NEWS RELEASE

# Landmark ADMIRAL Study Publication with CareDx's AlloSure Kidney is the First Long-Term Multicenter Prospective Clinical Validation for Routine Organ Transplant Surveillance

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ADMIRAL Study Shows AlloSure Detects Clinical and Subclinical ABMR and TCMR, and Predicts Long-Term Outcomes for Kidney Transplant Patients

AlloSure Showed 62% Improvement Over Standard of Care Serum Creatinine

SOUTH SAN FRANCISCO, Calif., Jan. 12, 2022 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq: CDNA) – The Transplant Company™ focused on the discovery, development, and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients – today announced the publication[1] of results from a large, multicenter prospective study showing that AlloSure® Kidney is an early and accurate measure of allograft injury in routine organ transplant surveillance, and is able to predict long-term graft survival outcomes.

The **ADMIRAL study**, Assessing AlloSure Dd-cfDNA Monitoring Insights of Renal Allografts With Longitudinal Surveillance (NCT04566055), monitored 1,092 kidney transplant patients, in a real-world setting, from seven transplant centers for up to three years using the AlloSure Kidney donor-derived cell-free DNA (dd-cfDNA) as part of the standard of care. The demographic characteristics of the study participants included a diverse population that is consistent with the U.S. adult population reported to the United Network of Organ Sharing (UNOS) registry, including 28% African American and 17% Hispanic patients.

The study results published in **Kidney International**[1] showed that AlloSure Kidney can be:

- Used in both subclinical and clinical rejection: Elevated AlloSure dd-cfDNA (≥0.5%) strongly correlated with clinical and subclinical allograft rejection ($p<0.001$).
- Predictor of de novo donor-specific antibody (dnDSA) formation: Elevated AlloSure dd-cfDNA ≥ 0.5% associated with a 271% increased risk of dnDSA development ($p=0.001$).
- Leading indicator of donor-specific antibodies: AlloSure dd-cfDNA was elevated 91 days (median) ahead of DSA identification.
- Superior to serum creatinine: AlloSure showed a 62% relative improvement over serum creatinine in identifying subclinical and clinical rejection (area under the curve [AUC] of 80% vs. 49% respectively).
- Used to identify estimated glomerular filtration rate(eGFR) decline: Persistently elevated AlloSure (>1 result above 0.5%) predicted a > 25% decline in eGFR over 3 years (HR 1.97, $p = 0.041$), while persistently low levels identify allograft quiescence.

“We are proud to continue to bring transplant innovation for patients, where AlloSure is now the first donor-derived cell-free DNA test to demonstrate clinical utility in prediction of de novo donor-specific antibody, and both subclinical and clinical rejection in a long-term study,” said Reg Seeto, CEO and President of CareDx. “ADMIRAL continues CareDx’s 20-year commitment to setting scientific standards through the investment in a prospective, multi-center study that followed over 1,000 patients that included a diverse sample set.”

“The results of the ADMIRAL study confirm that AlloSure Kidney is fundamentally changing transplant care by being an effective non-invasive service that can be used routinely in the surveillance setting to assess organ health,” said Matthew R. Weir, MD, Attending Physician and Director of the Division of Nephrology in the Department of Medicine at the University of Maryland Hospital, Baltimore. “The predictive value of the test along with its improvement over standard of care serum creatinine for rejection surveillance, makes AlloSure Kidney an invaluable tool for renal transplant physicians working to preserve donated kidneys and keep patients healthy and off dialysis.”

About CareDx – The Transplant Company

CareDx, Inc., headquartered in South San Francisco, California, is a leading precision medicine solutions company focused on the discovery, development and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers. CareDx offers testing services, products, and digital healthcare solutions along the pre- and post-transplant patient journey and is the leading provider of genomics-based information for transplant patients. For more information, please visit: **www.CareDx.com**.

Forward Looking Statements

This press release includes forward-looking statements related to CareDx, Inc., including statements regarding the potential benefits and results that may be achieved with AlloSure® Kidney on transplant patients and the value of ADMIRAL study. These forward-looking statements are based upon information that is currently available to CareDx

and its current expectations, speak only as of the date hereof, and are subject to risks and uncertainties that could cause actual results to differ materially from those projected, including risks that CareDx does not realize the expected benefits of AlloSure® Kidney or ADMIRAL study; general economic and market factors; and other risks discussed in CareDx's filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed by CareDx with the SEC on February 24, 2021, the quarterly report on Form 10-Q for the first quarter of 2021 ended on March 31, 2021 filed by CareDx with the SEC on May 5, 2021, the quarterly report on Form 10-Q for the second quarter of 2021 ended on June 30, 2021 filed by CareDx with the SEC on July 29, 2021, the quarterly report on Form 10-Q for the third quarter of 2021 ended on September 30, 2021, filed by CareDx with the SEC on October 28, 2021, and other reports that CareDx has filed with the SEC. Any of these may cause CareDx's actual results, performance, or achievements to differ materially and adversely from those anticipated or implied by CareDx's forward-looking statements. CareDx expressly disclaims any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.

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1. Bu L, Gupta G, Pai A, et al, Validation and clinical outcome in assessing donor-derived cell freeDNA monitoring insights of kidney allografts with longitudinal surveillance (ADMIRAL) study., Kidney International (2022), doi: **https://doi.org/10.1016/j.kint.2021.11.034**.