

Drug combo slows progression in advanced breast cancer

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(HealthDay)—Treatment with a combination of alpelisib and fulvestrant

prolongs progression-free survival among patients with *PIK3CA*-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, according to a phase 3 study recently published in the *New England Journal of Medicine*.

Fabrice André, M.D., from the Institut Gustave Roussy in Paris, and colleagues randomly assigned patients with HR-positive, HER2-negative advanced breast [cancer](#) who had previously received endocrine therapy to either alpelisib (300 mg per day) plus fulvestrant (500 mg every 28 days and once on day 15) or placebo plus fulvestrant. In total, 572 patients were randomly assigned, including 341 patients with confirmed tumor-tissue *PIK3CA* mutations.

The researchers found that among patients with *PIK3CA*-mutated cancer, [progression-free survival](#) at a median follow-up of 20 months was 11.0 months in the alpelisib-fulvestrant group versus 5.7 months in the placebo-fulvestrant group (hazard ratio for progression or death, 0.65; 95 percent confidence interval, 0.50 to 0.85; P *PIK3CA*-mutated cancer, the hazard ratio was 0.85 (95 percent confidence interval, 0.58 to 1.25). Yet for all patients without *PIK3CA*-mutated cancer, the overall response was greater with alpelisib-fulvestrant than with placebo-fulvestrant (26.6 versus 12.8 percent). The most frequent adverse events of grade 3 or 4 were hyperglycemia (36.6 percent in the alpelisib-fulvestrant group versus 0.7 percent in the placebo-fulvestrant group) and rash (9.9 versus 0.3 percent). In the alpelisib-fulvestrant group, diarrhea of grade 3 occurred in 6.7 percent of patients versus 0.3 percent in the placebo-fulvestrant group. One-quarter of patients discontinued alpelisib due to adverse events versus 4.2 percent in the placebo-fulvestrant group.

"These results show improvements in patients' outcomes with the addition of an α -specific PI3K inhibitor to [standard treatment](#) for *PIK3CA*-mutated, HR-positive, HER2-negative advanced breast cancer,

findings that validate *PIK3CA* as an important treatment target in this population," the authors write.

Several authors disclosed financial ties to [pharmaceutical companies](#), including Novartis, which manufactures alpelisib and funded the study.

More information: [Abstract/Full Text \(subscription or payment may be required\)](#)

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