



October 24, 2014

## **Myriad Establishes Tumor BRACAnalysis CDx(TM) Laboratory in Europe**

### **Tumor BRACAnalysis CDx Will Identify More Patients for Treatment With PARP Inhibitors**

SALT LAKE CITY and ZURICH, Oct. 24, 2014 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (Nasdaq:MYGN) today announced it has established a Tumor BRACAnalysis CDx laboratory in Europe. Myriad's next-generation Tumor BRACAnalysis CDx test is a companion diagnostic that will identify up to 50 percent more patients with BRAC mutations who may benefit from treatment with PARP inhibitors, such as olaparib, compared to conventional germline testing alone.

Olaparib is a novel PARP inhibitor being developed by AstraZeneca. Earlier today, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended marketing authorization for olaparib as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. It is estimated that more than 22 percent of all ovarian cancer patients carry a deleterious germline or somatic mutation in the BRCA1 or BRCA2 genes and may benefit from olaparib therapy.

"BRCA mutation screening is critical in ovarian cancer patients to identify the subset of women who might benefit from PARP inhibitors," said Colin Hayward, M.D., European Medical Director at Myriad. "Tumor BRACAnalysis CDx testing is the best method for screening ovarian cancer patients because it detects both germline and somatic mutations, significantly increasing the total number of patients who may benefit from this life-saving drug."

More than eight years ago, Myriad pioneered the development of germline BRCA testing as a companion diagnostic for use with PARP inhibitors and other agents. The new Tumor BRACAnalysis CDx test will expand the reach of this important new therapeutic class to many more ovarian cancer patients. Tumor BRACAnalysis CDx will be widely available throughout all of Europe and testing will be conducted in the Company's laboratories in Munich, Germany. Key features of the Tumor BRACAnalysis CDx test are:

- Up to 50 percent additional BRCA-deficient tumors detected to more accurately identify patients who are candidates for therapy with olaparib;
- Expected 3 percent variant of uncertain significance (VUS) rate for BRCA1/BRCA2 mutations, ensuring a clearer management pathway for ovarian cancer patients;
- An average 14-day laboratory turnaround time, allowing physicians and patients to make critical treatment decisions.

Last month at the European Society for Medical Oncology (ESMO) annual meeting in Madrid, Spain, Myriad presented a study analyzing approximately 130 previously untreated, high-grade ovarian cancer patients for germline BRCA mutations in blood samples and somatic mutations in tissue samples. In the study, the researchers also tested patients undergoing surgery for both of these types of mutations. Of 92 patients who were tested for both germline and somatic markers, nearly 20 percent of patients were found to have germline mutations through a blood test. Meanwhile, testing with the Tumor BRACAnalysis CDx test identified all 20 percent of patients with germline mutations and an additional eight percent of patients with a somatic BRCA1/BRCA2 mutation, representing a 44 percent increase in the number of mutations identified.

"Several clinical studies have shown that the Tumor BRACAnalysis CDx test outperformed germline testing alone in terms of identifying more patients who are candidates for treatment with PARP inhibitors," said Hayward. "We believe these results combined with the positive CHMP recommendations for olaparib will open doors to a new era of personalized medicine for patients with platinum-sensitive ovarian cancer by helping target PARP therapy to the right patients."

#### **About Tumor BRACAnalysis CDx™**

Myriad's Tumor BRACAnalysis CDx is the most robust and accurate companion diagnostic test for identifying both germline (hereditary) and somatic (tumor) cancer-causing mutations in the BRCA1 and BRCA2 genes. Tumor BRACAnalysis CDx has undergone significant analytic validation and has been shown to identify up to 50 percent more patients with cancer-causing BRCA1/BRCA2 mutations compared to germline testing alone. Myriad is actively collaborating with leading pharmaceutical companies to develop Tumor BRACAnalysis CDx as a companion diagnostic for use with certain PARP inhibitors, platinum-based drugs and other chemotherapeutic agents. In the United States, the testing will be done at the Company's laboratory in Salt Lake City. In Europe, the test will be performed at the Company's laboratory in Munich.

## 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 websites: [www.myriad.com](http://www.myriad.com).

Myriad, the Myriad logo, BART, BRACAnalysis, Colaris, Colaris AP, myPath, myRisk, myRisk Hereditary Cancer, myChoice, myPlan Lung Cancer, BRACAnalysis CDx, HRD, Vectra and Prolaris are trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and foreign countries. MYGN-F, MYGN-G

## About Myriad Genetics GmbH

Myriad Genetics GmbH is based in Zurich, Switzerland and is the international subsidiary of Myriad Genetics Inc., 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. For more information on how Myriad Genetics GmbH is making a difference, please visit the Company's European website: [www.myriadgenetics.eu](http://www.myriadgenetics.eu).

## 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 launch of the Tumor BRACAnalysis CDx test in Europe; the Company's belief that the Tumor BRACAnalysis CDx test will identify up to 50 percent more patients who may benefit from treatment with olaparib compared to conventional germline testing alone; the estimate that 22 percent of all ovarian cancer patients carry a deleterious germline or somatic mutation in the BRCA1 or BRCA2 genes which would predict responsiveness to olaparib therapy; BRCA mutation screening testing being critical in ovarian cancer patients to identify the subset of women who might benefit from olaparib; Tumor BRACAnalysis CDx testing being the best method for screening ovarian cancer patients because it detects both germline and somatic mutations, significantly increasing the total number of patients who may benefit from this life-saving drug; the Tumor BRACAnalysis CDx test expanding the reach of this important new therapeutic class to many more ovarian cancer patients; the availability of the Tumor BRACAnalysis CDx test throughout all of Europe and testing being conducted in the Company's laboratory in Munich, Germany; the listed key features of the Tumor BRACAnalysis CDx test; the Company's belief that these results combined with the positive CHMP recommendations for olaparib will open doors to a new era of personalized medicine for patients with platinum-sensitive ovarian cancer by helping target PARP therapy to the right patients; and the Company's strategic directives under the captions "About Tumor BRACAnalysis CDx", "About Myriad Genetics" and "About Myriad Genetics GmbH. 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 pharmaceutical and clinical 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 or our ability to obtain reimbursement for our new tests at comparable levels to our existing tests; 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 we may not be successful in transitioning from our existing product portfolio to our new products, such as our myRisk Hereditary Cancer test, which represents the next generation of our existing hereditary cancer franchise; the risk that we may not be able to generate sufficient revenue from our existing tests and our new tests or develop new tests; the risk that licenses to the technology underlying our molecular diagnostic tests and pharmaceutical and clinical services and any future tests 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 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; 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; 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.

CONTACT: Media Contact:

Ron Rogers

(801) 584-3065

rrogers@myriad.com

Investor Contact:

Scott Gleason

(801) 584-1143

sgleason@myriad.com