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Myriad's BRACAnalysis CDx® Test Successfully Identified Metastatic Breast Cancer Patients with Improved Outcomes from AstraZeneca's PARP Inhibitor, Olaparib

SALT LAKE CITY, Feb. 17, 2017 (GLOBE NEWSWIRE) -- [Myriad Genetics](#), Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced new findings from the OlympiAD study that show its BRACAnalysis CDx® test successfully identified patients with HER2-negative metastatic breast cancer who have *BRCA* mutations and who had improved response with Lynparza (olaparib), AstraZeneca's PARP inhibitor.

The high level results — announced earlier today from AstraZeneca — are the first reported clinical data from the OlympiAD study ([NCT02000622](#)), which assessed the efficacy and safety of olaparib monotherapy versus physicians' choice of chemotherapy (i.e., capecitabine, vinorelbine or eribulin) in the treatment of metastatic breast cancer. Of the 302 patients in the study, 98 percent (297/302) tested positive for germline *BRCA1/2* mutations as determined by Myriad's FDA-approved BRACAnalysis CDx test. The results demonstrated a statistically-significant improvement of progression-free survival (PFS) among *BRCA*-mutated patients treated with olaparib compared to those treated with physicians' choice.

"We believe the results of the OlympiAD trial support use of the BRACAnalysis CDx test to help inform treatment decisions in the metastatic breast cancer setting and will expand the patient population who can benefit from *BRCA* testing," said Johnathan Lancaster, M.D., Ph.D., chief medical officer of Myriad Genetic Laboratories. "This study underscores Myriad's commitment to our pharmaceutical partners and to advancing the field of personalized medicine so that new effective treatment options are available to patients."

It is estimated there are approximately 60,000 patients with metastatic breast cancer, two thirds of whom are not currently eligible for *BRCA* testing based upon family and personal history alone or current testing criteria. If approved as a new indication this would triple the number of patients with metastatic breast cancer who would benefit from *BRCA* testing.

The ongoing collaboration between Myriad and AstraZeneca to develop a novel companion diagnostic test to identify candidates for treatment with olaparib began in 2007. 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 reviewed and 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 ovarian cancer patients with deleterious or suspected deleterious germline *BRCA* variants eligible for treatment with Lynparza™ (olaparib). 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.

About Lynparza

Lynparza (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour 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 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. It is also approved in the US as monotherapy in patients with deleterious or suspected deleterious germline *BRCA*-mutated (as detected by an FDA-test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Lynparza is currently being investigated in another separate non-metastatic breast cancer Phase III study called OLYMPIA. This study is still open and recruiting patients internationally.

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 three strategic imperatives: transitioning and expanding its hereditary cancer testing markets, diversifying its product portfolio through the introduction of new products and increasing the revenue contribution from international markets. 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 related to the ability of the BRACAnalysis CDx test to successfully identify metastatic breast cancer patients with improved outcomes from olaparib; the results of the study demonstrating a statistically-significant improvement of progression-free survival (PFS) among BRCA-mutated patients treated with olaparib compared to those treated with physicians' choice; the Company's belief that the results of the OlympiAD trial support use of the BRACAnalysis CDx test to help inform treatment decisions in the metastatic breast cancer setting and will expand the patient population who can benefit from BRCA testing; the importance of the BRACAnalysis CDx test for this patient population and the ability to identify patients likely to benefit from PARP inhibition therapy; the number of patients with metastatic breast cancer who would benefit from BRCA testing if approved as a new indication; the Company's ongoing collaboration with AstraZeneca to develop a novel companion diagnostic test to identify candidates for treatment with olaparib; and the Company's strategic directives under the captions "About BRACAnalysis CDx," and "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 set forth in or implied by forward-looking statements. These risks and uncertainties include, but are not limited to: the risk that sales and profit margins of our molecular diagnostic tests and pharmaceutical and clinical services may decline; risks related to our ability to transition from our existing product portfolio to our new tests, including unexpected costs and delays; risks related to decisions or changes in 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 and any future tests and services are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with operating our laboratory testing facilities and our healthcare clinic; risks related to public concern over 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; risks related to our projections about our business, results of operations and financial condition; risks related to the potential market opportunity for our products and services; 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 or other intellectual property; 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; and other factors discussed under the heading "Risk Factors" contained in Item 1A of our most recent Annual Report on Form 10-K for the fiscal year ended June 30, 2016, 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. All information in this press release is as of the date of the release, and Myriad undertakes no duty to update this information unless required by law.

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