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AlloSure Featured in Journal of the American Society of Nephrology

Cell-free-DNA test identifies active rejection in kidney transplant patients

BRISBANE, Calif., March 09, 2017 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq:CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant recipients, announces a ground-breaking publication:

A new report in the *Journal of the American Society of Nephrology* describes the performance of AlloSure®, a method of measuring donor-derived cell-free DNA (dd-cfDNA) in the blood of renal transplant recipients. Increased levels of dd-cfDNA detected using AlloSure are associated with active rejection of the allograft. Accurate and timely detection of allograft rejection and effective treatment are essential for long-term survival of renal transplants.

"The DART study evidence suggests that AlloSure, a non-invasive blood test, may enable more frequent, quantitative, and safer assessment of allograft rejection and injury. AlloSure, as part of a surveillance strategy, could help identify patients with ongoing organ injury," explains principal investigator, Daniel C. Brennan, M.D. at the Division of Nephrology, Washington University School of Medicine in St. Louis.

To investigate the use of AlloSure as a surveillance tool, the authors prospectively collected blood specimens from renal transplant patients at scheduled intervals and at the time of clinically indicated biopsies.

Key Findings of the Study:

- | AlloSure provides clear stratification of patients for probability of rejection
 - Active rejection patients showed median AlloSure levels at 1.6%
 - Antibody-mediated rejection patients showed median AlloSure levels at 2.9%
 - Non-rejection patients showed median AlloSure levels of 0.21%
- | AlloSure was superior to serum creatinine in identifying which patients had active rejection
- | Study centers applied different protocols of use and frequency of renal biopsies

Roy D. Bloom, M.D., Medical Director of Renal Transplantation at University of Pennsylvania Health System stated, "This is the first report to establish clinical performance characteristics for this emerging molecular biomarker in renal transplant patients with a now validated assay of dd-cfDNA in the largest (N =398 patients) prospective, multicenter observational study of dd-cfDNA. The study population is representative of the spectrum renal transplant recipients in the United States. We applied the Banff working group's international histopathology classification criteria to establish the reference cases of rejection. Elevations in AlloSure were found to be strongly correlated with active rejection, especially with antibody-mediated rejection (ABMR)." ABMR is increasingly recognized as the form of immune-mediated injury causing long-term graft loss.

James P. Yee M.D., Ph.D., Chief Medical Officer at CareDx, Inc. commented, "We're excited with this first publication from the DART study which clinically validates the performance of AlloSure. With this test, CareDx has delivered on its promise to provide a blood-based test that measures dd-cfDNA in transplantation to identify patients with active rejections. This progress was made possible by excellent collaboration from 14 major renal transplant centers and their patients who volunteered to participate in the study."

Here is a link to the abstract online:

<http://jasn.asnjournals.org/content/early/2017/03/08/ASN.2016091034.abstract>

NOTES FOR CITATION

"Cell-free DNA and Active Rejection in Kidney Allografts", by Roy D. Bloom, Jonathan S. Bromberg, Emilio Poggio, Suphamai Bunnapradist, Anthony Langone, Puneet Sood, Arthur Matas, Shikha Mehta, Roslyn B. Mannon, Asif Sharfuddin, Bernard Fischbach, Mohanram Narayanan, Stanley Jordan, David Cohen, Matthew Weir, David Hiller, Preethi Prasad, Robert N. Woodward, Marica Grskovic, John Sninsky, James P. Yee, and Daniel C. Brennan, for the Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Active Rejection in Kidney Transplant Recipients (DART) Study Investigators. (DOI: 10.1681/ASN.2016091034), published online in advance of the *Journal of the American Society of*

About the Journal of the American Society of Nephrology:

The Journal of the American Society of Nephrology (Print ISSN: 1046-6673; Online ISSN: 1533-3450) is an official publication of the American Society of Nephrology. JASN publishes highly competitive original manuscripts, brief reviews, and special articles in areas of basic and clinical science relevant to the broad discipline of nephrology. Subject matter appropriate for JASN includes, but is not restricted to, the following: cell biology; developmental biology; genetics; cell and transport physiology; hemodynamics and vascular regulation; immunology and pathology; pathophysiology of renal disease and progression; mineral metabolism and bone disease; clinical nephrology, epidemiology, and outcomes; dialysis; and transplantation. The editors encourage only the submission of meritorious research that will communicate important advances in the field of nephrology. The Journal of the American Society of Nephrology had an impact factor of 9.43 as of 2014.

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. 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.

CareDx, with its presence through Olerup, also develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs.

For more information, please visit: www.CareDx.com.

Forward Looking Statements

This press release contains forward-looking statements about our business, research, development and commercialization efforts including, but not limited to the development, commercialization, utility, performance and adoption of AlloSure. These forward-looking statements are based upon information that is currently available to us and our current expectations, speak only as of the date hereof, and are subject to numerous risks and uncertainties, including risk associated with successful research, development and planned commercialization of our technologies, that are described in our filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed by us with the SEC on March 29, 2016 and the Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016 filed by us with the SEC on November 14, 2016. Any of these may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. We expressly disclaim any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.

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