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Study Finds Wide Gap in Quality of BRCA1/2 Variant Classification Between Myriad Genetics and A Common Public Database

26 Percent Discordance Rates Observed in Public Databases

SALT LAKE CITY, April 17, 2017 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (NASDAQ:MYGN), a leader in molecular diagnostics and personalized medicine, today announced that new data comparing *BRCA1* and *BRCA2* variant classifications between Myriad Genetics and a commonly used public genetic database was published in the journal The Oncologist.[1] A key finding was that the public database provided discrepant variant classifications more than 26 percent of the time, which can introduce uncertainty and diminish patient care.

The study, done in collaboration with William Gradishar, M.D., from the Feinberg School of Medicine at Northwestern University, evaluated 4,250 *BRCA1* and *BRCA2* variants. Overall, 73.2 percent of variant classifications analyzed were fully concordant, while 26.7 percent were not. Most of the discordant classifications had definitive classifications of pathogenic or benign from Myriad, compared to "variant of uncertain significance" (VUS) classifications in the public database.

"The high degree of discordance seen in this study signals a cautionary note. As a repository of actual patient results, it means that different labs are providing different results to patients for the same genetic mutation. By definition, this means that some patients are receiving incorrect results that may have life-changing or -threatening implications," said Dr. Gradishar. "The discordance observed within these databases between labs also highlights why public databases do not accommodate the consistent standard of variant classification needed for clinical use. Although efforts are underway to resolve the quality problems within public databases, it is unlikely the issue will be resolved soon and users of public databases likely will continue to encounter discrepancies. At this time, labs should not use public databases in any way in clinical variant classification."

These findings are consistent with previously published studies. A study by Vail et al. compared the interpretation of more than 2,000 BRCA1/2 variants among five public databases and found substantial disparity of variant classifications among and within publicly accessible variant databases.[2] For VUSs in particular, there is no agreement once the variant is observed in a least four of the five databases in this study. Another study by Balmana et al. assessed conflicting interpretations of genetic variants in the Prospective Registry of Multiplex Testing (PROMPT) and found significant conflicting interpretations of genetic variants in that database.[3] Specifically, among variants entered into the PROMPT registry database with classifications from multiple labs, 26 percent had discrepant classifications; 36 percent of which would affect patient management.

"There are important clinical implications concerning the high VUS and discordance rates observed in public databases," said Johnathan Lancaster, M.D., Ph.D., chief medical officer, Myriad Genetic Laboratories. "Dr. Gradishar's findings reinforce the need for clinical laboratories to invest in meticulous research so that patients can receive the appropriate medical interventions. Over the past 25 years, Myriad has made substantial investments and published more than 8,000 definitively classified variants in peer reviewed publications as well as the details of our variant classification programs to advance the science of variant classification."

A recent study published by Kurian et al. showed that many surgeons manage patients with BRCA1/2 VUS the same as patients with BRCA1/2 pathogenic mutations and that half of average-risk patients with VUS undergo bilateral mastectomy.[4] The analysis by Gradishar et al. found that in cases where other commercial laboratories had a VUS classification in the database, 40 to 60 percent of these variants have a definitive classification (pathogenic or benign) by Myriad, which may have helped to avoid many unnecessary surgeries.

Myriad's ability to more definitively classify genetic variants stems from its proprietary myVision™ Variant Classification Program and more than 25-years of experience.

"Variant classification is a complicated endeavour and multiple studies have shown that it matters when patients are tested by laboratories that have not invested in the necessary research but are dependent in part on public databases," said Dr. Lancaster. "Myriad is the unquestioned leader in genetic testing for hereditary cancers. Over the last 25-years, Myriad has

delivered millions of test results, which means the myVision program is based on the largest and most robust database in the industry to identify, classify, and assign clinical significance to genetic variants."

Key features of the myVision variant classification program include:

- Classification by industry-leading experts. The Myriad Variant Classification Program consists of a large and diverse team of scientists with hundreds of years of cumulative experience who determine the clinical significance of variants.
- Innovative and exclusive technologies. myVision employs cutting-edge statistical techniques developed after testing more than 500,000 patients. And, we continue to evaluate variants over time as new data and technology become available.
- Dramatically declining VUS rates. Myriad has reduced the *BRCA1/2* VUS rates from 40 percent to 1.6 percent, dramatically lower than any other laboratory.
- Reviewed by the U.S. Food and Drug Administration. as a part of the BRACAnalysis CDx premarket approval submission.
- Lifetime commitment to every patient tested. When a VUS is reclassified as clinically actionable in the future, an amended report will be made available to the patient, which is unique to Myriad's program.

Follow Myriad Genetics on Twitter via @MyriadGenetics to stay informed about news and updates about the Company.

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.

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 discrepant variant classifications in public databases and the resulting impact on patient care; the timing as to when this issue will be resolved; the likelihood that users of public databases will continue to encounter discrepancies; whether labs should be using public databases in any way in clinical variant classification; the implications concerning the high VUS and discordance rates observed in public databases; 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 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 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.

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[1] Gradishar W, Johnson K, Brown K, et al: Clinical Variant Classification: A Comparison of Public Databases and a Commercial Testing Laboratory. *The Oncologist*. April 12, 2017. Accessed online at: http://theoncologist.alphamedpress.org/.

[2] Vail PJ, Morris B, vanKan A, et al: Comparison of locus-specific databases for BRCA1 and BRCA2 variants reveals disparity in variant classification within and among databases. *J Community Genet* 6:351-359, 2015.

[3] Balmana J, Digiovanni L, Gaddam P, et al: Conflicting interpretation of genetic variants and cancer risk by commercial laboratories as assessed by the Prospective Registry of Multiplex Testing. J Clin Oncol 34:4071-4078, 2016.

[4] Kurian A, Li Y, Hamilton A, et al: Gaps in Incorporating Germline Genetic Testing Into Treatment Decision-Making for Early-Stage Breast Cancer. April 12, 2017. Accessed online at: www.jco.org.

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