INTRODUCTION

There is no consensus on next-line treatment for patients with HR+, HER2– breast cancer (BC) after progression on aromatase inhibitors (AI) or fulvestrant. Alpelisib is a PI3K inhibitor targeting the PIK3CA mutation in tumor tissue with a demonstrated activity in PIK3CA-mutated BC.

METHODS

In this PFS analysis of the BYLieve study, patients (pts) with HR+, HER2– BC with ≥1 prior line of hormonal therapy (n=126) were randomized 1:1 to receive alpelisib 300 mg QD + endocrine therapy (ET) (fulvestrant or letrozole) or ET alone.

RESULTS

In summary, alpelisib + ET (fulvestrant or letrozole) may be considered for patients with HR+, HER2– BC progressing on AI or fulvestrant. Median PFS was 10.3 months (95% CI 7.3-12.9 mo) in Cohort A and 5.7 months (95% CI 4.5-7.2 mo) in Cohort B. Median OS was 56.6 months (95% CI 47.0-67.1 mo) in Cohort A and 42.4 months (95% CI 36.5-58.3 mo) in Cohort B. No new safety signals were identified.

CONCLUSIONS

Alpelisib + ET (fulvestrant or letrozole) may be considered for patients with HR+, HER2– BC progressing on AI or fulvestrant. Median PFS was 10.3 months (95% CI 7.3-12.9 mo) in Cohort A and 5.7 months (95% CI 4.5-7.2 mo) in Cohort B. Median OS was 56.6 months (95% CI 47.0-67.1 mo) in Cohort A and 42.4 months (95% CI 36.5-58.3 mo) in Cohort B. No new safety signals were identified.

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