CareDx Presents Validation of AlloSure® at AACC Conference Session on Emerging Topics in Laboratory Medicine

BRISBANE, Calif., August 4, 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, presented on the analytical validation of AlloSure at the 68th American Conference on Clinical Chemistry (AACC) in Philadelphia, PA. The CareDx abstract at AACC was one of 22 selected for an oral presentation from over 800 submitted abstracts.

AlloSure is a clinical-grade proprietary Next-Generation Sequencing (NGS) based test to detect donor-derived cell-free DNA (dd-cfDNA) in solid organ transplant recipients. The analytical validation of AlloSure included all internal processes from sample accessioning to results reporting. The steps taken by CareDx for the analytical validation of AlloSure meet and exceed the recommended standards of several laboratory guideline groups, including the CLIA / CAP Guidelines, and NGS recommendations from professional groups, including the Association of Molecular Pathology (AMP), the American College of Medical Genetics (ACMG) and the European Society of Human Genetics (ESHG).

The NGS accuracy of AlloSure was evaluated using the only human genome reference material, RM8398, from the NIST Genome-in-a-Bottle program. Reference materials with known levels of cfDNA were obtained from Horizon Discovery to validate the performance of AlloSure to quantify dd-cfDNA. Linearity was confirmed with both samples from healthy volunteers and mock samples generated by mixing healthy volunteer plasma. The linear quantifiable range of AlloSure encompasses the range critical for clinical decisions. Throughout all validation experiments, AlloSure results are precise across the tested range.

At the AACC presentation, CareDx also described clinical validation results from paired biopsy & blood samples in transplant recipients. Studies have shown that AlloSure results discriminate between patient samples with and without allograft rejection.

“We are honored that the organizers and attendees recognize the importance of clinical-grade cell-free DNA testing,” says presenter Robert Woodward, PhD, Senior Director of R & D at CareDx. “The distinct focus on cell-free DNA as a biomarker with a wide range of applications is evident this year at AACC. I trust our research contributions will advance this biomarker, similar to AlloMap, toward the ultimate goal of improving the long-term health of transplant patients.”

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. CareDx offers 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 developing additional products for transplant monitoring using a variety of technologies, including AlloSure®, a proprietary next-generation sequencing–based test to detect donor-derived cell-free DNA (dd-cfDNA) 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. Olerup SSP® is a set of HLA typing tools used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. XM-ONE® is 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 the continued successful development and planned commercialization of AlloSure, 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.