PRESS RELEASE
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Devyser seeks to secure FDA approval for NGS test for kidney transplant monitoring

Devyser has entered an agreement with Thermo Fisher Scientific to collaborate on obtaining U.S. Food and Drug Administration (FDA) approval for One Lambda™ Devyser Accept cfDNA, their cobranded NGS solution for detecting donor-derived cell-free DNA (ddcfDNA) in blood samples from kidney-transplanted patients. Once approved, this will be the first FDA-approved Devyser post-transplant monitoring product.

“Securing FDA-approval for One Lambda Devyser Accept cfDNA has the potential to change how kidney transplant monitoring is done in the United States. The collaboration with Thermo Fisher Scientific, the world leader in serving science, is a great opportunity for us to combine the strengths of both companies to fast-track studies and complete the necessary regulatory activities to obtain FDA approval in the shortest time possible. With Thermo Fisher’s expertise and experience working with regulators, we are confident that this collaboration will secure the most efficient pathway for FDA-approval of our post-transplant product in the U.S.,” says Fredrik Alpsten, Devyser CEO.

Thermo Fisher is the exclusive distributor of Devyser’s transplantation products globally. This includes One Lambda™ Devyser Accept cfDNA and One Lambda™ Devyser Chimerism for screening and follow-up of post stem cell transplantation, along with the corresponding software solutions.

“We are pleased to further our collaboration with Devyser, with the ultimate aim of enabling our customers to enhance surveillance and improve quality of life for the more than 150,000 Americans living with a kidney transplant," says Tina Liedtky, President, Transplant Diagnostics, Thermo Fisher Scientific.

One Lambda Devyser Accept cfDNA is CE-IVDR marked but not FDA-cleared. Availability in each country depends on local regulatory marketing authorization status. Please consult your local sales representative for details.

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About Devyser
Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 65 countries. Our products are used for advanced genetic testing in the hereditary disease, oncology and transplant fields, to enable targeted cancer treatment, the diagnosis of a large number of genetic diseases, and transplant patient follow-up. Devyser's products, and unique, patented solution requiring only one test tube, simplify genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. Our goal is for every patient to receive a correct diagnosis in the shortest possible time. Sustainability is a central part of our business and an important prerequisite for long term value creation.

Devyser was founded in 2004 and is based in Stockholm, Sweden with eight in-house sales offices in Europe and the US. The company also runs Devyser Genomic Laboratories, a CLIA certified laboratory in Atlanta, US. In 2022, Devyser's quality management system was certified according to the IVDR and a number of the company's products have since been certified according to the IVDR.

Devyser's shares are listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company's Certified Adviser is Redeye AB.

For more information, visit **www.devyser.com**.