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Myriad Receives FDA Approval of BRACAnalysis CDx® as Companion Diagnostic for Lynparza™ (olaparib) In Patients with Metastatic Breast Cancer

SALT LAKE CITY, Jan. 12, 2018 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced that the U.S. Food and Drug Administration (FDA) approved BRACAnalysis CDx® for use as a companion diagnostic by healthcare professionals to identify patients with HER2-negative metastatic breast cancer who have a germline BRCA mutation and are candidates for treatment with the PARP inhibitor Lynparza (olaparib), marketed by AstraZeneca and Merck, known as MSD outside of the U.S. and Canada. BRACAnalysis CDx is the first and only FDA-approved test for use in this indication.

"This important advance underscores the need for patients with HER2-negative metastatic breast cancer to know their *BRCA* status with an FDA approved test to help ensure that they will receive the best available therapy," said Johnathan Lancaster, M.D., Ph.D., chief medical officer of Myriad Genetics. "As shown in the OlympiAD study, Myriad's BRACAnalysis CDx test was proven to accurately identify those patients who had a germline BRCA mutation and may benefit from Lynparza."

The approval also adds to the body of knowledge about the clinical use and value of companion diagnostics to enable personalized medicine for people with cancer.

"We congratulate AstraZeneca and Merck on obtaining FDA approval of Lynparza for patients with metastatic breast cancer, which is the first approval of a PARP inhibitor outside of ovarian cancer. As the pioneers in identifying likely responders to PARP inhibitors, we are excited to broaden the use of BRACAnalysis CDx as the companion diagnostic for this important new indication," said Mark C. Capone, president and CEO, Myriad Genetics. "We will be actively working with all stakeholders to raise awareness so that patients can be immediately tested to determine if they are likely to benefit from Lynparza."

Approximately one in eight women are diagnosed with breast cancer in the United States, and one-third are diagnosed with or will progress to the metastatic stage of the disease.

"There are more than 155,000 patients with metastatic breast cancer in the United States, and we estimate that 125,000 do not know their BRCA status," said Lancaster. "This new FDA approval of BRACAnalysis CDx for patients with metastatic breast cancer significantly expands the population who can access *BRCA* testing and potentially benefit from PARP inhibition therapy."

The collaboration with AstraZeneca to develop a novel companion diagnostic test to identify candidates for treatment with olaparib began in 2007. The new metastatic breast cancer indication is the second FDA approval of BRACAnalysis CDx for use in conjunction with Lynparza. In Dec. 2014, Myriad received FDA approval for BRACAnalysis CDx to help identify patients with advanced ovarian cancer who are eligible for fourth-line treatment with olaparib. BRACAnalysis CDx is Myriad's first FDA-approved companion diagnostic and was the first-ever laboratory developed test approved by the FDA.

About 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. Results of the test are used as an aid in identifying breast and ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants, who are or may become eligible for treatment with Lynparza® (olaparib). Detection of deleterious or suspected deleterious germline BRCA variants by the BRACAnalysis CDx test in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) maintenance therapy. This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108. Learn more at: <http://myriadmychoice.com/>.

About Lynparza

Lynparza (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that exploits tumor DNA damage response (DDR) pathway deficiencies to preferentially kill cancer cells. Lynparza is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DNA damage response (DDR) mechanisms in cancer cells. Lynparza is currently approved in the United States for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy and for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Patients are selected for therapy based on Myriad's FDA-approved companion diagnostic. It is also approved by regulatory health authorities in the EU for use as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

In July 2017, AstraZeneca and Merck announced a global strategic oncology collaboration to jointly co-develop and co-commercialize Lynparza.

About Myriad Genetics

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: Stabilizing hereditary cancer revenue, growing new product volume, expanding reimbursement coverage for new products, increasing RNA kit revenue internationally and improving profitability with Elevate 2020. For more information on how Myriad is making a difference, please visit the Company's website: www.myriad.com.

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Safe Harbor Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the ability of the Company's FDA approved test to help ensure that HER2-negative metastatic breast cancer patients will receive the best available therapy; the OlympiAD study and FDA's approval of BRCA*Analysis* CDx® for use in HER2-negative metastatic breast cancer patient broadening the use of BRCA*Analysis* CDx® as a companion diagnostic; the Company actively working with all stakeholders to raise awareness so that patients can be immediately tested to determine if they are likely to benefit from Lynparza; one-third of breast cancer patients being diagnosed with or progressing to the metastatic stage of the disease; this new FDA approval of BRCA*Analysis* CDx® for patients with metastatic breast cancer significantly expanding the population who can access BRCA testing and potentially benefit from PARP inhibition therapy; the 155,000 patients with metastatic breast cancer in the United States, and our estimates that 125,000 do not know their BRCA status, now potentially gaining access; and the Company's strategic directives under the caption "About Myriad Genetics." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described or implied in the forward-looking statements. These risks include, but are not limited to: the risk that sales and profit margins of our existing molecular diagnostic tests and pharmaceutical and clinical services may decline or will not continue to increase at historical rates; risks related to our ability to transition from our existing product portfolio to our new tests; risks related to changes in the governmental or private insurers' reimbursement levels for our tests or our ability to obtain reimbursement for our new tests at comparable levels to our existing tests; risks related to increased competition and the development of new competing tests and services; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and pharmaceutical and clinical services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and pharmaceutical and clinical services, including our ability to successfully generate revenue outside the United States; the risk that licenses to the technology underlying our molecular diagnostic tests and pharmaceutical and clinical services tests and any future tests are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with operating our laboratory testing facilities; risks related to public concern over our genetic testing in general or our tests in particular; risks related to regulatory requirements or enforcement in the United States and foreign countries and changes in the structure of the healthcare system or healthcare payment systems; risks related to our ability to obtain new corporate collaborations or licenses and acquire new technologies or businesses on satisfactory terms, if at all; risks related to our ability to successfully integrate and derive benefits from any technologies or businesses that we license or acquire, including but not limited to our acquisition of Assurex, Sividon and the Clinic; risks related to our projections about the potential market opportunity for our products; the risk that we or our licensors may be unable to protect or that third parties will infringe the proprietary technologies underlying our tests; the risk of patent-infringement claims or challenges to the validity of our patents; risks related to changes in intellectual property laws covering our molecular diagnostic tests and pharmaceutical and clinical services and patents or enforcement in the United States and

foreign countries, such as the Supreme Court decision in the lawsuit brought against us by the Association for Molecular Pathology et al; risks of new, changing and competitive technologies and regulations in the United States and internationally; the risk that we may be unable to comply with financial operating covenants under our credit or lending agreements; the risk that we will be unable to pay, when due, amounts due under our credit or lending agreements; and other factors discussed under the heading "Risk Factors" contained in Item 1A of our Annual report on Form 10-K for the fiscal year ended June 30, 2017, which has been filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

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