



NEWS RELEASE

CareDx Announces Clinical Validation Results for AlloHeme™, the First AI-Powered NGS Surveillance Solution for AML and MDS Post-Cell Therapy

2026-02-12

AlloHeme Identified Cancer Relapse Earlier Than Standard Monitoring Methods in AML and MDS Patients Following Allogeneic HCT

Ultra-Sensitive, Non-Invasive Surveillance Solution Expected to Launch Commercially in the U.S. in 2027 as Part of CareDx's Transplant+ Precision Medicine Portfolio

BRISBANE, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA) — The Transplant Company™, a leading precision medicine company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers, today announced pivotal clinical validation results of AlloHeme™, a non-invasive, next-generation sequencing (NGS)-based, and artificial intelligence (AI)-powered monitoring test designed to predict relapse in patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) following allogeneic hematopoietic cell transplant (HCT). This approach enables the detection of emerging relapse signals earlier than traditional bone marrow-based or marker-specific methods, offering a universal, ultra-sensitive, blood-based surveillance solution for post-HCT AML and MDS patients. The data, generated as part of the ACROBAT study (NCT04635384), were presented at the 2026 Tandem Meetings and will also be reviewed alongside commercial launch plans during CareDx's investor webcast on February 12, 2026, at investors.caredx.com.

The successful clinical validation of AlloHeme represents a key milestone in CareDx's Transplant+ strategy, expanding the Company's precision medicine capabilities into cell therapy, hematology, and oncology by enabling highly sensitive, tumor-naive surveillance for relapse following HCT in patients with AML and MDS. By addressing a

major gap in post-HCT relapse monitoring for AML and MDS patients, this initiative broadens CareDx's impact beyond solid organ transplantation and into areas of growing clinical need.

"Cancer relapse remains a leading cause of mortality in patients with AML and MDS post allogeneic hematopoietic cell transplantation," said Dr. Jeff Teuteberg, MD, CareDx Chief Medical Officer. "AlloHeme represents the next wave of innovation within CareDx's Transplant+ strategy as we expand from solid organ transplantation into cell therapy, by providing clinicians with a highly sensitive, blood-based tool that can help identify relapse earlier. The ACROBAT data highlight the potential clinical value this test offers physicians, patients, and cell therapy centers. We are excited to bring this innovative technology to market in a capacity that only CareDx offers – alongside a full suite of patient and digital solutions for the cell therapy community."

The ACROBAT study is a prospective, multi-center, observational trial conducted across 11 U.S. transplant centers. The 24-month analysis included 198 evaluable subjects and 40 relapse events. AlloHeme demonstrated strong clinical performance, including 85% sensitivity and 92% specificity. This translated to a 95% negative predictive value, 79% positive predictive value, and an area under the curve of 0.89. The assay identified relapse a median of 41 days before clinical detection. At 6 months post-transplant, patients with positive AlloHeme results showed a 12-fold higher relapse risk compared to patients with negative AlloHeme results ($p < 0.001$). AlloHeme also demonstrated greater sensitivity and lead time than traditional standard of care testing, including more invasive bone marrow and multi-parameter flow cytometry (MFC-MRD), as reported by sites in the clinical trial.

"These data represent an important step forward in relapse surveillance for AML and MDS," said Dr. Ran Reshef, MD, MSc, Professor of Medicine at Columbia University and Director of Translational Research for the Blood and Marrow Transplantation Program. "AlloHeme offers a simple, effective strategy to identify high-risk patients early, potentially opening the door for preemptive interventions to prevent relapse and improve survival."

A Strategic Expansion into Cell Therapy

The introduction of AlloHeme represents a significant step in CareDx's Transplant+ strategic expansion into the cell therapy and hematologic malignancy market, where AML and MDS currently lack a highly sensitive and universally applicable commercial molecular monitoring solution. CareDx's Transplant+ strategy includes developing a suite of molecular tools for cell therapy, hematology, and oncology that span allogeneic HCT relapse detection and chimeric antigen receptor T-cell therapy (CAR-T) persistence monitoring.

CareDx anticipates a sequenced U.S. launch of AlloHeme beginning with CLIA readiness in 2026, followed by commercial introduction in 2027 and payer coverage anticipated in 2028.

About CareDx

CareDx is a precision medicine company dedicated to improving outcomes for transplant patients and advancing organ health. The Company's integrated solutions include non-invasive molecular testing for heart, kidney, and lung transplants; laboratory products; digital health technologies; and patient solutions that support care before and after transplant. CareDx 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 including statements regarding the potential benefits and results that may be achieved with AlloHeme. 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 AlloHeme, risks that the findings in the ACROBAT study supporting the data may be inaccurate, general economic and market factors, and other risks discussed in CareDx's filings with the Securities and Exchange Commission (the "SEC"), including, but not limited to, the Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed by CareDx with the SEC on February 28, 2025, the Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 filed by CareDx with the SEC on November 4, 2025, 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. You are cautioned not to place undue reliance on these forward-looking statements. CareDx expressly disclaims any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

CareDx, Inc.

Media

Natasha Moshirian Wagner

nwagner@CareDx.com

Investor Relations

Caroline Corner

investor@CareDx.com

Source: CareDx, Inc.