Characterization of Response to Everolimus in BOLERO-2: A Phase III Trial of Everolimus Plus Exemestane in Postmenopausal Women With HR⁺, HER2⁻ Advanced Breast Cancer

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INTRODUCTION

- Study Design and Participants
- Secondary: Postmenopausal women with HER2⁻ advanced breast cancer who had received one or two prior endocrine therapies. Patients were randomized 1:1 to treatment with everolimus (EVE) plus exemestane (EXE) or placebo (PBO) plus EXE. Randomization was stratified according to the presence of visceral disease at baseline.

METHODS

- Primary Endpoint: Progression-free survival (PFS) in the intent-to-treat (ITT) population.
- Secondary Endpoints: Overall response rate (ORR), clinical benefit rate (CBR), duration of response (DoR), and safety.

RESULTS

- At the 18-month median follow-up, the ORR by local tumor assessment was significantly higher in the EVE + EXE group versus the PBO + EXE group (12.6% [n=61] vs 1.7% [n=4], respectively; p < 0.0001). The CBR was also significantly higher in the EVE + EXE group (50% [95% confidence interval 34% - 63%]) compared with the PBO + EXE group (20% [95% confidence interval 11% - 31%], p < 0.0001).

CONCLUSIONS

- The combination of EVE + EXE significantly improved the ORR versus PBO + EXE in patients with HR⁺, HER2⁻ advanced breast cancer.

Abbreviations: BC, breast cancer; CBR, clinical benefit rate; ER, estrogen receptor; ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; ITT, intent-to-treat; PBO, placebo; PFS, progression-free survival; PK, pharmacokinetics; QOL, quality of life; R, randomization; SD, stable disease; TNM, tumor-nodemetastasis; WHO, World Health Organization; WSS, worst score summary.