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Myriad to seek USFDA approval of BRAC analysis CDx

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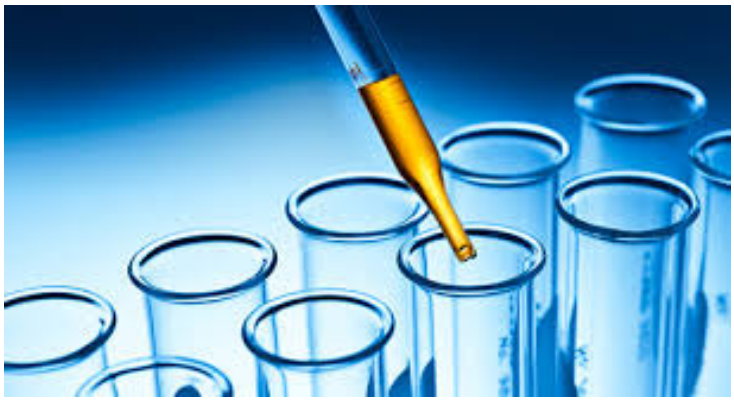

Myriad Genetics, Inc. a global leader in molecular diagnostics, has announced that the AstraZeneca/Merck Phase III PROfound study (NCT02987543) met its primary endpoint and demonstrated that men with metastatic castration-resistant prostate (mCRPC) cancer selected for *BRCA1*/2 or *ATM gene mutations*, a subpopulation of homologous recombination repair gene mutations, lived for longer time without disease progression when treated with Lynparza® (olaparib), a novel PARP inhibitor. Myriad will file a supplementary Premarket Approval Application (sPMA) with the U.S. Food and Drug Administration (FDA) to authorize BRACAnalysis CDx as a companion diagnostic test for olaparib in mCRPC patients with germline BRCA mutations.

“The PROfound trial confirmed the potential benefits of using biomarkers to help guide care for men with metastatic castration-resistant prostate cancer,” said Johnathan Lancaster, M.D., Ph.D., chief medical officer, Myriad Genetics. “This study is another example of Myriad’s commitment to help our pharmaceutical partners achieve and deliver precision medicine for people with cancer.”

The topline results – announced earlier today by AstraZeneca and Merck – are the first reported clinical results from the PROfound study, which assessed the efficacy and safety of olaparib versus enzalutamide or abiraterone acetate in subjects with metastatic castration-resistant prostate cancer who have failed prior treatment with a new hormonal agent and have homologous recombination repair gene mutations. The results demonstrated a statistically-significant and clinically-meaningful improvement of radiographic progression-free survival among patients selected for mutations in*BRCA1/2* or *ATM* and were treated with olaparib.

“We congratulate AstraZeneca and Merck on the successful completion of the PROfound trial and look forward to expanding the population of people who can potentially benefit from testing with BRACAnalysis CDx,” said Nicole Lambert, president, Myriad Oncology. “Importantly, this study is another example of Myriad’s commitment to leverage our portfolio of tumor and germline tests to develop and deliver precision medicine for people with cancer.”

The collaboration between Myriad and AstraZeneca on olaparib began in 2007 and has resulted in multiple regulatory

approvals for BRACAnalysis CDx.

BRACAnalysis CDx is an in vitro diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the *BRCA1* and BRCA2 genes using genomic DNA obtained from whole blood specimens collected in EDTA. Single nucleotide variants and small insertions and deletions (indels) are identified by polymerase chain reaction (PCR) and Sanger sequencing. Large deletions and duplications in *BRCA1* and *BRCA2* are detected using multiplex PCR.