

**Tumor Board Tuesday – Dr. Maryam Lustberg & Dr. Jasmine S. Sukumar, 09/20/22:  
PIK3CA - Metastatic (Stage 4) Breast Cancer**

**Posttest Rationale**

**1. What would be your next step if a PIK3CA mutation wasn't detected in plasma?**

- a. Start Alpelisib + fulvestrant
- b. Retest the patient using tumor tissue
- c. Retest the patient using plasma
- d. Start an aromatase inhibitor

**Rationale:** If a patient is being tested for a PIK3CA mutation and the mutation isn't detected in plasma, a patient should be retested using tumor tissue.

**Reference:** PIK3CA Mutation Testing in HR+/HER2- mBC | HCP. [www.hcp.novartis.com](http://www.hcp.novartis.com). Accessed August 9, 2022. <https://www.hcp.novartis.com/products/piqray/metastatic-breast-cancer/test-for-pik3ca-mutations/pik3ca-mutation-testing/>

**2. What therapy would you recommend for a male patient who has Stage 4 (M1) breast cancer disease with tumor HR+/HER2- that has a PIK3CA mutation. Patient has previously tried an aromatase inhibitor + a GnRH analog?**

- a. Alpelisib + fulvestrant
- b. Olaparib
- c. Talazoparib
- d. Fulvestrant

**Rationale:** According to NCCN guidelines, Alpelisib + fulvestrant is recommended for metastatic breast cancer with tumor HR+/HER2- that has a PIK3CA mutation. Olaparib and Talazoparib is recommended for any breast cancer subtype with a BRCA1 or BRCA2 mutation.

In SOLAR-1 clinical trial, patients with PIK3CA mutation were randomized to Alpelisib + fulvestrant or Placebo + fulvestrant. In the cohort of patients with PIK3CA-mutated cancer, progression-free survival at a median follow-up of 20 months was 11.0 months (95% confidence interval [CI], 7.5 to 14.5) in the alpelisib–fulvestrant group, as compared with 5.7 months (95% CI, 3.7 to 7.4) in the placebo–fulvestrant group (hazard ratio for progression or death, 0.65; 95% CI, 0.50 to 0.85;  $P < 0.001$ ). Overall response among all the patients in the cohort with PIK3CA-mutated cancer was greater with alpelisib–fulvestrant than with placebo–fulvestrant (26.6% vs. 12.8%).

**References:** National Comprehensive Cancer Network. Breast Cancer (Version 4.2022). [http://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Accessed August 9, 2022.

André, F., et al. (2019). "Alpelisib for PIK3CA-Mutated, Hormone Receptor–Positive Advanced Breast Cancer." *New England Journal of Medicine* 380(20): 1929-1940.