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Myriad Genetics grants second manufacturing and marketing approval for BRACAnalysis Diagnostic System

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The decision allows physicians to use BRACAnalysis to identify women with ovarian cancer who have a germline BRCA mutation and are eligible for first-line maintenance therapy with Lynparza.



Myriad Genetic Laboratories, a wholly-owned subsidiary of Myriad Genetics has announced the Japanese Ministry of Health, Labour, and Welfare has granted a second manufacturing and marketing approval for Myriad's BRACAnalysis Diagnostic System (i.e., "BRACAnalysis") as a companion diagnostic with the PARP inhibitor, Lynparza (olaparib). Lynparza is marketed by AstraZeneca and MSD (known as Merck & Co., Inc. in the United States and Canada).

The decision allows physicians to use BRACAnalysis to identify women with ovarian cancer who have a germline*BRCA* mutation and are eligible for first-line maintenance therapy with Lynparza. BRACAnalysis previously was approved in Japan for use in patients with unresectable or recurrent breast cancer and is the only companion diagnostic test for a PARP inhibitor to receive regulatory approval in Japan.

"The approval of BRACAnalysis for women with ovarian cancer is a major milestone for precision oncology in Japan," said Gary A. King, executive vice president of International Operations, Myriad Genetics. "We will work with our commercial partners in Japan to expand access to BRACAnalysis and Lynparza."

Myriad will continue to commercialize BRACAnalysis in exclusive partnership with SRL Inc., a subsidiary of Miraca Group, and one of the largest laboratory service providers in Japan. According to Japan's National Cancer Center, there are approximately 10,000 patients diagnosed with ovarian cancer each year.

"The new approval shows the need for women with ovarian cancer to receive a BRACAnalysis test at the time of diagnosis so they can know their treatment options," said Professor Daisuke Aoki, M.D., Ph.D., Department of Obstetrics and Gynecology, Keio University School of Medicine and Chairperson of the Japan Society of Gynecologic Oncology. "Women who are found to carry a germline *BRCA*mutation are candidates for treatment with Lynparza."

“The approval of BRACAnalysis as a companion diagnostic for Lynparza in women with ovarian cancer represents significant progress in delivering precision medicine to Japanese patients via our long-standing collaboration with Myriad Genetics Inc.,” said Ruth March, Ph.D., senior vice president and head of Precision Medicine, Oncology R&D, AstraZeneca.

BRACAnalysis is a diagnostic system that classifies a patient’s clinically significant variants (DNA sequence variations) in the germline *BRCA1* and *BRCA2* genes. Variants are classified into one of the five categories; “Deleterious,” “Suspected Deleterious,” “Variant of Uncertain Significance,” “Favor Polymorphism,” or “Polymorphism.” Once the classification is completed, the results are sent to medical personnel in Japan for determining the eligibility of patients for treatment with Lynparza.

Myriad has been collaborating with AstraZeneca since 2007 on the development of companion diagnostics for Lynparza. BRACAnalysis CDx was approved by the United States Food and Drug Administration (FDA) in December 2014 for patients with advanced ovarian cancer and again in January 2018 for patients with HER2-negative metastatic breast cancer. The test is marketed in the United States as BRACAnalysis CDx.

Lynparza is the first approved oral poly ADP-ribose polymerase (PARP) inhibitor and the first targeted treatment to potentially exploit DNA damage response (DDR) pathway deficiencies, such as *BRCA* mutations, to preferentially kill cancer cells. Specifically, in vitro studies have shown that Lynparza-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes, resulting in DNA damage and cancer cell death. Lynparza is being investigated in a range of DDR-deficient tumour types and is the foundation of AstraZeneca’s industry-leading portfolio of compounds targeting DDR mechanisms in cancer cells. Lynparza® is a registered trademark of AstraZeneca. In July 2017, AstraZeneca and Merck announced a global strategic oncology collaboration to jointly co-develop and co-commercialize Lynparza.

Since the establishment in 1970, SRL, Inc., a member of the Miraca Group, Japan-based leading healthcare group, has been providing comprehensive testing services as the largest commercial clinical laboratory in Japan. SRL carries out nearly 400,000,000 tests per year, covering a wide range of testing services including general/emergency testing, esoteric/research testing, companion diagnostics tests, genomic analysis, and etc.

Myriad Genetics Inc., is a leading personalized medicine company dedicated to being a trusted advisor transforming patient lives worldwide with pioneering molecular diagnostics. Myriad discovers and commercializes molecular diagnostic tests that: determine the risk of developing disease, accurately diagnose disease, assess the risk of disease progression, and guide treatment decisions across six major medical specialties where molecular diagnostics can significantly improve patient care and lower healthcare costs. Myriad is focused on five strategic imperatives: build upon a solid hereditary cancer foundation, growing new product volume, expanding reimbursement coverage for new products, increasing RNA kit revenue internationally and improving profitability with Elevate 2020.