BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Myriad, AstraZeneca and Merck expand companion diagnostic partnership

05 April 2019 | News

BRACAnalysis CDx® Test Will Be Used to Identify Germline BRCA Mutations in Men with Metastatic Castrate-Resistant Prostate Cancer

Myriad Genetics, a leader in personalized medicine has announced that it has expanded its companion diagnostic collaboration with AstraZeneca and Merck (known as MSD outside the US and Canada).

Under the expanded collaboration, the companies will use BRACAnalysis CDx® to identify germline BRCA mutations in men who have metastatic castrate-resistant prostate (mCRPC) cancer and are enrolled in the Phase III PROfound study. If the study is successful, Myriad intends to file a supplementary premarket approval application with U.S. Food and Drug Administration (FDA) for BRACAnalysis CDx to be used as a companion diagnostic to Lynparza® (olaparib) for its use in this patient population.

Nicole Lambert, president, Myriad Oncology said, "Our companion diagnostic collaboration with AstraZeneca and Merck has led to significant advancements in precision treatment for patients with ovarian, breast cancer. However, there is a significant unmet medical need in men with metastatic castration-resistant prostate cancer and BRCA1/2 mutations, which is an area where the utility of PARP inhibitors is being explored. We look forward to this exciting opportunity to potentially expand the use of BRACAnalysis CDx in this setting."

The collaboration between Myriad and AstraZeneca on Lynparza began in 2007 and has resulted in multiple regulatory approvals for BRACAnalysis CDx.

On February 2019 the Japanese Ministry of Health, Labour, and Welfare approved BRACAnalysis CDx as a companion diagnostic to identify patients with germline BRCA mutated (BRCAm) advanced ovarian cancer who are eligible for first-line maintenance therapy with Lynparza.

On December 2018 FDA approved BRACAnalysis CDx as a companion diagnostic to identify patients with germline BRCAm advanced ovarian cancer in complete or partial response to first-line platinum-based chemotherapy and who are eligible for first-line maintenance treatment with Lynparza.

On March 2018 The Japanese Ministry of Health, Labour, and Welfare approved BRACAnalysis CDx as a companion diagnostic to identify patients with germline BRCAm metastatic breast cancer who have been previously treated with chemotherapy and are eligible for treatment with Lynparza.

On January 2018 FDA approved BRACAnalysis CDx as a companion diagnostic to identify patients with germline BRCAm metastatic breast cancer who have been previously treated with chemotherapy and are eligible treatment with Lynparza.

On August 2017 FDA approved BRACAnalysis CDx as a complementary diagnostic to identify patients with recurrent platinum-sensitive germline BRCAm ovarian cancer who are eligible for maintenance treatment with Lynparza.

On Dec. 2014 FDA approved BRACAnalysis CDx as a companion diagnostic to identify patients with advanced germline BRCAm ovarian cancer who have been treated with 3 or more lines of chemotherapy and are eligible for treatment with Lynparza.