BRACAnalysis CDx approved as Talzena companion dx

Oct. 22, 2018—Myriad Genetics announced that the FDA has approved its BRACAnalysis CDx to identify patients with HER2-negative metastatic breast cancer who have a germline BRCA mutation and are eligible for treatment with Pfizer's PARP inhibitor, Talzena (talazoparib). Talzena is indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated HER2-negative locally advanced or metastatic breast cancer.

"We congratulate Pfizer on obtaining FDA approval of Talzena for certain patients living with metastatic breast cancer, and we are excited to expand the use of BRACAnalysis CDx as the companion diagnostic test," Lloyd Sanders, president, Myriad Oncology, said in a press release. "We estimate there are more than 60,000 patients diagnosed with or who progress to metastatic breast cancer in the United States every year who qualify for a BRACAnalysis CDx test."

The FDA approvals are based on results from the EMBRACA trial, which evaluated Talzena versus physician's choice of chemotherapy in patients with germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer.