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Myriad Receives FDA Approval of BRACAnalysis CDx(TM) as Companion Diagnostic for Lynparza(TM) (olaparib) in Ovarian Cancer Patients

BRACAnalysis CDx is First and Only FDA-Approved Test to Assess BRCA Status

SALT LAKE CITY, Dec. 19, 2014 (GLOBE NEWSWIRE) -- [Myriad Genetics](#), Inc. (Nasdaq:MYGN) today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for BRACAnalysis CDx to be used as the only companion diagnostic in conjunction with AstraZeneca's drug Lynparza™ (olaparib). Lynparza is the first poly ADP-ribose polymerase (PARP) inhibitor for patients with germline mutations in *BRCA1/2* advanced ovarian cancer who have had three or more lines of chemotherapy. BRACAnalysis CDx is Myriad's first FDA-approved companion diagnostic for use with a novel PARP inhibitor.

"Myriad is excited to offer the first and only FDA-approved companion diagnostic for Lynparza, which we believe opens a new door in personalized medicine and represents a big step forward in tailoring treatment for women with ovarian cancer," said Mark Capone, president, Myriad Genetic Laboratories. "Less than 25 percent of ovarian cancer patients know their germline *BRCA* status, which is critical for any ovarian cancer patient who may be considered for treatment with Lynparza."

BRACAnalysis CDx is a highly accurate molecular companion diagnostic test that identifies deleterious or suspected deleterious mutations in the *BRCA1* and *BRCA2* genes, using DNA obtained from a blood sample. BRACAnalysis CDx was proven in clinical studies to effectively identify patients with *BRCA* mutations who would be candidates for Lynparza. The approval of BRACAnalysis CDx demonstrates Myriad's commitment to developing companion diagnostics and is the culmination of an intensive, multiyear scientific collaboration with AstraZeneca to advance personalized medicine for women with ovarian cancer.

"Myriad has proven its ability to navigate a rigorous FDA regulatory approval process that included a comprehensive review of our DNA sequencing, large rearrangement detection and variant interpretation processes. Patients can be confident their BRACAnalysis CDx test results from Myriad are highly accurate," said Capone. "Our scientific excellence, reputation for high quality and regulatory experience are key reasons why Myriad is fast becoming the partner of choice for many biopharmaceutical companies seeking to co-develop companion diagnostic tests. We hope to expand our collaborations and further diversify our product portfolio."

Myriad is committed to being a leader in companion diagnostics for personalized healthcare. The Company is actively collaborating with several biopharmaceutical companies to further evaluate BRACAnalysis CDx as an investigational companion diagnostic for use with other PARP inhibitors and chemotherapeutic agents and for use in many other solid tumor types. BRACAnalysis CDx testing will be performed in Myriad's laboratory in Salt Lake City, Utah. For more information, please visit www.myriad.com or call customer service at 1-800-469-7423.

About BRACAnalysis CDx™

Intended Use: 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 Myriad Genetics

Myriad Genetics is a leading molecular diagnostic company dedicated to making a difference in patients' lives through the discovery and commercialization of transformative tests to assess a person's risk of developing disease, guide treatment decisions and assess risk of disease progression and recurrence. Myriad is focused on strategic directives to grow our markets, introduce new products, including companion diagnostics, as well as to expand internationally. For more information on how Myriad is making a difference, please visit the Company's websites: 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 an FDA-approved BRACAnalysis CDx test providing additional assurance that patients are receiving the most accurate test results and improving patient care by identifying candidates for treatment with Lynparza (olaparib); the Company's commitment to developing companion diagnostics; the Company becoming the partner of choice for many biopharmaceutical companies seeking to co-develop companion diagnostics; the Company's hopes to expand its collaborations and further diversify its portfolio; the Company's ongoing collaborations with biopharmaceutical companies to further evaluate BRACAnalysis CDx for use with other PARP inhibitors and chemotherapeutic agents and for use in other solid tumor types; the location of BRACAnalysis testing; and the Company's strategic directives under the caption "About Myriad Genetics." 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 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, including unexpected costs and delays; 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 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; 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; 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 Annual Report on Form 10-K for the fiscal year ended June 30, 2014, 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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