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Myriad myRisk™ Hereditary Cancer Test Is Highly Accurate in Key Validation Study

Five Studies to be Presented at the American Society of Human Genetics Annual Meeting

SALT LAKE CITY, Oct. 24, 2013 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (Nasdaq:MYGN) today announced it will present data this week at the American Society of Human Genetics (ASHG) annual meeting in Boston showing that the Myriad myRisk Hereditary Cancer test meets rigorous quality standards and provides clinical sequencing results equivalent to 99.99 percent accuracy. Myriad myRisk Hereditary Cancer is a new diagnostic test that provides patients with information about their hereditary risk for eight major cancers including breast, colorectal, ovarian, endometrial, pancreatic, prostate, gastric cancers and melanoma.

"Next-generation DNA sequencing offers the ability to test many genes at once, but it must be optimized to ensure clinical accuracy. We've invested three years of research to optimize our Myriad myRisk Hereditary Cancer test, and the validation data show that Myriad myRisk Hereditary Cancer offers 99.99 specificity and sensitivity which means it provides unprecedented quality and accuracy equal to the gold standard Sanger sequencing," said Richard J. Wenstrup, M.D., chief medical officer of Myriad. "As next-generation technology advances, mutation classification techniques also must evolve to ensure high quality data interpretation for clinical decision making. Myriad has developed a robust variant classification program called Myriad myVision™ to achieve highly accurate, clinically actionable, genetic test results for patients and healthcare providers."

The five studies being presented at the ASHG annual meeting include:

Development of a Next Generation Sequencing Panel to Assess Hereditary Cancer Risk that Includes Clinical Diagnostic Analysis of the *BRCA1* and *BRCA2* Genes. [Roa et al., Poster: Oct. 24, 2013, 11:30 a.m. — 12:30 p.m. ET]

This study validated the myRisk Hereditary Cancer test, which is a 25-gene panel that uses next generation sequencing (NGS) technology. The study compared the myRisk Hereditary Cancer test to the gold standard Sanger sequencing for evaluation of *BRCA1* and *BRCA2* mutations in 1,864 patient samples. myRisk Hereditary Cancer detected 15,877 variants compared to 15,878 variants using Sanger sequencing, resulting in an analytic sensitivity > 99.99 percent. These data show that a NGS gene panel designed to meet rigorous quality standards can provide clinical sequencing results that are equivalent to those obtained from Sanger DNA sequencing analysis (i.e., greater sensitivity without loss of specificity). In this validation study, Myriad's myRisk Hereditary Cancer test was shown to be highly effective and provided high quality, accurate results for clinical decision-making purposes.

A Clinical History Weighting Algorithm Accurately Classifies *BRCA1* and *BRCA2* Variants. [Bowles et al., Poster: Oct. 25, 2013, 10:30 — 11:30 a.m. ET]

This study evaluated a clinical history weighting algorithm designed to provide highly accurate classifications for *BRCA1* and *BRCA2* variants of uncertain significance and which is integral to Myriad's proprietary myVision™ Variant Classification Program. The algorithm is based on the premise that disease-associated mutations will be observed more often in individuals at high risk for carrying a mutation, as determined by personal and family history. Statistical analysis weights the family histories of each patient carrying a variant of interest and compares those histories to control patients carrying variants known to be benign or deleterious. Data from more than 400,000 patients were used to develop the algorithm, which was validated against 6,000 *BRCA1* and *BRCA2* variants. The results showed that the clinical history weighting algorithm accurately classified well-documented variants associated with *BRCA1* and *BRCA2* and allowed classification with fewer observations than other techniques, providing timely and accurate classifications to guide clinical care. Importantly, this clinical history weighting algorithm facilitated the accurate reclassification of *BRCA1* and *BRCA2* variants of uncertain significance, which will improve the clinical management of patients at risk for hereditary cancer.

Frequencies of *BRCA1*, *BRCA2*, *PALB2*, and *CDKN2A* Germline Mutations in Familial Pancreatic Cancer (FPC): A PACGENE study. [Zhen/Petersen et al., Poster: Oct. 24, 2013, 10:30 — 11:30 a.m. ET]

This study assessed the frequency of germline mutations in four of the genes in the myRisk Hereditary Cancer panel — *BRCA1*, *BRCA2*, *PALB2*, and *CDKN2A* — in patients with familial pancreatic cancer. Using samples from a large pancreatic cancer registry, the DNA from 80 patients who met familial pancreatic cancer criteria was tested. The frequencies for deleterious or suspected deleterious mutations and variants of uncertain significance (VUS) among the patients tested totaled

13.8 percent: *BRCA1* (2.9 percent), no VUS; *BRCA2* (4.4 percent), no VUS; *PALB2* (1.3 percent), no VUS; *CDKN2A* (5.2 percent), 3 VUS. These data show the genetic heterogeneity of germline mutations in patients with familial pancreatic cancer and strongly suggest that these patients are appropriate candidates for genetic testing using a hereditary cancer panel that tests for multiple genes to prevent a misdiagnosis.

