IMDX Supports AST and ASHI STAR Working Group's Call for Decentralized Transplant Monitoring

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- *American Journal of Transplantation* position paper also highlights value of absolute quantification of dd-cfDNA as a diagnostic marker, a key feature of iMDx's flagship GraftAssure™ family of assays

NASHVILLE, Tenn., Jan. 13, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today congratulated the STAR working group on its position paper in the *American Journal of Transplantation* in recognizing the need for decentralized organ health testing in the global transplant community.

Specifically, the publication states, "High-quality, standardized decentralized dd-cfDNA testing is the essential prerequisite for conducting real-world evidence-generating multicenter studies to establish the appropriate context of use for this promising assay."

"We completely agree with the working group's conclusion. It's high time that we give transplant centers the tools that they need to build guidelines and manage patients themselves," iMDx CEO Josh Riggs said. "Such a full-throated call for access to test kits is great for us as an indicator of pent-up industry demand for what we are building. We are also pleased with the positive details throughout the paper regarding absolute quantification and the potential value of having onsite testing. This conclusion directly aligns with iMDx's strategy and is supportive of our flagship GraftAssure family of assays."

STAR is a joint group between the American Society of Transplantation (AST) and the American Society for Histocompatibility and Immunogenetics (ASHI). AST and ASHI are the professional societies representing the clinicians and laboratories that serve the transplant community. STAR stands for **S**ensitization in **T**ransplantation: **A**ssessment of **R**isk. One of STAR's working groups focuses on dd-cfDNA, and this publication is a conclusion from that group.

"We congratulate the STAR working group's great position paper on the analytical validity of dd-cfDNA methods," iMDx Chief Science Officer Dr. Ekkehard Schuetz said. "It is clearly articulated that the future is a decentralized high-quality assay with transparent quality control, which will facilitate broader, faster, and more cost-effective access to dd-cfDNA as the most promising rejection biomarker that it is."

iMDx seeks to deliver the industry-leading molecular diagnostic test kit for clinical use that decentralizes access to organ health testing for kidney transplant patients. The company expects that enabling decentralized testing will deliver new value in the roughly $1 billion-plus addressable market for kitted transplant rejection testing. iMDx believes that decentralizing access to transplanted organ rejection

testing will bring care closer to the patient and help hospitals to operate more sustainably, as well as create a rapidly growing, high-margin, recurring business model.

Link to paper: https://www.sciencedirect.com/science/article/pii/S1600613525029508

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 Nashville.
- GraftAssureIQ – A research-use-only (RUO) kit intended and labeled for non-clinical applications.
- GraftAssureDx – The in vitro diagnostic (IVD) kit currently in development 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.

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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, demand for iMDx's products and what the company is building, the expectation that decentralized testing will deliver new value in the roughly $1 billion-plus addressable market for kitted transplant rejection testing, the belief that democratizing access to transplanted organ rejection testing creates a rapidly growing, high-margin, recurring business model, 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.

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