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CareDx Donor-Derived Cell-Free DNA Assay Selected to Support NIH-Funded CTOT-19 Clinical Trial for Transplant Patients

CareDx Proprietary Surveillance Solution to Provide Clinical Validity Information for Kidney Transplant Patients

BRISBANE, Calif., Sept. 14, 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 that its proprietary donor-derived cell-free DNA (dd-cfDNA) technology has been selected to be studied in a major National Institutes of Health (NIH)-sponsored multicenter study of clinical outcomes in kidney transplantation. The Clinical Trials in Organ Transplantation (CTOT) project is a cooperative research program sponsored by the National Institute of Allergy and Infectious Diseases (NIAID).

Earlier this year, preliminary evidence from CareDx sponsored studies was presented at the International Society of Heart and Lung Transplant (ISHLT) annual meeting and at the American Transplant Congress (ATC). Initial results demonstrated that dd-cfDNA increased prior to acute rejection events in transplanted hearts and kidneys, and decreased following courses of immunosuppressive drug regimens to treatment rejection.

"The collaboration between CTOT and CareDx to perform the dd-cfDNA assay on samples obtained from the CTOT-19 trial as a noninvasive biomarker for kidney transplant rejection has the potential to provide new information that could positively impact the care of kidney transplant recipients," said Dr. Peter Heeger, principal investigator of CTOT-19, Director of Transplant Research, member of the Immunology Institute and the Recanati Miller Transplant Institute at the Icahn School of Medicine at Mount Sinai in New York. Dr. Heeger and his colleagues are leading clinical research to better understand underlying cellular and molecular mechanisms involved in allograft rejection and tolerance, assess the utility of biomarkers in predicting long-term outcomes, and evaluate treatment strategies for transplant recipients.

"We are very excited to provide our dd-cfDNA assay as part of the NIH consortium Clinical Trials in Organ Transplantation study (CTOT-19) trial. This collaboration aligns with our mission to provide novel surveillance management solutions for patients," said James Yee, MD, Ph.D., Chief Medical Officer of CareDx.

The purpose of the CTOT-19 clinical trial is to evaluate whether taking infliximab, which blocks TNF-alpha, just prior to transplant surgery along with usual transplant medicines will protect the donated kidney from damage caused by TNF-alpha and help keep the transplanted kidney healthy for a longer period of time. The CTOT-19 study will also provide new evidence for the role of the novel dd-cfDNA biomarker to determine the current status and predict future outcomes of the transplanted kidneys.

About CTOT

The Clinical Trials in Organ Transplantation (CTOT) project is a cooperative research program sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). CTOT is an investigative consortium for conducting clinical and associated mechanistic studies that will lead to improved outcomes for transplant recipients. The purpose of these studies is to improve short and long-term graft and patient survival. For more information, please visit: <https://www.ctotstudies.org/>.

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. The Company is currently investigating a research use only donor-derived cell-free DNA-based test for heart transplant recipients. 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.

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