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Myriad Validates Active Surveillance Threshold With Prolaris(R) for Men With Prostate Cancer

Additional Data Show Prolaris Changed Treatment Plans in 48 Percent of Cases

SALT LAKE CITY, May 15, 2015 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (Nasdaq:MYGN) today presented clinical data for its Prolaris test at the 2015 American Urological Association (AUA) Annual Meeting being held May 15 to 19 in New Orleans, La. The results highlighted and underscored the significant ability of the Prolaris test to help physicians improve care for men diagnosed with prostate cancer.

In this pioneering study, Myriad presented important new clinical validation data that establishes an active surveillance (AS) threshold for men with localized prostate cancer. Specifically, the AS threshold is a composite of the Prolaris test score and clinicopathologic features. In the validation data featured at AUA, the pre-defined AS threshold was evaluated in 765 conservatively managed men, and the clinical endpoint was 10-year risk of prostate cancer mortality. The results showed that at the AS threshold, the predicted 10-year survival rate of prostate cancer patients was 97 percent. Conversely, there was a three percent risk of 10-year, prostate-specific mortality. Importantly, however, there were no observed prostate cancer-specific deaths over 10 years among men whose scores fell below the AS threshold.

Additionally, a separate analysis of 4,218 patients was performed to determine what percentage of patients who were clinically tested with Prolaris would be candidates for active surveillance based on the validated AS threshold. Of this commercial cohort, 36 percent qualified for active surveillance based on their clinical features alone. However, when the Prolaris test was added to the clinical risk assessment, 60 percent of these patients fell below the AS threshold, representing a significant increase in the total number of candidates who may be eligible for active surveillance.

Table 1: Analysis of Commercial Cohort (N=4,218)

	Clinical Features Alone	Prolaris + Clinical Features "AS Threshold"	% Increase
Number of Men Eligible for AS	n=1,518 (36 percent)	n=2,530 (60 percent)	n=1,012 (24 percent)

"Active surveillance is an important treatment option for men with prostate cancer. The Prolaris active surveillance threshold represents a significant change in the treatment of prostate cancer because it provides valuable mortality prognostic information at the time of diagnosis," said Michael Brawer, M.D., vice president of Medical Affairs, Myriad Genetic Laboratories. "Men whose combined Prolaris Scores and clinicopathologic features fall below the AS threshold can have confidence that active surveillance is an appropriate option for them instead of surgery, radiation or chemotherapy."

PROCEDE 1000 Final Analysis

In a podium presentation, Neal Shore, M.D., medical director at Carolina Urologic Research Center, presented the final results from PROCEDE 1000, the largest prospective clinical utility study to measure the impact of the Prolaris test on the treatment of men with localized prostate cancer. The analysis of 1,206 patients demonstrated that physicians changed their treatment plans in 48 percent of cases after receiving the Prolaris test results. Of these changes, 72.1 percent were reductions in treatment, and 26.9 percent were increases in treatment.

"We are very impressed by these real-world data. Prolaris does what it is designed to do: help physicians determine the aggressiveness of prostate cancer and thus personalize treatment plans for their patients based upon that information," said Dr. Shore. "Men with a high Prolaris Score, who are at high risk of disease-specific mortality or recurrence, are receiving more aggressive treatment, which should help save more lives. Meanwhile, more patients with a low Prolaris Score are receiving active surveillance, which spares them from the side effects frequently associated with more aggressive treatments."

About Prolaris®

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 prostate cancer patients. 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, see our digital media kit at www.myriad.com/media-kit/aua15 or visit: www.prolaris.com.

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 initiatives to grow existing markets, diversify through the introduction of new products, including companion diagnostics, and expand internationally. For more information on how Myriad is making a difference, please visit the Company's website: www.myriad.com.

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 presentation of new clinical data on Prolaris at the AUA 2015 meeting; the ability of the Prolaris test to help physicians improve care for men diagnosed with localized prostate cancer; the ability of Prolaris to set a new standard of care for prognostic genetic testing in men with localized prostate cancer**;** 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 or will not continue to increase at historical rates; risks related to our ability to transition from our existing to new testing services, including unexpected costs and delays; risks related to decisions or 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 in our most recent 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. 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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