Insight Molecular Diagnostics Completes Key Milestones Advancing GraftAssureDx Toward FDA Submission

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- Three-site reproducibility study completed by Tampa General Hospital, Mayo Clinic, and Baylor Scott & White Health
- Sufficient clinical samples collected to support statistical analysis and FDA submission
- Company achieved final ISO 13485 certification on Feb. 26, enabling U.K. and E.U. regulatory submissions

NASHVILLE, Tenn., March 03, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc. (Nasdaq: IMDX) ("iMDx") today announced that in February the company completed several major milestones to support the GraftAssureDx™ test kit clinical trial for its planned in vitro diagnostic (IVD) De Novo submission to the U.S. Food and Drug Administration (FDA) and also received its ISO 13485 certification.

Beginning in 2026, 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 $2 billion-plus addressable market for regulated transplant rejection testing.

Milestones completed in February include the conclusion of the three-site reproducibility study for GraftAssureDx, performed at Tampa General Hospital, Mayo Clinic and Baylor Scott & White Health, the collection of what the company believes is sufficient clinical samples to execute its submission, and the receipt of ISO 13485 certification, described in more detail below.

The company is rapidly finishing the remainder of its internal analytical performance studies. Of the approximately 12,000 instrument and assay cycles needed to support the FDA submission package, about 340 remain.

The IVD submission can be broken down into two categories – (1) the clinical validation studies that happen at the clinical trial sites, and (2) the internal analytical performance studies, performed at the company's Nashville laboratory.

On the clinical validation, iMDx has received what it believes should be sufficient clinical samples to execute the FDA submission. Our clinical trial site partners are continuing to collect and test those patient samples, as well as perform patient biopsies to confirm that the assay performed as it should. We are pleased with the level of engagement at these major transplant hospitals and are working closely with our site partners to move as efficiently as possible, recognizing that certain clinical activities remain outside of our direct control.

A reproducibility study at three clinical trial sites, Tampa General Hospital, Mayo Clinic, and Baylor Scott & White Health, is also part of our analytical validation. This reproducibility study was finished at the clinical trial sites on February 23, representing the conclusion of a major milestone.

“Our clinical trial sites have now collected the needed number of samples to finalize the clinical trial part for our FDA submission, based on the projected 25% to 30% organ rejection rate, and those results are being gathered at the sites,” said iMDx Chief Science Officer Dr. Ekkehard Schuetz. “This combined with the reproducibility study conclusion represents two major milestones, and we are thrilled about the collaboration with our clinical partners to help us achieve our goal of finalizing our de-novo submission.”

Regarding internal analytical performance studies, as noted above, we are working diligently to complete the large-scale precision and repeatability study using our final IVD software combined with the finalized Bio-Rad equipment and reagents.

“We feel confident about every IVD work stream that is within our control, and we are very close to executing our submission to the FDA,” said iMDx Chief Technology Officer Johnson Chiang. “We are proud of our team’s ability to manage complexity and coordinate with multiple stakeholders, including our kit manufacturer, software vendor, the clinical trial sites, and Bio-Rad, which has also been working tirelessly to support a timely submission.”

Preparing for global manufacturing, it is also worth noting that achieving ISO 13485 means that our independent European auditor, TÜV SÜD, has certified that iMDx runs its operations under a disciplined, *regulator-aligned* quality management system. We believe that this certification showcases reduced risk of surprises in the FDA review, as well as reduced quality risk regarding future manufacturing and commercialization.

The ISO13485 certification at the end of February also immediately paves the way for an IVD submission in the U.K., which then will be followed by an IVD-R submission for the EU during 2026, which is also already in preparation.

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.

GraftAssureCore™,GraftAssureIQ™, GraftAssureDx™, VitaGraft™, GraftAssure™, DetermaIO™, and DetermaCNI™ are trademarks of Insight Molecular Diagnostics Inc.

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 expected FDA submission, future plans to submit in the UK and EU, anticipated added value of the Company's GraftAssureDx kit to the roughly $2 billion-plus addressable market, future manufacturing and commercialization 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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