

June 1, 2018

# Myriad Genetics Presents Second Pivotal Validation Study for riskScore™ Test at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

riskScore Provides Women Who Test Negative for Hereditary Breast Cancer Mutations Definitive Information about their 5-Year and Lifetime Risk of Breast Cancer

SALT LAKE CITY, June 01, 2018 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced that results from a second major clinical validation study of its polygenic riskScore™ test will be featured in an oral presentation at the 2018 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, III.

riskScore is an innovative test that combines 86 DNA variants with a person's family and medical history, to determine a woman's five-year and lifetime risk of breast cancer. The key finding from this prospective clinical trial is that the riskScore test can accurately predict the five-year and lifetime risk of breast cancer in women who test negative for a hereditary mutation using the myRisk<sup>®</sup> Hereditary Cancer test.

"Women who undergo hereditary cancer testing and test negative for mutations in known breast cancer genes, frequently still have questions about their risk of breast cancer," said Johnathan Lancaster, M.D. Ph.D., gynecologic oncologist and chief medical officer, Myriad Genetics. "riskScore answers many of those questions by providing a definitive risk determination with a test that has been highly validated."

In March, *MIT Technology Review* magazine named riskScore as one of the top 10 Breakthrough Technologies for 2018. riskScore currently is available for women of European descent and who receive a negative myRisk Hereditary Cancer test result. However, every patient tested with the myRisk Hereditary Cancer test, regardless of ethnicity, will receive their lifetime breast cancer risk estimates according to Tyrer-Cuzick, which is a model that estimates risk based on family history and clinical features. Myriad is working to expand the riskScore test to other ethnicities in the future.

A summary of the oral presentation appears below and more information about the company's presentation can be found on the <u>ASCO website</u>. Follow Myriad on Twitter via @MyriadGenetics and stay informed about symposium news and updates by using the hashtag #ASCO18.

### myRisk® Hereditary Cancer with riskScore™ Oral Presentation

**Title:** Validation of a combined residual risk score for healthy unaffected women presenting to breast cancer screening centers.

Presenter: Kathryn Dalton, DO, Cape Cod Healthcare.

Date: Sunday, June 3, 2018, 8:00—11:00 a.m.

Location: Oral Presentation, 1507

The objective of this study was to independently validate the riskScore test in a prospective, general patient population. riskScore is a novel test that combines data from the Tyrer-Cuzick model with genetic markers, called single nucleotide polymorphisms (SNPs), to comprise a combined risk score that accounts for clinical, familial and genetic variables. The study included 518 women: 256 women recently diagnosed with breast cancer and 262 unaffected women (controls). The results show that riskScore is a highly statistically significant predictor of the 5-year and lifetime risk of breast cancer (p=2.6x10<sup>-12</sup> and p=2.5x10<sup>-12</sup>, respectively). Moreover, riskScore was statistically significantly superior to Tyrer-Cuzick alone for both 5-year and lifetime risk of breast cancer (1.9x10<sup>-8</sup> and p=2.4x10<sup>-8</sup>, respectively), underscoring the independent contribution of the SNPs to the combined test score. Importantly, a separate analysis of the 86 SNPs in the controls showed that about half of those women tested had an increased risk of breast cancer compared to the general population (Graph 1).

# **Graph 1: Breast Cancer Risk Profile of Unaffected Women**

Graph 1 is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/96cfd16a-482b-44c4-95f5-60476f99a648.

"Individually, the 86 DNA variants may have a small effect on breast cancer risk. However, this study shows that when you combine them, it is possible to more accurately predict a woman's risk of breast cancer versus relying on family history and clinical features alone," said Kathryn Dalton, DO, lead investigator, and breast surgeon at Cape Cod Healthcare General and Specialty Surgery in Hyannis, MA. "Importantly, this genetic information can be used to identify those women who are at normal risk and can be followed with routine screening and those who are at higher risk and may benefit from additional monitoring."

These results from this new study add to the growing body of evidence in support of riskScore. In December 2017, the <u>first major clinical validation study</u> of the combined clinical risk score (riskScore + Tyrer-Cuzick) was presented at the San Antonio Breast Cancer Symposium. In September 2017, the <u>validation of the SNP genetic markers</u> in more than 17,000 patients was presented at 36th Annual Conference of the National Society of Genetic Counselors.

#### About riskScore™

riskScore is a new clinically validated personalized medicine tool that enhances Myriad's myRisk<sup>®</sup> Hereditary Cancer test. riskScore helps to further predict a women's lifetime risk of developing breast cancer using clinical risk factors and genetic-markers throughout the genome. The test incorporates data from more than 80 DNA variants, called single nucleotide polymorphisms, identified through 20 years of genome wide association studies in breast cancer and was validated in Myriad's laboratory to predict breast cancer risk in women of European descent. This data is then combined with a best-inclass family and personal history algorithm, the Tyrer-Cuzick model, to provide every patient with individualized breast cancer risk.

# About Myriad myRisk® Hereditary Cancer

The <u>Myriad myRisk Hereditary Cancer</u> test uses an extensive number of sophisticated technologies and proprietary algorithms to evaluate 28 clinically significant genes associated with eight hereditary cancer sites including: breast, colon, ovarian, endometrial, pancreatic, prostate and gastric cancers and melanoma.

## **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 five strategic imperatives: stabilizing hereditary cancer revenue, growing new product volume, expanding reimbursement coverage for new products, increasing RNA kit revenue internationally and improving profitability with Elevate 2020. For more information on how Myriad is making a difference, please visit the Company's website: <a href="https://www.myriad.com">www.myriad.com</a>.

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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 the results from a second major clinical validation study of the Company's polygenic riskScore™ test being featured in an oral presentation at the 2018 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, III.; the Company's work to expand the riskScore test to other ethnicities in the future; 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 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 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 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 most recent Annual Report on Form 10-K, 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.

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