 52) or to AI (n = 58). Median age was 58 yrs. Fifty% of the pts had liver metastases. Median interval from the time of primary diagnosis to first metastasis was 11.2 mos (9.1 mos in the EVE+AI arm and 16.0 months in the AI arm). A total of 88 PFS events were recorded, 40 in the EVE+AI arm and 48 in the AI arm. Median PFS was 9.9 mos (95%CI: 7.4-13.8) in the EVE+AI arm vs 7.2 mos (95%CI: 4.7-10.9) in the AI arm (HR 0.764, 95%CI: 0.501-1.164). EVE dose reductions were reported for 28 pts. Treatment related adverse events (AEs) were reported for 45 (87%) pts in the EVE+AI arm and for 15 (26%) pts in the AI arm. In the EVE-AI arm, 16 pts discontinued EVE because of AEs or non-compliance. In the AI arm one pts only discontinued therapy because of AE. Most common G>/=2 AEs in the EVE-AI arm were stomatitis (19.2%), neutropenia (9.6%), interstitial pneumonia (7.7%) and skin toxicity (7.7%).

Conclusions: At our knowledge, this is the first randomized trial of maintenance endocrine therapy after CT for HR+/HER2- MBC. In these high risk MBC pts deemed suitable for first-line CT, maintenance therapy with AI resulted in a median PFS of 7.2 mos only. Adding EVE resulted in a 2.7 mos non significant PFS prolongation. No new safety signals emerged from this study.

Clinical trial identification: EudraCT: 2013-004153-24.

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