iMDx Prepares for U.S. Commercial Launch of GraftAssureDx as Clinical Trial Nears Completion

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- GraftAssure™ technology adoption further broadens with 20 global transplant centers engaged by year-end 2025, including first Canadian site
- GraftAssureDx™ FDA IVD approval application 95% complete at year-end; expect full submission in coming weeks
- Accelerating planned UK CE mark and EU IVDR submission to first half 2026, following successful TÜV SÜD ISO 13485 stage 1 & 2 audit completions in Q4 2025
- Strong engagement from clinical community on GraftAssureCore™ kidney registry with 17 U.S. transplant centers now planning to send samples in 2026
- Management to be in San Francisco for meetings during "JPM Week," January 12 to 15, 2026

NASHVILLE, Tenn., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today provided a year-end business update regarding its commercial progress, its GraftAssureDx™ test kit clinical trial and planned *in vitro* diagnostic (IVD) *de novo* submission to the United States Food & Drug Administration (FDA), as well as its plans for additional regulatory submissions and registry study progress in 2026.

"We are very excited about 2026 and being on the cusp of our FDA submission. As we put GraftAssureDx software through its final paces in late November and early December, which involved rigorous quality control testing, we found minor issues that needed to be addressed. We are moving quickly to complete the trial and submit our data package," iMDx CEO Josh Riggs said. "We are driving toward making 2026 the year that transplant centers will regain control of their patient samples. With our partner Bio-Rad at our side, we're confident that we'll be able to meet domestic and global demand for in-house post-transplant management."

"We are very pleased with the iMDx team's progress and the innovative and collaborative nature of our relationship," said Bio-Rad Senior Vice President of Corporate Development Jonathan Seaton. "We are looking forward to welcoming GraftAssureDx as a valuable assay for the transplant industry that is enabled by Bio-Rad's best-in-class digital PCR portfolio."

iMDx seeks 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 $1 billion-plus addressable market for *kitted* transplant rejection testing.

Update on regulatory submission timelines

The company estimates that about 95% of the work for its FDA submission is complete, including GraftAssureDx kitted product design, development, technical transfer to manufacturing, and production, all under a regulated quality management system.

“The GraftAssure assays being run at pilot sites are performing exceptionally well, giving us high confidence in the clinical data being generated for the FDA,” iMDx Chief Science Officer Dr. Ekkehard Schuetz said. “Most of our major FDA submission work streams were completed by year-end. Our remaining items were related to the rigorous quality control process for newly developed regulated software. We are diligently working towards a submission to the FDA for IVD clearance, which includes our full clinical trial data package.”

In parallel to managing its FDA timeline, iMDx is also making rapid progress outside of the U.S., positioning the company well for continued growth beyond 2026. The company expects an accelerated submission for European regulatory authorization now in the first half of 2026 after having completed a successful audit from the certification body, TÜV SÜD. Such regulatory compliance supports market access in Europe.

Market expansion through clinical engagement and innovation

Since the company’s third quarter update in November 2025, iMDx has made steady progress in driving clinical community engagement, both through its GraftAssureIQ kitted assay pilot site program, and through promoting its novel registry utilizing the GraftAssureCore lab-developed test.

After welcoming another transplant center that is performing research with GraftAssureIQ, which is also the company’s first hospital in Canada, iMDx now has 20 global transplant centers engaged with iMDx regarding GraftAssure™ technology.

In transplant diagnostics, clinical registries also play an important strategic role by producing real-world evidence that translates into innovation in routine clinical practice, as well as supports stakeholder adoption and payer reimbursement.

Through the launch of its GraftAssure Lowering Allograft rejeCTIon by Combination, or GALACTIC, registry study, iMDx is making progress toward driving clinical adoption and building a scientific case for why digital PCR, which is natively quantitative, can enable use cases for dd-cfDNA testing beyond what’s currently on the market. To that end, iMDx recently established a multi-year target of engaging with 50 U.S. transplant centers to evaluate the clinical utility of its combined score. This combined score uses two independent measurements of dd-cfDNA, which the company believes improves the clinical performance of dd-cfDNA compared to currently available options.

Since November, iMDx has identified internal champions at 17 transplant centers, which have started the process to participate in the GraftAssureCore registry study. These centers represent nearly 10% of total U.S. transplanted organ volume. All participating centers have an option to convert to in-house testing.

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. In 2025, the company rebranded its VitaGraft assay (previously known as VitaGraft Kidney), which is a lab developed test (LDT), to GraftAssureCore. For purposes of this press release, references to GraftAssureCore shall be deemed to include the test previously marketed as VitaGraft.
- 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.

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, iMDx's anticipated U.S. commercial launch of GraftAssureDx, the company's regulatory submission timelines and progress, including iMDx's plans to submit GraftAssureDx for FDA review and the company's plans to submit for European regulatory authorization in the first half of 2026, the company's ability to meet domestic and global demand for in-house post-transplant management, anticipated continued growth beyond 2026, progress toward driving clinical adoption and building a scientific case for digital PCR, 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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