FDA approves Myriad MyChoice CDx

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January 2020—The FDA has approved Myriad Genetics' MyChoice CDx for use as a companion diagnostic to identify women with advanced ovarian cancer who are candidates for Zejula (niraparib) in the late-line treatment setting. The FDA also approved the expanded use of Zejula (GlaxoSmithKline) for the treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer patients who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency.

MyChoice CDx determines homologous recombination deficiency status by detecting *BRCA1* and *BRCA2* (sequencing and large rearrangement) variants with comprehensive assessment of genomic instability using three biomarkers—loss of heterozygosity, telomeric allelic imbalance, and large-scale state transitions.

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