Real-World Effectiveness of Alpelisib + Fulvestrant Compared With Standard Treatment Among Patients With Hormone-Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative, PIK3CA-Mutated Advanced Breast Cancer in the Post-CDK4/6 Inhibitor Setting

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Background
• In the BYLieve trial, alpelisib + fulvestrant (n=9) compared to 1.8 (95% CI, 1.68-3.58) months with placebo + fulvestrant (n=11; hazard ratio 1.58, 95% CI 0.76-3.32, p=0.228) for progression-free survival (PFS), with an estimated median PFS of 6.0 months (95% CI 1.3-11.5) with alpelisib + fulvestrant and 2.5 months (95% CI 1.7-4.3) with placebo + fulvestrant. PFS was improved in a small subgroup of patients who received prior CDK4/6i's.

Objective
• To perform a retrospective evaluation of alpelisib + fulvestrant compared with placebo + fulvestrant in patients with HR+/HER2- breast cancer with PIK3CA-mutation who progressed on or after CDK4/6i-based therapy.

Methods
• Two Real-World Cohorts: CGDB (Novartis), Flatiron Health (Merck, Pfizer, AstraZeneca, etc.). CGDB was curated by abstractors from electronic health records (EHR). Flatiron included patients having a structured activity within 90 days of index date at or before 90 days of index date, and those in BYLieve.

Results
• Patients ≥18 years of age at index date, had at least 1 next-generation sequencing test conducted. Inclusion criteria for the CGDB required patients to have at least 2 documented clinical visits in the Flatiron Health network on or after 11 January 2011 and a setting prior to index date including CDK4/6i-mutated disease previously treated with a selective PI3K inhibitor, in combination with fulvestrant.

Conclusions
• The secondary objective was to evaluate the rate of patients who remained progression-free at 6 months with alpelisib + fulvestrant in the real-world cohort was estimated to be 42.2% (95% CI 34.1-50.2) compared with 17.1% (95% CI 11.5-24.9) with placebo + fulvestrant. Differences exist in the assessment of progression data, with local assessment via RECIST for the BYLieve trial and Surveillance for the CGDB.

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Disclosures
• All authors declare no conflicts of interest.

References