Real-World Evidence and Industry Momentum Builds for iMDx's Flagship GraftAssure Assay

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- Positive real-world head-to-head data on GraftAssure™ assay to be presented at the 39th European Immunogenetics and Histocompatibility Conference (EFI2026), April 21–24, 2026 in Edinburgh, Scotland
- Three posters to be presented at the 63rd European Renal Association (ERA) Congress, June 3–6, 2026 in Glasgow, Scotland
- Favorable real-world evidence poster to be presented at the American Transplant Congress (ATC), June 20–24, 2026 in Boston
- Unaudited first quarter 2026 cash balance of $29.4 million is in line with year-end and Q4 2025 conference call guidance
- Company to host fireside chat and one-on-one meetings with investors at Needham Virtual Healthcare Conference on Wednesday, April 15th

NASHVILLE, Tenn., April 14, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today announced that its industry conference schedule this spring will highlight new independent clinical data supporting its GraftAssure™ technology and support continued commercial and clinical engagement with the global transplant community.

The positive data presented on iMDx's flagship GraftAssure technology will be presented by independent researchers, at leading institutions from the U.S., U.K. and the E.U., at three large international congresses in immunogenetics, nephrology, and transplantation. The release of this data furthers the partnership that iMDx has leveraged with the international transplant community, allowing the company's partners to take control of their testing needs and deliver fast turnaround results.

"We are excited to help transplant centers get the tools they need to manage their patients," iMDx CEO Josh Riggs said. "And we are thrilled that independent researchers are starting to publish their own data using our assay."

At both EFI and ATC, beyond the respective GraftAssure data presentations, iMDx will have a strong exhibiting presence to drive additional participation in the company's GALACTIC registry study (U.S. only, described below) and use of GraftAssureIQ, the research-use-only version of its assay. The company will also be coordinating with top transplant physicians on future applications of GraftAssure, beyond kidney transplant rejection testing.

For context, iMDx is seeking to deliver the industry-leading molecular diagnostic test kit for clinical use that expands and improves access to organ health testing for kidney transplant patients. The company expects that enabling localized testing will deliver new value in the roughly $2 billion addressable market for kitted transplant rejection testing.

As detailed in the company's recent quarterly shareholder letter, iMDx submitted GraftAssureDx for regulatory review on March 25, 2026. GraftAssureDx represents, to iMDx's knowledge, the first ever kitted dd-cfDNA assay to be submitted to the FDA for regulatory review. As such, the submission to the FDA is following the Class II *de novo* pathway, which the FDA uses for new, moderate-risk medical devices that do not fall into a pre-existing category.

Separately Tuesday, iMDx issued a reminder that it would be hosting a fireside chat at the 25th Annual Needham Virtual Healthcare Conference on April 15, 2026. (Please see Webcast link below.) The company also reported a preliminary unaudited first quarter 2026 laboratory services revenue and a cash on hand update.

As a reminder, relative to the company's strategic goal of selling diagnostic test kits for clinical use, iMDx considers itself to be essentially "pre-revenue." The company recognized $32,000 in laboratory services revenue in the first quarter of 2026, which are contracted services performed at the request of select clients.

In addition, iMDx's unaudited first quarter ending cash balance, including restricted cash, of $29.4 million reflects approximately $24.6 million in net proceeds from the company's February registered direct financing, along with other cash inflows and outflows during the quarter. This is in line with the company's projections given on its March 26, 2026 quarterly conference call.

Attendance at 25th Annual Needham Virtual Healthcare Conference

On April 15th, Chief Executive Officer Josh Riggs and Chief Financial Officer Andrea James will attend the 25th Annual Needham Virtual Healthcare Conference.

Event: 25th Annual Needham Virtual Healthcare Conference
Presentation Date: April 15, 2026
Format: Virtual fireside chat and one-on-one meetings
Webcast: Click here

Investors wishing to book a meeting are encouraged to reach out to their Needham sales representative.

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, upcoming presentations and attendance by iMDx at industry conferences, the company's plans to deliver GraftAssureDx as an industry-leading molecular diagnostic kit for clinical use,the FDA's review of iMDx's submission of GraftAssureDx, the company's GALACTIC registry study, iMDx's preliminary financial results (including preliminary laboratory services revenue for the quarter ended March 31, 2026, and cash information as of March 31, 2026), and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management.

The company's preliminary unaudited first quarter 2026 revenue and cash amount at March 31, 2026, included in this press release are based on the management's initial analysis of results of operations for

the first quarter of 2026 and may be adjusted as a result of, among other things, completion of our review procedures. The company's consolidated financial statements for the first quarter of 2026 are not yet available, remain subject to completion of our review procedures, financial closing procedures and potential final adjustments and have not been reviewed by the company's independent registered public accounting firm. This financial information does not represent a comprehensive statement of the company's financial results for the first quarter of 2026 and are not necessarily indicative of future results. There can be no assurance that actual results will not differ from the preliminary estimates in this press release. The company expects to file its full financial results for its first quarter 2026 in due course, along with the filing of its Quarterly Report on Form 10-Q with the Securities and Exchange Commission.

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.

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 in development for use in clinical decision-making.

This press release concerns references to certain products which are under clinical investigation, and which have not yet been cleared 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.

Registry Study

The GALACTIC registry study (GraftAssure Lowering Allograft rejeCTIon by Combination) is designed to drive clinical adoption and build a scientific case for iMDx's unique combined score, which uses two independent measurements of dd-cfDNA. All participating registry centers will have an option to convert to in-house testing.

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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