Detection of Large Rearrangements in *PMS2*. [Mancini-DiNardo et al., Podium: Oct. 25, 2013, 3:15 p.m. ET]

This study evaluated the frequency of large rearrangements (LR) in the *PMS2* gene, which are associated with hereditary colon cancer. While inactivation of *PMS2* is caused largely by sequencing mutations, a significant proportion of all PMS2 mutations have been reported to be large rearrangements. In this study, the analysis of data from patients who received full gene sequencing and LR analysis of *MLH1*, *MSH2*, *MSH6* and *PMS2*, demonstrated that deleterious and suspected deleterious mutations in *PMS2* comprise 14.3 percent of all mutations detected in these hereditary colon cancer predisposing genes (108/755). Among the *PMS2* mutation-positive patients, 25 percent of the mutations were LR compared with 75 percent that were sequencing mutations. This study showed that LR are a significant portion of *PMS2* mutations. Since mutations within *PMS2* alone are clinically actionable, it is critically important to accurately assess patients' *PMS2* large rearrangement status. The multifaceted process used in this study provided patients with an accurate diagnosis.

Clinical Presentation of Patients with Mutations in the *APC* Regions Associated with AFAP. [Kaushik et al., Poster: Oct. 25, 2013, 11:30 a.m. — 12:30 p.m. ET]

This study evaluated the polyp history of patients with mutations in three areas of the *APC* gene associated with Attenuated Familial Adenomatous Polyposis (AFAP) compared to mutations elsewhere in the gene. AFAP is a subtype of familial adenomatous polyposis (FAP) and people with FAP/AFAP are at increased risk of hereditary colorectal cancer. A total of 1,534 individuals with mutations in the *APC* genes were included in this study. *APC* mutations in the three gene regions associated with AFAP were identified in 30.1 percent of patients. Of these, 65.7 percent developed less than 100 colorectal adenomas. A total of 69.9 percent were found to carry an APC mutation in the remainder of the gene not associated with AFAP. Of these, 25 percent developed less than 100 polyps. The majority of patients with an APC mutation in the three regions associated with AFAP were over the age of 40 (72.7 percent), while the majority of patients with mutations elsewhere in the *APC* gene were aged 20 to 40 (57.1 percent). This data showed a trend of less severe polyps and later age of testing among patients with a mutation in the three main regions of *APC* associated with AFAP. However, a substantial number of patients were found to have more than 100 colorectal adenomas regardless of the region the mutation was found in, suggesting that there is no definitive genotype/phenotype correlation between *APC* mutations and AFAP/FAP. This study supports expanding the use of genetic testing earlier in life for patients with AFAP.

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's portfolio of molecular diagnostic tests is based on an understanding of the role genes play in human disease and was developed with a commitment to improving an individual's decision-making process for monitoring and treating disease. Myriad is focused on strategic directives to introduce new products, including companion diagnostics, as well as expanding internationally. For more information on how Myriad is making a difference, please visit the Company's website at: www.myriad.com and our social media channels: Twitter and Facebook.

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 the Company's anticipated presentations and participation at the American Society of Human Genetics annual meeting in Boston; the importance of Myriad myRisk Hereditary Cancer testing based on study results; the quality and accuracy of Myriad myRisk Hereditary Cancer testing; the use of myRisk Hereditary Cancer testing to accurately diagnose patients and select appropriate medical management; the ability of Myriad myVision to achieve accurate, clinically-actionable genetic test results for patients and healthcare providers; and the Company's strategic directives under the caption "About Myriad Genetics". These "forward-looking statements" are management's present 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 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 companion diagnostic services may decline or will not continue to increase at historical rates; risks related to changes in the governmental or private insurers reimbursement levels for our tests; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and companion diagnostic services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and companion diagnostic 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 companion diagnostic 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 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 increased competition and the development of new competing tests 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; risks related to changes in intellectual property laws covering our molecular diagnostic tests and companion diagnostic 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 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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