

Lophius Biosciences Press Release, Newly-released Scientific Publication

February 08, 2018 – T-Track® CMV is a Highly Sensitive Immune-Monitoring Tool for Risk Stratification of Renal Transplant Recipients

Regensburg, Germany, February 08, 2018 – **Lophius Biosciences GmbH** today announced the publication of a peer-reviewed scientific paper covering the company's CE-marked *in vitro* diagnostic test T-Track® CMV in a clinical study with kidney transplant patients. The scientific publication outlines that T-Track® CMV is a highly sensitive assay for the immune monitoring of Cytomegalovirus (CMV)-seropositive renal transplant recipients, with the potential use for the risk assessment of CMV-related clinical complications. The paper was published in *Transplant International*¹.

In this prospective longitudinal multicenter study, 86 kidney transplant recipients were followed over 6 months post-transplantation. CMV-specific cell-mediated immunity was monitored using T-Track® CMV, in parallel to the assessment of CMV viral load and of clinical complications. This study demonstrated the capability of T-Track® CMV not only to measure CMV-specific cell-mediated immunity in immunocompromised patients with high sensitivity (with 88-92% positive tests in patients under immunosuppressive treatment, compared to 95% before transplantation), but also to monitor changes in the patients' CMV-specific immune status following the administration of immunosuppressive drugs. In addition, T-Track® CMV test results (in response to one of the antigens provided in the IVD kit) were significantly higher in patients with a protective immunity, compared to patients requiring antiviral treatment, highlighting the potential predictive value of the assay.

“The recent publication nicely shows that T-Track® CMV is a valuable tool for the risk stratification of transplant patients and gives an outlook towards its ability to support personalized CMV management. Together with results of on-going clinical studies in allogeneic hematopoietic stem cell and solid-organ transplant recipients we are looking forward to broaden the routine use of our test and making the clinical advantages available to a large number of transplant patients”, said Bernd Merkl, CEO & Managing Director of Lophius Biosciences GmbH.

- 1) Banas et al. (2017). Clinical validation of a novel enzyme-linked immunosorbent spot assay-based *in vitro* diagnostic assay to monitor cytomegalovirus-specific cell-mediated immunity in kidney transplant recipients: a multicenter, longitudinal, prospective, observational study. *Transpl Int*. doi: 10.1111/tri.13110. [[Read more](#)]



Background CMV, CMV-specific cell-mediated immunity & T-Track® CMV

The replication of CMV, with a high seroprevalence in the human population of 30-90%, is efficiently controlled in healthy individuals by the immune system primarily via cell-mediated immunity. To avoid uncontrolled CMV replication, immunosuppressed patients like transplant recipients are treated with antiviral medication either prophylactically in the first months after transplantation or preemptively based on CMV viral load measurement. However, optimal duration of either prophylaxis or of virological monitoring is not well defined. In the current setting, assessment of CMV-specific immunity and the ability of immunosuppressed patients to control virus replication via their immune system are not taken into consideration. On the one hand this may result in overtreatment of patients with reconstituted and protective CMV immunity. Avoiding unnecessary antiviral treatment would prevent unwanted side effects for the patients and increased costs for the healthcare system. On the other hand it may expose patients with delayed immune reconstitution to higher risk for CMV disease. Therefore, it is equally important to identify these patients with CMV-specific immunity monitoring.

By measuring CMV-specific cell-mediated immunity, T-Track® CMV adds an additional dimension to anti-CMV treatment decision-making, complementing the currently used viral load tests. The close monitoring of CMV-specific immunity using T-Track® CMV together with CMV viral load measurement has the potential to improve risk stratification of patients and to help clinicians in their decision to start, discontinue or adjust antiviral treatment.

About Lophius Biosciences

Lophius Biosciences is a privately held German biotechnology company focusing on the development and marketing of innovative immune diagnostic systems to improve therapy control and personalized treatment of patients in the area of transplantation, infectious and autoimmune diseases. The company's developments are based on its expertise in cell-mediated immunity as well as on its proprietary T-activation® and Reverse T Cell Technology platforms. Whereas the T-activation® technology platform allows an efficient stimulation of a broad spectrum of clinically-relevant immune effector cells to accurately measure the cell-mediated immunity, the Reverse T Cell Technology platform can distinguish between active and memory T cells to develop innovative diagnostics.

With its T-Track® CMV leading product, Lophius offers a highly sensitive, reliable and standardized CE-marked *in vitro* diagnostic solution to measure the functionality of CMV-specific cell-mediated immunity. T-Track® CMV assists clinicians in the risk stratification of CMV disease in immunocompromised patients, toward an improved and individualized patient management.



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