IMDX Enrolls First Patient in GraftAssureDx Clinical Trial and Welcomes New Hospital Participants

Sep 08, 2025

- **iMDx's ClinicalTrials.gov listing now names 10 leading transplant centers, up from 5 previously**
- **GraftAssureDx remains on track for FDA submission by end of 2025, commercial launch in 2026**

NASHVILLE, Tenn., Sept. 08, 2025 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics, or iMDx, (Nasdaq: IMDX), today announced that it is actively enrolling patients in its clinical trial to assess GraftAssureDx and that last week, it enrolled the first patient. In addition, the official clinical trial listing now names 10 leading transplant centers, up from five previously.

The ongoing clinical trial is an important step toward obtaining regulatory authorization to deliver an organ transplant rejection monitoring test kit to the estimated $1 billion addressable market for kitted transplant rejection testing.

The goal of this observational study is to determine that the GraftAssureDx kitted test can assess rejection in kidney transplant recipients. The company anticipates enrolling up to 125 patients and completing the trial by year-end.

"We are proud of our momentum at the start of this study as well as the top-tier roster of sites participating," said iMDx CEO Josh Riggs. "I would also like to congratulate iMDx Chief Science Officer Prof. Dr. Ekkehard Schuetz and our clinical team for their diligence and timeliness in initiating this study. The first patient was enrolled on September 2nd, sites now are actively enrolling, and we remain highly focused on submitting GraftAssureDx for FDA review by year end."

The GraftAssureDx kitted test would be the third version in the GraftAssure family of assays and iMDx is seeking FDA authorization for its clinical use. Currently, iMDx offers GraftAssureCore, which is its laboratory developed test that has achieved Medicare reimbursement of $2,753 per result, and GraftAssureIQ, its research-use-only kitted assay that is available for sale for research purposes.

About the Clinical Trial:

Investors can read more about our clinical trial (NCT07060716) at www.clinicaltrials.gov, or by clicking here: Validation of Donor-Derived Cell-Free DNA (Dd-cfDNA) for Kidney Transplant Monitoring

iMDx Transplant Products and Product Candidates in Development

The company'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, and iMDx is now commercializing that technology using a market disruptive approach. Its transplant diagnostics under the GraftAssure™ brand include the following:

- **GraftAssureCore** – The company's laboratory-developed test (LDT), currently reimbursed by CMS and performed at its CLIA-certified laboratory in Nashville. The company is in the process of rebranding its VitaGraft assay (previously known as VitaGraft Kidney), which is a lab developed test, under the name 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, which the company intends to submit for FDA authorization in 2025.

About Insight Molecular Diagnostics Inc.

Insight Molecular Diagnostics Inc., or iMDx, formerly Oncocyte Corp. (OCX), is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. iMDx utilizes a novel approach to quantification of donor-derived cell-free DNA, or dd-cfDNA, an established molecular biomarker of transplant rejection.

iMDx™, GraftAssureCore™, GraftAssureIQ™, GraftAssureDx™, and VitaGraft™ are trademarks of Insight Molecular Diagnostics Inc.

Insight Molecular Diagnostics (Nasdaq: IMDX) moved its headquarters from Irvine, Calif., to Nashville, Tenn., in June 2025. The company's new NASDAQ symbol became effective June 18. 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, anticipated FDA submission by end of 2025 and commercial launch in 2026, the belief that the ongoing clinical trial is an important step to obtaining regulatory authorization to deliver an organ transplant rejection monitoring test kit to the estimated $1 billion addressable market for kitted transplant rejection testing, the anticipation that up to 125 patients will be enrolled and the trial will be completed by year-end, 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 iMDx's 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 iMDx 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 iMDx, particularly those mentioned in the “Risk Factors” and other cautionary statements found in iMDx’s 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. iMDx 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.

Investor Contact:

Doug Farrell
LifeSci Advisors LLC
dfarrell@lifesciadvisors.com

Source: Insight Molecular Diagnostics Inc.

Powered by SITECORE