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Supreme Court of the United States to Hear Isolated DNA Patent Case

SALT LAKE CITY, Nov. 30, 2012 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (Nasdaq:MYGN) reported today that the Supreme Court of the United States granted *certiorari* agreeing to hear the case of *The Association for Molecular Pathology, et al., v. Myriad Genetics, Inc., et al* (Docket No. 12-398). The Supreme Court will review the earlier decision by the U.S. Court of Appeals for the Federal Circuit, which declared that Myriad's composition of matter claims covering isolated DNA of the BRCA 1 and BRCA 2 genes are patent-eligible under Section 101 of the United States Patent Act.

"Two previous decisions by the Federal Circuit Court of Appeals confirmed the patentability of our groundbreaking diagnostic test that has helped close to one million people learn about their hereditary cancer risk," said Peter Meldrum, President and CEO of Myriad Genetics. "Myriad devoted more than 17 years and \$500 million to develop its BRACAnalysis® test. The discovery and development of pioneering diagnostics and therapeutics require a huge investment and our U.S. patent system is the engine that drives this innovation. This case has great importance for the hundreds of millions of patients whose lives are saved and enhanced by the life science industry's products."

About Genetic Patents and Genetic Testing

The BRACAnalysis test detects the presence of the BRCA1 and BRCA2 genetic mutations that can help determine a patient's risk of breast and [ovarian cancer](#) and inform treatment options. Women who test positive using Myriad's BRACAnalysis have an 82 percent higher risk of developing [breast cancer](#) and a 44 percent higher risk of ovarian cancer in their lifetimes. The test is widely available for all women with a family history of cancer and is cost effective for both patients and the healthcare system. Approximately one million women have already benefited from taking the BRACAnalysis test.

Myriad supports research studies on BRCA1, BRCA2 and other genes. More than 18,000 scientists have studied the BRCAgenes and published more than 9,000 research papers, making these genes among the most widely researched genes in history. In addition, Myriad has facilitated research through a partnership with the National Institutes of Health and provided at-cost testing for nearly 6,000 researchers receiving NIH grants.

Health economic studies conclude that Myriad's genetic tests are fairly priced. Excerpts supporting this conclusion include the following:

- A study published in Genetics In Medicine noted, "Prices for *BRCA1* and 2 testing do not reflect an obvious price premium attributable to exclusive patent rights..."
- An Advisory Committee report to the Secretary of Health and Human Services stated, "...the per-unit price of the full-sequenced *BRCA* test, which often is cited as being priced very high, was actually quite comparable to the price of full-sequenced tests done on colon cancer, for which associated patents are nonexclusively licensed."

Additionally, Myriad has also established a Financial Assistance Program, which provides coverage at no charge to low-income patients who lack insurance. Over the past three years alone, more than 5,000 people have received free BRACAnalysis testing from Myriad. Approximately 95% of all patients in the United States have access to BRACAnalysis either through private insurance, Medicare or Medicaid. The average out-of-pocket cost to a patient is less than \$100.

Even though Myriad automatically retests all positive results to confirm the findings at no additional charge to the patient, second-opinion testing is also available for all patients. Since 1999, many laboratories have performed confirmatory and second-opinion testing. The NCBI Genetic Testing Registry lists seven laboratories in the United States that conduct second-opinion testing on the *BRCA 1* gene and six laboratories that test the *BRCA 2* gene.

About Myriad's Patent Landscape

Myriad's intellectual property for its BRACAnalysis® test is strong, with 24 issued patents and more than 500 claims. This provides Myriad with extensive patent protection through 2018.

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 genetic risk of developing disease, guide treatment decisions and assess risk of disease progression and recurrence. Myriad's portfolio of molecular diagnostic tests are based on an understanding of the role genes play in human disease and were developed with a commitment to improving an individual's decision making process for monitoring and treating disease. Myriad is focused on strategic directives to introduce new products, including companion diagnostics, as well as expanding internationally. 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 the potential impact this case and appeal will have on Myriad and its operations, as well as industry as a whole; the length and degree of the Company's patent protection through 2018; the success of Myriad in defending this case and appeal before the U. S. Supreme Court; 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 existing molecular diagnostic tests and companion diagnostic services may decline or will not continue to increase at historical rates; the risk that we may be unable to expand into new markets outside of the United States; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and companion diagnostic services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and companion diagnostic 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 companion diagnostic services and any future products are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with manufacturing our products or 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 healthcare payment systems; risks related to our ability to obtain new corporate collaborations 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 acquire; the development of competing tests and services; the risk that we or our licensors may be unable to protect the proprietary technologies underlying our tests; the risk of patent-infringement and invalidity claims or challenges of our patents; 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 in our most recent Annual Report on Form 10-K 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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