AlloSure™ Shows Promise to Detect Rejection in Transplant Patients with a Simple Blood Test

CareDx at the Forefront of Personalized Medicine in Transplantation

CareDx to hold Conference Call on June 13, 2016 at 4pm ET

BRISBANE, Calif., June 13, 2016 (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 patients, reported the first results of increased levels of donor-derived cell-free DNA (dd-cfDNA) with acute kidney rejection to the DART study clinical investigators attending the American Transplant Congress. The study demonstrated increased levels of dd-cfDNA in acute rejection using the non-invasive AlloSure™ assay.

The DART study (Circulating Donor-Derived Cell-Free DNA in blood for diagnosing Acute Rejection in Kidney Transplant Recipients) (NCT02424227) is a prospective, observational clinical study designed to collect prospective data on levels of dd-cfDNA in subjects with stable function of the transplanted organ, experiencing acute organ rejection and non-rejection organ injury as well as following changes in immunosuppressive treatment. The study, which included 14 transplant centers across the United States, entered 401 subjects and has already collected specimens from over 1,248 visits before enrollment was closed.

Levels of dd-cfDNA were measured using AlloSure, a proprietary, clinical-grade targeted next-generation sequencing (NGS) testing service that was developed and rigorously validated at CareDx's CLIA-CAP clinical reference laboratory following the comprehensive and detailed recommendations and guidelines for NGS laboratory procedures and bioinformatics analysis from professional societies and organizations. Based on the thorough analytical validity and first analysis clinical validation data, CareDx and the clinical investigators will prioritize pre-specified analysis plans and submit results for scientific peer-review. CareDx will engage with payors to ensure future access to this novel non-invasive test for transplant surveillance.

Daniel C. Brennan, MD, FACP, Alan A. and Edith L. Wolff Professor of Renal Diseases and the Director of Transplant Nephrology at Washington University School of Medicine in St. Louis, Missouri, said, "The DART study provides promising evidence from a prospective multi-center study for clinical validity of donor-derived cell-free DNA for non-invasive diagnosis of renal transplant rejection. I look forward to forthcoming results describing additional analyses of data."

James P. Yee, MD, PhD, Chief Medical Officer, said, "We deeply appreciate the participation of study subjects and dedicated clinical investigators. Results from this study will inform the design of an interventional clinical trial expected to begin later this year to address the critical unmet clinical diagnostic needs of kidney transplant patients."

Significant unmet clinical diagnostic needs remain in renal transplant care: i) approximately 20% of kidney transplants fail by 5 years, and the mortality rate in this population is approximately 37%, ii) over 20% of kidney transplants every year are re-transplants, and iii) approximately 20% of renal transplant patients die within 5 years despite having a functioning kidney transplant. The renal needle biopsies, though a mainstay for kidney transplant diagnosis of acute allograft rejection, are invasive and are compromised by sampling heterogeneity and subjective interpretation. Meanwhile, creatinine testing, though non-invasive and inexpensive, is non-specific and lacks sufficient sensitivity.

The consequence of non-optimal transplant diagnostics are significant; namely, a patient that returns to dialysis costs more than $70,000 per year. In addition, median annual Medicare overall cost of care for a beneficiary whose renal transplant failed was 500% more than the median annual overall cost of care for a beneficiary with a functioning transplant. Lastly, the potent immunosuppressive medications and chronic immunosuppression of transplant patients result in significant increases in infections and malignancies relative to a non-transplant population.

The samples and data from the DART study further expand the CareDx clinical study and registry archive that support ongoing and future efforts to increase the precision of care and improve overall management of organ transplant recipients.

In additional news, the Center for Medicare and Medicaid Services (CMS) has posted the preliminary gapfill rates submitted by each of the Medicare Administrative Contractor (MAC) regions on a state by state basis. The current median value would reduce the AlloMap® rate to $732 for 2017. “This is similar to the initial position taken by CMS in Q4 of 2016. Through communicating the potential impact on patient care, as well as the costs associated with testing, CareDx remains optimistic that this proposal will be reversed during the open comment period that runs through July 10th,” said Peter Maag, President and CEO, CareDx. “We remain committed to support transplant patients in providing novel, cost-effective diagnostic solutions.”

Conference Call Information:
Individuals interested in listening to the conference call may do so by dialing 1-855-420-0616 for domestic callers or 1-678- 304-6848 for international callers.
Please reference Conference ID 27585467. To listen to a live webcast, please visit the investor relations section of CareDx's website at: www.caredx.com.

A replay of the call will be available beginning June 13, 2016 at 4:00pm PT/ 7:00pm ET until 4:00 pm PT/ 7:00pm ET on June 14, 2016. To access the replay, dial 1-855-859-2056 or 1-855-859-2056 and reference Conference ID: 27585467. The webcast will also be available on CareDx's website for one year following the completion of the call.

About CareDx
CareDx, Inc., headquartered in Brisbane, California, is a global molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. The Company markets AlloMap®, a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate to severe acute cellular rejection. CareDx is pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure™, a next-generation sequencing–based test to detect donor-derived cell-free DNA after transplantation.

CareDx's, with its presence through Olerup AB, 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. Olerup SSP®, a set of HLA typing is used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation; and XM-ONE®, the first standardized test that quickly identifies a patient's antigens against HLA Class I, Class II or antibodies against a donor's endothelium. For more information, please visit: www.CareDx.com.

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Forward Looking Statements
*In addition to historical information, this press release contains forward-looking statements with respect to our business, research, development and commercialization efforts and anticipated future financial results. 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 risks related to our ability to complete diagnostic studies, including obtaining sufficient clinical samples and participation of clinical investigators in such studies, the timeline for completion of research efforts, development and commercialization of additional diagnostic solutions including cell-free DNA, which is a lengthy and complex process that may not be successful**, our dependence on Medicare for a substantial portion of our revenue, and our dependence on health insurers and other third-party payers to provide coverage for our current test and future tests, if any**. *These factors, together with those 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, 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.*