myChoice HRD increases eligible patients, 8/16

August 2016—Myriad Genetics announced that its myChoice HRD test successfully identified an increased number of patients with ovarian cancer who may benefit from treatment with niraparib, an investigational oral PARP inhibitor being developed by Tesaro. The announcement follows results of the NOVA study, which evaluated the safety and efficacy of niraparib as a maintenance therapy in more than 500 patients with recurrent ovarian cancer. The primary outcome was the prolongation of progression-free survival. Patients were divided into two groups: those with a germline BRCA mutation and those without. Patients without a germline BRCA mutation were evaluated for homologous recombination deficiency using Myriad's myChoice HRD test. Patients in both groups were randomized to receive niraparib or placebo.

The study demonstrated that the myChoice HRD test approximately doubled the number of patients who may benefit from niraparib treatment than identified by the BRACAnalysis CDx test. Patients who were germline BRCA negative but myChoice HRD positive experienced a more than threefold increase in median PFS with niraparib compared with placebo.

In a separate release, Myriad announced that two analyses demonstrating the utility of the myRisk Hereditary Cancer test were presented at the American Society of Clinical Oncology annual meeting in June.

One study evaluated the magnitude of invasive breast cancer risk associated with mutations across a 25-gene panel test. A total of 95,561 patients underwent clinical testing with the myRisk Hereditary Cancer test. Seven percent of patients tested positive for a deleterious mutation. Forty-four percent of mutations occurred in BRCA1/2 genes or other genes associated with breast cancer risk (40 percent). There was a significant association with personal breast cancer history and mutations in BRCA1/2, PTEN, TP53, PALB2, CHEK2, BARD1, and ATM.

The other study evaluated the magnitude of ovarian cancer risk with mutations across the 25 genes in the myRisk panel. Data from 95,561 patients were analyzed to examine the association between deleterious mutations and personal history of ovarian cancer. The results showed that seven percent of patients tested positive for a deleterious mutation. Among 5,020 women affected by ovarian cancer, 14 percent had a deleterious mutation. Eleven genes were associated with a significant risk, including the first report of ovarian cancer risk associated with the ATM gene. One-third of mutations in patients were in non-BRCA and non-Lynch genes, demonstrating that panel testing with the myRisk test identified a broader spectrum of associated cancers.

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