iMDx GraftAssure Assay Guides Use of Potentially Kidney-Graft-Saving Drug in New Lancet Group Publication

Jul 23, 2026

- Study published by Lancet Regional Health helps doctors manage new class of drugs for kidney transplant patients suffering organ rejection
- Serial monitoring of patients through donor-derived cell-free DNA (dd-cfDNA) testing helps to guide treatment decisions
- New study signals GraftAssure™ assay's market expansion opportunity as drugs to treat organ rejection work their way through clinical trials
- iMDx has received confirmation of Medicare reimbursement coverage for treatment response monitoring with dd-cfDNA testing

NASHVILLE, Tenn., July 23, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc. (Nasdaq: IMDX) ("iMDx") today highlighted the publication of a new study in The Lancet Regional Health – Europe, part of the Lancet Group, demonstrating the potential role of donor-derived cell-free DNA (dd-cfDNA) monitoring to help guide treatment decisions for kidney transplant patients.

This newly published study is an extension of the landmark Phase 2 felzartamab study published in the New England Journal of Medicine (NEJM) in 2024, which also utilized GraftAssure testing technology. That earlier study generated significant enthusiasm within the transplant community by demonstrating that CD38-targeted therapy may offer a promising new approach to treating antibody-mediated rejection (AMR) in transplant recipients. In that study, thanks to dd-cfDNA testing, researchers were able to clearly show therapeutic efficacy that the drug was working. It also represented the first study to show that AMR could be stopped, which is a landmark development for transplant patients around the world because AMR is a leading cause of kidney allograft failure.

Following the NEJM study, clinicians continued to follow these patients and relied on iMDx's flagship GraftAssure testing technology to monitor for AMR recurrence by treating the patient whenever they saw a signal suggestive of AMR. This data, recently published in Lancet Regional Health, supports iMDx's assertions that dd-cfDNA testing can be used to actively manage patients that are at the highest risk of losing their transplanted kidney. This can represent a significant market expansion opportunity over the current predominant use case for dd-cfDNA testing, which is to rule out the need for an organ biopsy.

"These findings further illustrate the expanding clinical utility of dd-cfDNA testing beyond rejection detection, potentially enabling more personalized management of kidney transplant recipients and rational drug usage," iMDx Chief Science Officer Prof. Dr. Ekkehard Schuetz said. "Although we are of course cautious in our interpretations of small cohort studies, we are excited that the use of our dd-cfDNA test resulted in sparing roughly two-thirds of the drug compared to unguided administration every

four weeks, which is economically beneficial and reduces the number of patient hospital visits required for drug infusion. We are also thrilled that the study establishes that a prolonged treatment guided by dd-cfDNA testing is safe and accompanied by long-lasting treatment success."

The newly published study leveraged iMDx's flagship GraftAssure™ testing technology. iMDx provided the dd-cfDNA measurements via GraftAssureCore, which is the company's lab-developed test. The company also sells research-use-only test kits and is seeking to offer GraftAssureDx, a kit intended for clinical use that is currently under FDA review. The company seeks to give clinicians around the world localized access to dd-cfDNA testing technology, which would help clinicians to more effectively treat AMR with this emerging class of drugs.

On a related note, and favorably, iMDx received confirmation of Medicare reimbursement coverage for kidney transplant rejection treatment response monitoring testing, meaning that coverage would be provided for the use case suggested by the new Lancet study. The confirmation came from MolDX, which is a program run by the Centers for Medicare & Medicaid Services, or CMS, specifically designed to review and decide under what conditions the U.S. government will pay for genetic and molecular tests. This reimbursement confirmation was received last week separately and in addition to the favorable Medicare coverage decision that supports commercial adoption of the iMDx GraftAssure assay portfolio more broadly.

About iMDx's GraftAssure technology

iMDx is at a pivotal stage in commercializing its GraftAssure technology, which iMDx expects to be an industry-transforming transplanted organ rejection monitoring test. The company aims to deliver proven, more affordable, faster tests that can be run in-house at local transplant center laboratories. iMDx has designed a molecular test that it can sell as a test kit to help enable transplant center laboratories to run tests locally and deliver critical test results far more quickly than the current send-out tests. The company is now seeking FDA marketing authorization to sell these kits to transplant centers in the U.S.

Over time, iMDx sees three potential paradigm shifts in transplanted organ health monitoring:

- Bringing testing closer to the patient: The first is a shift in where donor-derived cell-free DNA (dd-cfDNA) testing is performed – migrating out of centralized reference laboratories and into hospital-based laboratories capable of delivering results locally. The company seeks to demonstrate that in-house testing is better for patients and physicians. (As a reminder, dd-cfDNA is an established biomarker for assessing the health of a transplanted organ through a simple blood draw.)
- Expanding the clinical role of dd-cfDNA: The second is the growing potential for dd-cfDNA testing, powered by digital PCR technology, to support earlier detection of allograft injury, longitudinal monitoring of transplant health, and assessment of response to emerging anti-rejection therapies.
- Advancing from rule-out to comprehensive decision support: The third is a transition from the current rule-out-biopsy testing paradigm toward a more comprehensive rule-out and rule-in approach, enabled by GraftAssure's ability to measure both dd-cfDNA percentage and absolute, true concentrations as copies per milliliter of plasma.

iMDx Transplant Products and Product Candidates in Development

iMDx's flagship transplant testing technology quantifies a molecular biomarker known as donor-derived cell-free DNA (dd-cfDNA). The Company's scientists in Germany and the U.S. have played a critical role over the past decade in developing the science that helped establish dd-cfDNA as a trusted biomarker of

transplant rejection. iMDx is commercializing this technology using a market-disruptive business strategy. Under the GraftAssure™ brand, iMDx's transplant diagnostics include the following:

- GraftAssureCore – The company's laboratory-developed test (LDT), currently reimbursed by CMS and performed at iMDx's CLIA-certified laboratory in Franklin, Tennessee.
- GraftAssureIQ – A research-use-only (RUO) kit intended and labeled for non-clinical applications.
- GraftAssureDx – The in vitro diagnostic (IVD) kit currently under FDA review for use in clinical decision-making.

About Insight Molecular Diagnostics, Inc.

Insight Molecular Diagnostics is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. Investors may visit https://investors.imdxinc.com/ for more information.

Forward-Looking Statements

Any statements that are not historical fact (including, but not limited to, statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, the company's efforts to commercialize, and the market expansion opportunity for, its GraftAssure technology, expected FDA marketing authorization to sell GraftAssureDx, anticipated paradigm shifts in transplanted organ health monitoring, transplant and other product candidates in development, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management.

Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Insight Molecular Diagnostics' third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Insight Molecular Diagnostics or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Insight Molecular Diagnostics, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Insight Molecular Diagnostics' Securities and Exchange Commission (SEC) filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Insight Molecular Diagnostics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

FDA

CAUTION: This press release concerns certain products that are under clinical investigation, and which have not yet been cleared or authorized for marketing by the U.S. Food and Drug Administration. These products are currently limited by federal law to investigational use, and no representation is made as to the safety or effectiveness of these products for the purposes for which they are being investigated.

Investor Contact:

Douglas Farrell
LifeSci Advisors LLC
imdx@lifesciadvisors.com

Source: Insight Molecular Diagnostics Inc.