



March 15, 2016

## **Myriad Presents Second Pivotal Validation Study for Its myPath® Melanoma Test**

### **myPath Melanoma Diagnoses Suspicious Lesions with >90 Percent Diagnostic Accuracy**

SALT LAKE CITY, March 15, 2016 (GLOBE NEWSWIRE) -- [Myriad Genetics](#), Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced the results from the second pivotal clinical validation study for the myPath® Melanoma test at the 2016 USCAP Annual Meeting in Seattle, Wash.

"There is significant emotional distress associated with a melanoma diagnosis and doctors want to provide their patients with accurate information," said Loren Clarke, M.D., medical director, Myriad Genetic Laboratories. "We're developing the myPath Melanoma test to help pathologists improve the diagnosis of melanoma, particularly for patients with difficult-to-diagnose skin lesions."

In the study with 736 patients, the myPath Melanoma test effectively diagnosed suspicious lesions with greater than 90 percent diagnostic accuracy, 91.5 percent sensitivity and 92.5 percent specificity. This second validation is consistent with the first validation study with 437 patients that demonstrated a diagnostic accuracy of greater than 90 percent.

"myPath Melanoma is an extremely robust diagnostic test with unmatched clinical validity data, having completed the largest clinical validation study for a melanoma diagnostic test," said Clarke. "We have now demonstrated in two pivotal validation studies that myPath Melanoma accurately differentiates patients with melanoma from those with benign moles."

The Company also announced that it will present new data on its myPlan® Lung Cancer prognostic test at USCAP. Details about the featured Myriad presentations at USCAP are below. Follow Myriad on Twitter via @MyriadGenetics and stay up-to-date by using the hashtag #USCAP16.

#### **myPath Melanoma Poster Presentation**

- | **Title:** An independent validation of a gene expression signature to differentiate malignant melanoma from benign melanocytic nevi.
- | **Date:** Tuesday, March 15, 2016: 1:00 to 4:30 p.m. PT.
- | **Location:** Poster 84.
- | **Presenter:** Hillary Kimbrell, M.D., Myriad Genetic Laboratories.

In this clinical validation study, 736 melanocytic lesions, diagnosed as either benign or malignant by a panel of three expert dermatopathologists, were evaluated using the myPath Melanoma gene expression test. The results showed that the myPath Melanoma test differentiated malignant melanoma from benign nevi with a sensitivity of 91.5 percent and specificity of 92.5 percent. These findings were consistent across melanoma subtypes. There were several instances where the myPath test score differed from the pre-test diagnosis, causing the dermatopathologists to revise their initial diagnosis. These findings demonstrate the ability of the myPath Melanoma test to help diagnose cases of melanoma in samples representative of those seen in routine clinical practice.

#### **myPlan Lung Cancer Poster Presentation**

- | **Title:** Cell cycle progression score is a promising predictor of recurrence in primary lung carcinoid tumors.
- | **Date:** Monday, March 14: 1:00 to 4:30 p.m. PT.
- | **Location:** Poster 1874.
- | **Presenter:** Neda Kalhor, M.D., MD Anderson Cancer Center.

This exploratory study evaluated the cell cycle progression (CCP) score in pulmonary carcinoid tumors resected at the MD Anderson Cancer Center. The study cohort included 93 patients, including 79 with typical carcinoids (TC) and 14 with atypical carcinoids (AC). The results showed a significant association between the CCP score and recurrence free survival (RFS) in this cohort. These early findings suggest the CCP score may help in effective stratification of primary lung carcinoids to identify high-risk tumors that may require adjuvant therapy.

### **About myPath<sup>®</sup> Melanoma**

myPath Melanoma is a clinically validated gene expression test designed to differentiate malignant melanoma from benign nevi across all major melanoma subtypes. Myriad myPath Melanoma is a unique test of 23 genes that provides valuable, additive diagnostic information unavailable from any other method — information that can help physicians deliver a more confident diagnosis. <https://www.myriad.com/products-services/melanoma/mypath-melanoma/>.

### **About Myriad myPlan<sup>®</sup> Lung Cancer**

Myriad myPlan Lung Cancer is a molecular prognostic test that measures the expression levels of cell cycle progression genes to provide an accurate assessment of cancer aggressiveness in patients with early-stage non-small cell lung adenocarcinoma. For more information visit: <https://www.myriad.com/products-services/lung-cancer/myplan-lung-cancer/>.

### **About Myriad Genetics**

For more than 25 years, Myriad Genetics Inc. has been 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 the myPath Melanoma test to help pathologists improve the diagnosis of melanoma; 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 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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