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CareDx Announces New Clinical Data on AlloMap Score Variability and Service to Support Assessment of Long-Term Transplant Recipient Risk

BRISBANE, Calif., Oct. 15, 2015 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq:CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant recipients, today announced the availability of new data related to the use of AlloMap[®] Score Variability (AMV) to predict the risk of future clinically significant events in heart transplant recipients. The publication, "Performance of gene-expression profiling test score variability to predict future clinical events in heart transplant recipients," was released earlier this month by the journal *BMC Cardiovascular Disorders* and is now available online.

The concept of AMV was developed over the course of five years and began as an observation of low score variability among stable patients who did not experience rejection episodes¹. Following that observation, investigators hypothesized that AMV might also predict future clinical events².

The use of AMV to predict future clinical events has now been evaluated in two published studies. The current study was performed by investigators from the Cardiac Allograft Rejection Gene Expression Observational II Study (CARGO II) and describes the performance characteristics of AMV³.

"While the potential clinical utility of AlloMap score variability to predict clinical events has been noted in previous publications, this is the first study to generate negative and positive predictive values in a patient population," said Dr. Johan Vanhaecke, Professor of Cardiology at the University of Leuven, senior author of the publication. "We are excited to have a new tool that will help us to identify which patients are at risk of future clinical events and thereby adjust patient management strategies."

The primary endpoint in this retrospective, case-control study was an event of significant graft dysfunction, death from any cause, or re-transplantation. Patients selected from the CARGO II cohort were assigned to either the event (n=36) or control (n=55) group. Results demonstrated that lower AMV was associated with a lower risk of future events, while higher AMV was associated with a higher risk of future events.

"The core of our mission is to transform long-term patient care in transplantation," commented Peter Maag, CEO of CareDx. "The findings of this study highlight CareDx's dedication to that mission. AMV allows us to provide clinicians with new insights that may be of use to assess long-term clinical risk and personalize patient care."

CareDx will begin providing AMV reports from its CLIA laboratory for eligible patients on October 19, 2015 to all health care providers who request to receive this information.

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. CareDx is also pursuing the development of additional products for post-transplant monitoring of other solid organs that use a variety of technologies, including next generation sequencing, to detect donor-derived cell-free DNA to monitor the health of organs after transplantation. For more information, please visit: www.CareDx.com.

Forward Looking Statements

This press release contains forward-looking statements including, but not limited to statements regarding the Company's expectations regarding future potential, development and commercial activities. 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 new markets; risk relating to new partnerships and commercialization of those relationships, 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 statements to reflect

events that occur or circumstances that exist after the date on which they were made.

¹ Deng, et al. Low Variability of Intraindividual Longitudinal Leukocyte Gene Expression Profiling Cardiac Allograft Rejection Scores. *Transplantation*. 2010; 90(4): 459-461.

² Deng, et al. Utility of Gene Expression Profiling Score Variability to Predict Clinical Events in Heart Transplant Recipients. *Transplantation*. 2014; 97(6): 708-714.

³ Crespo-Leiro, et al. Performance of gene-expression profiling test score variability to predict future clinical events in heart transplant recipients. *BMC Cardiovasc Disord* 2015; 15: 120.

CONTACT: Media Contacts

Molly Martell

Senior Director, Marketing

T: +1 415-728-6307

E: mmartell@caredx.com

Investor Contact

Westwicke Partners, LLC

Leigh J. Salvo Principal

T: +1 415-513-1281

E: leigh.salvo@westwicke.com



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