



April 7, 2014

## **Myriad Genetics Submits Premarket Approval to FDA for BRACAnalysis®**

### **BRACAnalysis to be Used as Companion Diagnostic for AstraZeneca's Olaparib**

SALT LAKE CITY, April 7, 2014 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (Nasdaq:MYGN) today announced that it has submitted the first module of a premarket approval (PMA) application to the Food and Drug Administration (FDA) for the use of BRACAnalysis® testing as a companion diagnostic with olaparib. Olaparib is an investigational, orally active poly-ADP ribose polymerase (PARP) inhibitor being developed by AstraZeneca.

"We believe an FDA-approved BRACAnalysis test will provide additional assurance that patients are receiving the most accurate test results and improve patient care by identifying candidates for treatment with olaparib," said Mark Capone, president of Myriad Genetics Laboratories. "Our PMA application for BRACAnalysis will provide the FDA with scientific data to evaluate the safety and effectiveness of BRACAnalysis as a companion diagnostic."

Consistent with the FDA's modular premarket approval process, Myriad submitted the first of four PMA modules and is working to submit the remaining modules according to a pre-specified plan. The modular approach allows FDA to review each module as it is received and provides Myriad with timely feedback from FDA in order to help resolve issues early in the review process.

"Our PMA submission is a milestone for Myriad and BRACAnalysis is one of the first laboratory developed tests submitted for FDA premarket approval," said Capone. "Our ability to navigate the regulatory process is benefitted by our extensive experience in testing 1.2 million patients and our commitment to high quality."

The collaboration between Myriad and AstraZeneca on olaparib began in 2007. Since then, the two companies have shared scientific insight and worked closely together to move cancer research forward. In 2012, Myriad made strides in developing BRACAnalysis as a companion diagnostic by retrospectively genotyping patients in a previously completed Phase 2 study of olaparib. This is a powerful example of how a companion diagnostic can advance the goals of personalized medicine by stratifying patients in a clinical trial.

#### **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's 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](http://www.myriad.com).

Myriad, the Myriad logo and Prolaris, Myriad myPath, Myriad myPlan, Myriad myRisk, are trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and foreign countries. MYGN-F, MYGN-G.

#### **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 an FDA-approved BRACAnalysis test providing additional assurance that patients are receiving the most accurate test results and improving patient care by identifying candidates for treatment with olaparib; the Company's PMA application for BRACAnalysis providing the FDA with scientific data to evaluate the safety and effectiveness of BRACAnalysis as a companion diagnostic; and the Company's strategic directives under the caption "About Myriad Genetics." These "forward-looking statements" are management's present 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 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 companion diagnostic services may decline or will not continue to increase at historical rates; risks related to changes in the governmental or private insurers reimbursement levels for our tests; 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 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; risks related to increased competition and the development of new competing tests 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; risks related to changes in intellectual property laws covering our molecular diagnostic tests and companion diagnostic 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 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.

CONTACT: Media Contact: Ron Rogers

(801) 584-3065

rrogers@myriad.com

Investor Contact: Scott Gleason

(801) 584-1143

sgleason@myriad.com