



Devyser receives EUR 750,000 Eurostars grant to develop novel DNA test for early detection of transplant rejection

Stockholm, January 19, 2021 – Devyser Diagnostics AB (publ), a Swedish molecular diagnostics company, today announced that it has been awarded funding through the Eurostars-2 program for the further development of its unique Next-Generation Sequencing based test for surveillance of graft status and early diagnosis of rejection in kidney transplant recipients. The grant awarded is EUR 750,000.

The ENVISAGE project is a consortium between Devyser and the University Hospital of Zurich (UHZ), aiming to further develop and perfect Devyser's proprietary Next-Generation Sequencing (NGS) based test for surveillance of graft status and early diagnosis of rejection in kidney transplant recipients. Through the detection and quantification of dd-cfDNA in plasma, the NGS test allows maximum sensitivity and specificity, providing precise and direct information to support long-term graft and patient survival. The grant amount is EUR 750,000 and the project period is 36 months starting January 2021.

Over 139,000 organs are transplanted annually world-wide and rejection is a major complication of transplantation since over 60 percent of kidney grafts are ultimately lost due to rejection. By early initiation of effective medical treatment rejection could be reversed. Existing analysis are expensive, and graft monitoring by testing dd-cfDNA has until now been infeasible. Through the ENVISAGE project, Devyser intends to provide a certified *In Vitro* diagnostics kit, including reagents, protocols and software for data analysis ready to implement for routine use.

"The Eurostar funding is very encouraging and enables us to finalize the development of this unique test approach with the potential to significantly reduce the rejection rate in organ transplants, starting in kidneys. The grant is also a clear validation of our technology and test method", says Fredrik Alpsten, CEO of Devyser Diagnostics AB.

"As our assay detects rejection at its onset, the earliest possible medical intervention could be facilitated increasing the likelihood that the graft is accepted by the patient. At a higher level, our NGS based test will allow routine testing at a low cost for the healthcare system and thereby support higher utilization of donor grafts", says Ulf Klangby, COO of Devyser Diagnostics AB.

UHZ is the largest organ transplantation centre in Switzerland, and together with the clinical Transplant Immunology Laboratory, it has created a unique biobank of samples from transplant recipients. Since 2008 it has performed over 900 adult kidney transplants and collected sequential serum samples post-transplantation, including donor and recipient pre-transplant DNA samples. UHZ has extensive knowledge in transplant immunology, graft rejection processes and rejection management strategies. Furthermore, the Transplant Immunology Laboratory has extensive experience from clinical amplicon-based NGS sequencing and has expertise in validating diagnostic

platforms for clinical use.

“We are very excited to have entered this joint development project with Devyser. Their products are made ideal for routine diagnostics, being simple, reproducible, and low prone to user-generated errors. By combining Devyser’s specialist competence in developing diagnostic kits for complex DNA testing, with our experience and expertise within transplantation, we will be able to conclude the development and have the test evaluated in the best possible clinical environment”, says Jakob Nilsson, Director of Transplant Immunology, Department of Immunology, University Hospital Zürich.

The NGS test will initially be optimised and validated for kidney transplants, but increasing the sensitivity and specificity to up to 99.99 percent will make the test universal for detection and quantification of chimerism in recipients of any type of solid transplant, with any kind of grafts.

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About Devyser Diagnostics AB (publ)

Devyser is specialized in the development, manufacture and sales of diagnostic kits. The products are used for complex DNA testing within oncology, hereditary diseases and transplantation. The products are used to guide targeted cancer therapies, to enable a wide array of genetic tests, as well as in post-transplant follow-up. Devyser’s product development focuses on simplifying and streamlining complex testing processes to improve throughput, reduce hands-on time and produce accurate and trusted results. Devyser was founded in 2004 and is based in Stockholm, Sweden.

Find out more about Devyser at www.devyser.com

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