PRESS RELEASE
25 November 2025 10:00:00 CET

Devyser advances U.S. clinical strategy with first patient enrolled in Devyser Accept cfDNA study

Devyser today announced the enrollment of the first patient in its Devyser Accept cfDNA clinical trial, a key milestone in the company's efforts to bring a targeted next-generation sequencing solution for kidney transplant monitoring to the U.S. diagnostic market.

The multicenter, prospective observational study will enroll up to 400 kidney transplant recipients across six of the leading U.S. transplant centers. The objective is to generate clinical evidence supporting the validation of the Accept cfDNA NGS assay by comparing cfDNA-based rejection signals with traditional kidney biopsy results.

Accept cfDNA is a targeted next-generation sequencing assay designed to measure donor-derived and recipient-derived circulating cell-free DNA. By leveraging genetic differences, specifically short insertions and deletions (indels), the assay aims to offer a sensitive, minimally invasive indicator of rejection risk, potentially reducing the need for biopsy-based assessments.

"Initiating enrollment in this study marks an important step toward our FDA submission pathway," said Jan Wahlström, CEO, Devyser. "Accept cfDNA has the potential to transform how clinicians monitor transplant health, making high-quality post-transplant surveillance more accessible and less invasive."

The study, registered under NCT07006831, is titled *"A Multicenter, Prospective Blood Collection Study in a Kidney Transplant Population"* and can be found on ClinicalTrials.gov.

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About Devyser
Devyser is redefining how laboratories approach genetic testing. As your true one-stop shop, we offer streamlined solutions for a wide range of conditions, helping labs overcome complexity, reduce turnaround times, and maximize efficiency.

Our technologies simplify workflows, minimize hands-on time, and deliver fast, accurate results. Every test is designed to empower labs to do more with less, freeing up resources while supporting better patient outcomes.

We specialize in diagnostic kits and advanced analysis services for clinical genetics and post-transplantation laboratories - two critical areas where accuracy and speed matter. With customers in 65+ countries, we also operate our own CLIA-certified laboratory, Devyser Genomic Laboratories, in Atlanta and maintain sales offices across Europe and the US.

Devyser is committed to regulatory excellence under IVDR, ensuring the highest quality standards across our growing product portfolio.

Founded in 2004 and headquartered in Stockholm, Devyser is listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company´s Certified Adviser is Redeye AB.

Discover how we're shaping the future of lab diagnostics at **www.devyser.com**.