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Myriad's BRACAnalysis CDx[®] Supplementary PMA Accepted by FDA for Review as a Companion Diagnostic for Lynparza[®] (olaparib) in Metastatic Breast Cancer

Company Expects FDA Priority Review to Conclude in the Fiscal Third-Quarter 2018

SALT LAKE CITY, Oct. 18, 2017 (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) has accepted its supplementary premarket approval (sPMA) application for BRACAnalysis CDx[®] to be used as a companion diagnostic with AstraZeneca's PARP inhibitor Lynparza[®] (olaparib) in patients with HER2-negative metastatic breast cancer. Myriad expects the FDA's priority review process to conclude in the fiscal third-quarter 2018.

Myriad's sPMA filing follows positive results from the Phase III OlympiAD trial, which demonstrated that Lynparza significantly reduced the risk of disease progression or death in patients with BRCA-mutated, HER2-negative metastatic breast cancer by 42 percent compared to standard therapy. The results of the OlympiAD trial were published in the [New England Journal of Medicine](#) in June.

"The acceptance of the sPMA for BRACAnalysis CDx is a significant step towards enabling personalized medicine for patients with metastatic breast cancer," said Mark C. Capone, president and CEO, Myriad Genetics. "As the pioneer in companion diagnostics for PARP inhibitors, we are excited to once again partner with AstraZeneca and broaden access to Lynparza for even more patients."

If approved, BRACAnalysis CDx would be the first and only FDA-approved companion diagnostic for use with a PARP inhibitor to identify HER2-negative metastatic breast cancer patients with a BRCA mutation who would benefit from a PARP inhibitor. The Company estimates there are approximately 125,000 patients with metastatic breast cancer who would immediately qualify for the BRACAnalysis CDx test, followed by 60,000 new patients per year on an ongoing basis.

The ongoing collaboration with 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 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 fourth line 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 also is 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. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. 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. In July 2017, AstraZeneca and Merck & Co., Inc., announced a global strategic oncology collaboration to jointly develop and commercialize AstraZeneca's Lynparza, the world's first and leading PARP inhibitor.

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: maintaining leadership in an expanding hereditary cancer market, 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 relating to related to the ability of the BRACAnalysis CDx test to successfully identify metastatic breast cancer patients with improved outcomes from olaparib; the Company's belief that BRACAnalysis CDx is a significant step towards enabling personalized medicine for patients with metastatic breast cancer; the Company's role as a pioneer in companion diagnostics for PARP inhibitors and ability to broaden access to Lynparza for even more patients; the size of 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 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 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 most recent Annual Report on Form 10-K, 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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