

**1530** Response rate by geographic region in patients with hormone receptor-positive, human epidermal growth factor receptor-2–negative advanced breast cancer from the SOLAR-1 trial

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**Background:** In patients (pts) with hormone receptor-positive (HR+), human epidermal growth factor receptor-2–negative (HER2–) advanced breast cancer (ABC), approximately 40% have tumors that exhibit PIK3CA mutations, resulting in

phosphatidylinositol 3-kinase (PI3K) pathway hyperactivation. Use of the oral  $\alpha$ -specific PI3K inhibitor alpelisib (ALP) + fulvestrant (FUL) significantly improved progression-free survival (PFS) in pts with ABC and a PIK3CA mutation (hazard ratio [HR]=0.65;  $P < 0.01$ ) in SOLAR-1, a phase 3, randomized, double-blind study in men and postmenopausal women with HR+, HER2-ABC that progressed on or after aromatase inhibitor treatment. Here we report results by major region from SOLAR-1.

**Methods:** Pts ( $N = 572$ ) received ALP 300 mg once daily (or placebo [PBO]) + FUL 500 mg every 28 days + Cycle 1, Day 15. Median PFS (mPFS) was estimated by Kaplan Meier in pts with a PIK3CA mutation ( $n = 341$ ). Data for Japan will be presented separately and were excluded.

**Results:** For the PIK3CA-mutant (mut) cohort, pts were enrolled in Europe (EU;  $n = 173$ ), North America (NA;  $n = 43$ ), Asia ( $n = 34$ ), and Latin America (LA;  $n = 31$ ). Pts in the ALP arm (vs PBO) in EU had mPFS of 11.0 mo (vs 3.6 mo; HR = 0.56; 95% CI 0.39-0.81) and overall response rate (ORR) of 27.9% (vs 11.5%); in NA, mPFS was 15.2 mo (vs 3.6 mo; HR = 0.41; 95% CI 0.19-0.91), ORR 21.1% (vs 16.7%); in Asia, mPFS was 14.5 mo (vs 9.0 mo; HR = 0.55; 95% CI 0.20-1.51), ORR 46.7% (vs 10.5%); and in LA, mPFS was 9.4 mo (vs 12.9 mo; HR = 1.43; 95% CI 0.54-3.79), ORR 21.4% (vs 17.6%). Among all pts (mut and non-mut) in the ALP arm, median ALP exposure in EU, NA, Asia, LA, and overall was 5.5, 5.5, 7.6, 6.0, and 5.5 mo, respectively. Median average daily dose for ALP was 283.3, 294.0, 298.1, 260.2, and 286.1 mg/d. Most common all-grade AEs were hyperglycemia in EU, Asia, LA (63%, 75%, 65%) and nausea in NA (66%); followed by diarrhea in EU, NA, LA (61%, 66%, 53%) and decreased appetite (58%) in Asia.

**Conclusions:** Consistent with the overall SOLAR-1 population of the PIK3CA-mut cohort, PFS was generally improved across regions in the ALP vs PBO arm; however, low PFS events and pt numbers in some regions may limit conclusions.

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