

# Myriad Genetics' Prolaris® Test Accurately Predicts the 10-Year Risk of Metastases in Men Treated for Prostate Cancer

## Strong Predictive Power in Both African American and Non-African American Patients

SALT LAKE CITY, May 12, 2017 (GLOBE NEWSWIRE) -- <u>Myriad Genetics</u>, Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced new data demonstrating the utility of the Prolaris<sup>®</sup> test to accurately predict the 10-year risk of metastases in men treated for prostate cancer. The data are being presented tomorrow at the American Urological Association (AUA) 2017 Annual Meeting in Boston, Mass.

This study was conducted in collaboration with Stephen Bardot, M.D., and colleagues at Ochsner Clinic in New Orleans, Louisiana. A total of 767 men with localized prostate cancer were evaluated using the Prolaris test plus CAPRA (i.e., clinical features) to predict the risk of metastatic disease up to 10 years following diagnosis. Approximately 40 percent of the patients in the study were African Americans (AA). Among all 767 patients 39 men, or 5.1 percent, developed metastases and among the 646 men who received definitive therapy (e.g., surgery, radiation, radiation and hormones) 28 men, or 4.3 percent, developed metastatic disease.

The results showed that the Prolaris test was a significant predictor of metastatic disease with a nearly 3-fold increased risk for each one-unit increase on the Prolaris test score (Hazard Ratio per unit score = 2.76; P =  $2.8 \times 10^{-11}$ ). Importantly, there was no difference in predictive performance between races (p=0.20) or treatment groups (p=0.09). When combined with CAPRA the Prolaris test was highly predictive of metastatic disease (HR for combined clinical risk (CCR) = 3.86; p=  $2.8 \times 10^{-23}$ ). Contrary to expectations, this large study found no evidence that AA men have more accretions are cancer than

<sup>23</sup>). Contrary to expectations, this large study found no evidence that AA men have more aggressive prostate cancer than non-AA men after accounting for all molecular and clinical information.

"Our study confirmed that the Prolaris test significantly predicts which men are likely to develop metastatic disease, regardless of race, risk group or treatment approach," said Dr. Bardot. "This study also included a large group of AA men which have historically been underrepresented in clinical outcomes studies. This study demonstrated that Prolaris provided more accurate precision in providing prognosis in African American and non-African Americans equally."

The findings from the current study are consistent with the findings of an earlier study that demonstrated the ability of the Prolaris test in predicting cancer progression, as measured by both biochemical recurrence and metastatic disease, after radical prostatectomy. That prior study found that patients with a high Prolaris test score had a six-fold higher risk of developing metastases compared to low risk patients.

Based on the strength of the data from these two outcomes studies, Myriad has added risk of metastases to the Prolaris test report for clinicians, making Prolaris the first and only genetic test to provide this endpoint as validated by two outcomes studies.

"Myriad Genetics is committed to innovation and being the leader in genetic testing for men diagnosed with prostate cancer," said Michael Brawer, M.D., senior vice president of Medical Affairs, Myriad Genetic Laboratories. "We have multiple outcome studies that show the ability of Prolaris to predict the 10-year risk of prostate cancer specific mortality, and we now have two studies that predict the risk that treatment will fail and men will end up with metastatic disease. We are excited to provide all of this relevant information in a single test report for clinicians."

Follow Myriad on Twitter via @MyriadGenetics and stay informed about symposium news and updates by using the hashtag #AUA17. Details of the presentation at AUA follow.

## **Featured Presentation**

**Title:** Evaluating the Prognostic Utility of the CCP Score for Predicting Prostate Cancer Aggressiveness in African American Men

**Presenter:** Steven Bardot, M.D., Ochsner Medical Center **Date:** Saturday, May 13, 2017: 7:00-9:00 a.m. ET. **Location:** Moderated Poster MP28-19; Room 253AB.

## About Prolaris<sup>®</sup>

Prolaris is a novel 46-gene RNA-expression test that directly measures tumor cell growth characteristics for stratifying the risk of disease-specific mortality in patients with prostate cancer. Prolaris provides a quantitative measure of the RNA expression levels of genes involved in the progression of tumor growth. Low gene expression is associated with a low risk of disease-specific mortality in men who may be candidates for active surveillance and high gene expression is associated with a higher risk of disease-specific mortality in patients who may benefit from additional therapy. For more information visit: <a href="https://www.prolaris.com">www.prolaris.com</a>.

### **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.

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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 Prolaris data being presented at the at the American Urological Association's 2017

Annual Meeting being held May 12-16, 2017 in Boston, Mass.; the utility of the Prolaris<sup>®</sup> test to accurately predict the 10year risk of metastases in men treated for prostate cancer; the ability of the Prolaris test to significantly predict which men are likely to develop metastatic disease, regardless of race, risk group or treatment approach; 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 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, 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 patentinfringement 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 Annual report on Form 10-K for the fiscal year ended June 30, 2016, 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.

Investor Contact: Scott Gleason (801) 584-1143 sgleason@myriad.com