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Myriad Genetics Expands Collaboration with AstraZeneca on Olaparib Phase 3 Clinical Trials

SALT LAKE CITY, Sept. 4, 2013 (GLOBE NEWSWIRE) -- Myriad Genetics, Inc. (Nasdaq:MYGN) announced today that it has entered into an expanded, nonexclusive global collaboration agreement with AstraZeneca to provide companion diagnostics for the olaparib Phase 3 clinical development program. Olaparib is an investigational orally active poly-ADP ribose polymerase (PARP) inhibitor being developed by AstraZeneca for the treatment of various tumor types including BRCA-mutated breast and ovarian cancers.

Under the expanded agreement, Myriad will build out a new laboratory within its Salt Lake City facility in accordance with U.S. Food and Drug Administration (FDA) regulations for companion diagnostic devices. In August, the FDA approved the Investigational Device Exemption (IDE) for BRACAnalysis® filed by Myriad, enabling clinical studies with olaparib to include BRACAnalysis testing as a companion diagnostic.

"We are excited to be expanding our companion diagnostic collaboration with AstraZeneca," said Peter D. Meldrum, president and CEO of Myriad. "We are working together to transform the future of personalized medicine and to deliver significant value for patients and the healthcare system, and we are committed to being a leader in companion diagnostics."

The collaboration builds on an existing agreement through which Myriad provided supply of BRACAnalysis to support the Phase 2 development program for olaparib in breast and ovarian cancers. Specific terms were not disclosed.

"Our hope is that the Phase 3 development program for olaparib will result in a new treatment option for patients suffering from BRCA-mutated ovarian and breast cancers, accompanied by a diagnostic to help physicians identify the patients for whom the therapy might be most appropriate," said Ruth March, vice president and head of Personalised Healthcare and Biomarkers at AstraZeneca. "Myriad is well positioned to provide high quality BRCA mutation testing services and the infrastructure to offer testing to support therapy choices."

Olaparib is a novel investigational PARP inhibitor that induces synthetic lethality in homozygous BRCA-deficient cells. Phase II clinical data presented at ASCO 2013 demonstrated that patients with BRCA mutated ovarian cancers received the most clinical benefit from maintenance treatment with olaparib. BRACAnalysis is the gold standard diagnostic test to confirm the presence of a BRCA gene mutation.

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 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.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.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 the success, completion and regulatory approval of the expanded collaboration with AstraZeneca to provide BRACAnalysis testing as a companion diagnostics for the olaparib Phase 3 clinical development program; the build out of a new laboratory within the Company's Salt Lake City facility in accordance with U.S. Food and Drug Administration (FDA) regulations for companion diagnostic devices to supply BRACAnalysis testing; 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.

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