



NEWS RELEASE

CareDx Enrolls First Patient in LungCare Registry Study to Measure Impact of Multimodality Assessment on Lung Transplant Patient Outcomes

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1,000 Patient ALAMO Study will Evaluate the Clinical Utility of LungCare to Detect Transplant Infection and Rejection
SOUTH SAN FRANCISCO, Calif., Dec. 16, 2021 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq: CDNA) – The Transplant Company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers, today announced the enrollment of the first patient in the multicenter, observational, prospective ALAMO registry to improve lung transplant patient care.

The AlloSure Lung Assessment and Metagenomic Outcomes (ALAMO) registry will enroll 1,000 patients from lung transplant centers across the United States. The registry will follow patients using LungCare, which includes commercially available AlloSure[®] Lung, and research use of AlloMap[®] Lung, AlloID, and other complementary tests. AlloSure is a donor-derived cfDNA test which identifies organ injury, AlloMap is a gene expression test which identifies immune quiescence, and AlloID is a metagenomic infectious disease test which identifies more than 100 pathogens specific to organ transplant patients.

The ALAMO registry will examine CareDx's LungCare to inform biopsy and treatment decisions following lung transplantation. Its primary endpoints are three-year survival without chronic lung allograft dysfunction (CLAD) and three-year, severe infection-free survival.

"Multimodality diagnostics are transforming the transplantation landscape, giving physicians multiple measures of organ health to detect possible infection and organ rejection earlier than invasive biopsies alone," said Dr. Sham Dholakia, Chief Medical Officer at CareDx. "Lung transplant recipients have the highest unmet needs in all of transplantation, including the highest rates of one-year acute rejection and the lowest five-year survival rate at

approximately 50%.¹ LungCare will be the most comprehensive assessment of allograft health ever measured.”

While transbronchial biopsies, the current standard of care, are a valuable tool for monitoring allograft health, they carry a 10.8% rate of moderate to severe complications including hemorrhaging and collapsed lung.^{2,3} Risks are even higher for complications due to the increased COVID transmission risk for these patients on immunosuppressive medications.

“The ALAMO study is going to be the first real-world data to show the potential of multimodality testing as a new standard of care to improve lung transplant clinical outcomes,” said Ali Mansour, MD, Advanced Lung Failure and Lung Transplant at Montefiore Medical Center. “Given the ongoing COVID risk to lung transplant patients with suppressed immune systems, this non-invasive panel represents an important potential diagnostic breakthrough as we do everything in our power to help physicians avoid unnecessary biopsies.”

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 patient enrollment in ALAMO registry on LungCare, ALAMO registry’s examination of LungCare to inform biopsy and treatment decisions, and the potential benefits and results that may be achieved through ALAMO registry and LungCare, including AlloSure, AlloMap and AlloID. 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 the CareDx does not realize the expected benefits of ALAMO registry and LungCare, including AlloSure, AlloMap and AlloID; risks that CareDx fails to enroll 1,000 patients in ALAMO registry as planned; risks that ALAMO registry fails to examine LungCare as planned to inform biopsy and treatment decisions after lung transplantation; 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 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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References:

1. UNOS Organ Procurement and Transplant Statistics website. www.optn.transplant.hrsa.gov. Accessed online December 14, 2021
2. Glanville AR. Bronchoscopic monitoring after lung transplantation. *Semin Respir Crit Care Med*. 2010 Apr;31(2):208-21. doi: 10.1055/s-0030-1249117.
3. Trulock EP, Ettinger NA, Brunt EM, et al. The role of transbronchial lung biopsy in the treatment of lung transplant recipients. An analysis of 200 consecutive procedures. *Chest*. 1992 Oct;102(4):1049-54. doi: 10.1378/chest.102.4.1049.