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CareDx and Allegheny General Hospital Launch Research Study of Novel Test to Screen Heart Transplant Recipients for Signs of Rejection

BRISBANE, Calif. and PITTSBURGH, July 31, 2014 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq:CDNA) a molecular diagnostics company focused on the development and commercialization of clinically differentiated, high value, non-invasive surveillance solutions for transplant recipients and Allegheny General Hospital (AGH), a leading transplant center located in Pittsburgh, today announced the enrollment of the first patients in a clinical study to assess the usefulness of cell-free DNA technology in diagnosing rejection in heart transplant recipients.

This study, known as Donor-derived cell-free DNA Outcomes AlloMap Registry (D-OAR), will examine the heart transplant patient's blood for circulating DNA from the donor to determine whether the presence of this biomarker can assist in diagnosing rejection. The study is based on the premise that donor derived cell-free DNA is released from the heart cells in response to injury from rejection.

The D-OAR trial is a sub-study of the long-term Outcomes AlloMap Registry (OAR), a multi-center, multi-year outcomes study correlating serial AlloMap® scores with cardiac dysfunction and biopsy proven rejection in heart transplant recipients. The AlloMap test has been shown to aid physicians in determining a transplant patient's risk of acute cellular rejection without requiring the use of invasive endomyocardial biopsy.

"This is the first time that clinicians will prospectively observe in patients cell-free DNA research test results together with commercially available AlloMap scores," said James Yee, MD, PhD, Chief Medical Officer at CareDx, Inc. "These two solutions are anticipated to provide complementary useful knowledge. Donor derived cell-free DNA is expected to reflect the status of the transplanted heart while AlloMap gene-expression profiling reflects the activation of the recipient's immune system."

"Circulating donor-derived DNA in the blood may serve as an important biomarker for immune surveillance and significantly improve the way we diagnose rejection in heart transplant patients," said Manreet Kanwar, MD, a cardiologist with Allegheny General's Advanced Heart Failure and Transplantation program, and the principal investigator of the study.

Allegheny General is one of three initial transplant centers in the United States participating in the D-OAR study. About 20 heart transplants are performed at AGH annually and the institution plans to enroll 16 patients in the study each year.

One of the leading enrollment centers in the U.S. for the OAR trial, AGH has 34 patients in the AlloMap registry and has already enrolled eight patients in the D-OAR sub-study.

"Better, reliable, non-invasive solutions are needed to diagnose rejection in heart transplant patients," said Srinivas Murali, MD, Director of the Cardiovascular Institute at Allegheny Health Network, and co-investigator of the study. "Combining analysis of cell-free DNA with AlloMap test results can potentially not only improve our diagnostic capabilities, but also facilitate early treatment for patients who develop rejection in their transplanted heart."

There are approximately 2,000 new heart transplants recipients annually in the United States, and over 20,000 living heart transplant recipients with a mean life expectancy of more than 10 years.

About AlloMap®

AlloMap Molecular Testing is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment. AlloMap is performed in the CLIA-certified and CAP-accredited clinical laboratory at CareDx and has been commercially available in the United States since 2005. AlloMap was cleared by the U.S. Food and Drug Administration in 2008 and was CE marked for the European Union in 2011. Recommended use of AlloMap for heart transplant rejection surveillance is included in the International Society for Heart and Lung Transplantation (ISHLT) Guidelines for the care of heart transplant recipients, published in August, 2010: "Gene Expression Profiling (AlloMap) can be used to rule out the presence of ACR of grade 2R or greater in appropriate low-risk patients, between 6 months and 5 years after HT." These guidelines represent the worldwide standard for the care of heart transplant patients.

About CareDx

CareDx, Inc., based in Brisbane, California, is a molecular diagnostics company focused on the discovery, development, and commercialization of clinically differentiated, high-value, non-invasive diagnostic surveillance solutions for transplant recipients. The company has commercialized AlloMap, a gene expression test that aids clinicians in identifying heart transplant recipients with stable graft function who have a low probability of moderate/severe acute cellular rejection. For more information, please visit: www.CareDxInc.com.

About AGH

Allegheny General Hospital (AGH) is the flagship medical center of Allegheny Health Network, an integrated healthcare delivery system serving the western Pennsylvania region. Comprised of eight hospitals, the Allegheny-Singer Research Institute; a soon-to open medical mall; and a healthcare group purchasing organization, Allegheny Health Network is committed to excellence in patient care, medical education and research. The Network employs approximately 17,000 people, including more than 2,100 physicians on its medical staff and serves as a clinical campus for both Temple University School of Medicine and Drexel University College of Medicine. Boasting one of the premier cardiac programs in the United States, AGH was home to the first heart-valve replacement in Pennsylvania and one of the first heart transplants in the country. AGH's pioneering researchers designed the first suture-less heart valve, an innovation that doubled the patient-survival rate in the United States, and the program continues to foster new innovations in cardiac care through its robust research efforts.

Forward Looking Statements

This press release contains forward-looking statements including, but not limited to, statements regarding the conduct, results and impact of the D-OAR study, the development of a cell-free DNA based test for heart transplant rejection and the impact of such a test on patient care and patient outcomes. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward looking statements including CareDx's limited operating history and experience with developing and releasing new products; risks relating to new test development and commercialization, as well as other risks stated in CareDx's filings with the SEC located at www.sec.gov. CareDx disclaims any obligation to publicly update or revise any forward-looking statement to reflect events that occur or circumstances that exist after the date on which they were made.

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