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Myriad's BRACAnalysis CDx® Test Effectively Identified Metastatic Breast Cancer Patients with Improved Outcomes from Pfizer's PARP Inhibitor, Talazoparib

SALT LAKE CITY, Dec. 12, 2017 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced that data from the EMBRACA trial showed Myriad's BRACAnalysis CDx® test successfully identified patients with metastatic breast cancer (MBC) who responded to Pfizer's investigational PARP inhibitor, talazoparib.

The EMBRACA trial (NCT01945775) data were presented last week at the 2017 San Antonio Breast Cancer Symposium (SABCS). The study included approximately 400 patients, all of whom tested positive for germline BRCA mutations as determined by Myriad's FDA-approved BRACAnalysis CDx test. As presented at SABCS, the results demonstrated that patients with gBRCA+ locally advanced and/or MBC demonstrated superior progression-free survival (PFS) in patients treated with talazoparib, compared to patients who received physician's choice standard-of-care chemotherapy. Additionally, the PFS benefit was consistent across metastatic BRCA-positive patients, including those with hormone receptor-positive and triple negative disease.

"BRACAnalysis CDx is the only germline companion diagnostic test approved by the FDA to identify patients with *BRCA1/2* mutations, and we are excited to support Pfizer's clinical development program and help identify patients who are most likely to benefit from talazoparib," said Mark C. Capone, president and CEO, Myriad Genetics. "As the pioneers in companion diagnostics for PARP inhibitors, we are excited that more patients may benefit from these novel drugs in the future."

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.

Myriad first announced its collaboration to develop a novel companion diagnostic test for talazoparib on Oct. 1, 2013. Under that agreement (originally with BioMarin; now Pfizer), Myriad plans to submit a supplementary premarket approval (sPMA) application to the U.S. Food and Drug Administration (FDA) under its existing *PMA for BRACAnalysis CDx* to include talazoparib.

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, 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 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.

United States and foreign countries. MYGN-F, MYGN-G

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 Company supporting Pfizer's clinical development program; BRACAnalysis CDx helping identify patients who are most likely to benefit from talazoparib; the possibility that more patients may benefit from PARP inhibitor drugs in the future; estimates of 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; the Company's plans to submit a supplementary premarket approval application to the U.S. Food and Drug Administration under its existing PMA for BRACAnalysis CDx to include talazoparib; ; 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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