



September 24, 2015

## **Myriad Genetics Presents New Data on Its Companion Diagnostic and Prostate Cancer Tests at the European Society for Medical Oncology Annual Meeting**

SALT LAKE CITY, Sept. 24, 2015 (GLOBE NEWSWIRE) -- [Myriad Genetics](#), Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced three poster presentations that will be featured at the 40th European Society for Medical Oncology (ESMO) meeting being held Sept. 25 to 29, 2015 in Vienna, Austria. The presentations include new studies on the myChoice™ HRD and Tumor BRACAnalysis CDx™ companion diagnostic tests and final results from the EMPATHY-P clinical utility study on Prolaris®.

"Myriad continues to place a strong emphasis on molecular diagnostic research with the goal of enabling personalized medicine and improving patient outcomes. We are presenting exciting new data on the unique ability of our companion diagnostics to identify the highest number of patients who may benefit from drugs that target the DNA-repair pathway, such as PARP inhibitors," said Jerry Lanchbury, Ph.D., chief scientific officer, Myriad. "We're also presenting the final results for the EMPATHY-P study that show the Prolaris test provides essential clinical information to help physicians select men with prostate cancer who are good candidates for active surveillance versus those who need more medical treatment based on a genetic evaluation of their tumor."

The list of key Myriad presentations at ESMO (#ECC2015) follows.

### **myChoice™ HRD**

**Title:** *DNA Repair Deficiencies in Ovarian Cancer: Genomic Analysis of High Grade Serous Ovarian Tumors from the NOVA Study.*

**Date:** *Saturday, Sept. 26, 2015: 4:45 to 6:45 p.m. CEST.*

**Location:** *Hall C, Poster P108.*

Homologous recombination deficiency was assessed on tumors obtained from 318 patients enrolled in the NOVA study, a Phase 3 clinical trial evaluating the PARP inhibitor niraparib as a treatment in patients with platinum-sensitive ovarian cancer. The results show that 100 percent of patients with a germline *BRCA* mutation and 55 percent of patients without a *BRCA* mutation were HRD positive as determined by the myChoice HRD test. Importantly, the myChoice HRD test, which uses three novel algorithms of DNA damage (LOH, LST, TAI), more clearly defined the HRD positive population in ovarian cancer than did LOH alone. These findings support the use of the myChoice HRD test to more effectively identify patients who may benefit from therapy with DNA-damaging agents, such as platinum drugs and PARP inhibitors.

### **Tumor BRACAnalysis CDx™**

**Title:** *Next Generation Sequencing of BRAC1 and BRCA2 Genes in Ovarian Tumors Captures Germline Mutations and Expands the Potential Treatment Group for the PARP Inhibitor Olaparib.*

**Date:** *Saturday, Sept. 26, 2015: 4:45 to 6:45 p.m. CEST.*

**Location:** *Hall C, Poster P116.*

This study assessed the ability of Tumor BRACAnalysis CDx, a tumor-based next generation sequencing (NGS) test, to detect germline *BRAC1/2* mutations in patients with high-grade serous ovarian cancer versus germline testing using Sanger sequencing in a reference laboratory. Tumor tissue was available from 54 patients to evaluate the Tumor BRACAnalysis CDx test. In all 54 cases, Tumor BRACAnalysis CDx correctly identified the deleterious *BRAC1/2* mutations, demonstrating 100 percent sensitivity. The study also showed that tumor cells have *de novo* somatic mutations not identifiable via germline testing alone. For example, Tumor BRACAnalysis CDx found 12 somatic *BRCA1/2* mutations, which represents an increase of 22 percent over germline testing in a sample set that had been specifically enriched for germline mutations. Importantly, patients with germline and tumor *BRAC1/2* mutations showed similar treatment response to olaparib, suggesting that tumor testing effectively identifies patients appropriate for treatment with PARP inhibitors.

***Title: Potential Reduction of Overtreatment of Localized Prostate Cancer Using a Cell Cycle Gene Expression Assay (Prolaris) in Biopsy Specimens: Results from the European Multi-Center EMPATHY-P Study.***

**Date: Monday, Sept. 28, 2015: 4:45 to 6:45 p.m. CEST.**

**Location: Hall C, Poster P072.**

The EMPATHY-P study evaluated the Prolaris test in 502 patient biopsy samples to determine the aggressiveness of prostate cancer in these newly diagnosed patients from five European countries including: Italy, Germany, Spain, Switzerland and the UK. The patients' biopsy samples also were evaluated using standard clinical pathology methods (D'Amico/AUA risk stratification) that were then compared to the Prolaris test results. The EMPATHY-P data show that overall the Prolaris test identified 54 percent of the European men with a risk profile that was different than would be expected using standard clinical pathology. Specifically, the EMPATHY-P study demonstrated that the Prolaris test score found 24 percent of European men had less aggressive prostate cancer and 30 percent of patients had more aggressive disease compared to standard clinical pathology measurements. These data demonstrate that the Prolaris test score can be used to personalize risk assessment for men with localized prostate cancer and identify good candidates for active surveillance.

**About myChoice™ HRD**

Myriad's myChoice HRD is the first homologous recombination deficiency test that can detect when a tumor has lost the ability to repair double-stranded DNA breaks, resulting in increased susceptibility to DNA-damaging drugs such as platinum drugs or PARP inhibitors. High myChoice HRD scores reflective of DNA repair deficiencies are prevalent in all breast cancer subtypes, ovarian and most other major cancers. In previously published data, Myriad showed that the myChoice HRD test predicted drug response to platinum therapy in certain patients with triple-negative breast and ovarian cancers. It is estimated that 1.8 million people in the United States and Europe who are diagnosed with cancers annually may be candidates for treatment with DNA-damaging agents.

**About Tumor BRACAnalysis CDx™**

Myriad's Tumor BRACAnalysis CDx is a companion diagnostic test for identifying both germline (hereditary) and somatic (tumor) cancer-causing mutations in the *BRCA1* and *BRCA2* genes. Tumor BRACAnalysis CDx has undergone significant analytic validation and has been shown to identify 44 percent more patients with cancer-causing *BRCA1/2* mutations compared to germline testing alone. Myriad is actively collaborating with leading pharmaceutical companies to develop Tumor BRACAnalysis CDx as a companion diagnostic for use with certain PARP inhibitors, platinum-based drugs and other chemotherapeutic agents. The test is currently available in Europe and will be performed at the Company's Munich laboratory. Prescribing physicians will receive Tumor BRACAnalysis CDx test results in approximately two weeks.

**About Prolaris®**

Prolaris is a prognostic test that measures the expression level of genes involved with tumor proliferation to predict disease outcome. Prolaris is the only test that provides insight into meaningful oncologic endpoints by predicting 10-year prostate cancer-specific mortality, thereby guiding medical management.

**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](http://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 our companion diagnostics to identify the highest number of patients who may benefit from drugs that target the DNA-repair pathway, such as PARP inhibitors; the ability of the Prolaris test to provide essential clinical information to help physicians select men with prostate cancer who are good candidates for active surveillance; the effectiveness and benefits of myChoice HRD, Tumor BRACAnalysis CDx and Prolaris in patient testing; 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 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 in our most recent Annual Report on Form 10-K for the fiscal year ended June 30, 2015, 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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