Lophius Biosciences Press Release, Newly-released Scientific Publications

April 05, 2017 – Clinical Validation of T-Track® CMV, a Highly Sensitive Immune-Monitoring Tool

Regensburg, Germany, April 05, 2017 – **Lophius Biosciences GmbH** today announced the publication of two peer-reviewed scientific papers covering the company's CE-marked *in vitro* diagnostic test T-Track® CMV. The scientific publications outline T-Track® CMV's high reliability and sensitivity as an immune-monitoring tool, with the potential to improve risk stratification of human cytomegalovirus (CMV)-related clinical complications in renal transplant recipients. Lophius Biosciences is a privately-held biotech company focusing on the development and marketing of innovative T cell-based diagnostic systems to improve therapy control and personalized treatment of patients in the area of transplantation, infectious and autoimmune diseases.

CMV is endemic in all human populations, with a high seroprevalence of 30%-90%. In healthy individuals, CMV replication is efficiently controlled by the immune system via cell-mediated immunity. However, in immunosuppressed patients, like transplant recipients, impaired functionality of cell-mediated immunity is often associated with severe clinical complications due to uncontrolled virus replication. Currently, in the absence of knowledge of their immunosuppressive state, patients are treated with antiviral medication either prophylactically in the first months after transplantation or following a preemptive strategy based on CMV viral load measurements only. Assessment of CMV-specific immunity and the ability of immunosuppressed patients to control virus replication via their immune system are not taken into consideration. This may result in overtreatment of patients, associated with unnecessary side effects and costs for the healthcare system.

By measuring CMV-specific cell-mediated immunity, T-Track® CMV adds a new dimension to antiviral treatment decision-making, complementing the currently-used viral load tests. The close monitoring of CMV-specific immune response 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.

The two scientific papers published in *BMC Immunology* [1, 2] show that the Lophius IVD test is a highly standardized, reliable immune-monitoring tool exhibiting great sensitivity for the measurement of the CMV-specific cell-mediated immune response. The performance of the test is based on the stimulation of isolated blood cells with CMV proteins "activated" with the proprietary Lophius T-activation® technology. In addition, a clinical study in hemodialysis CMV-seropositive patients prior to renal transplantation demonstrated a sensitivity for T-Track® CMV of 90%, greater than that of the competing solutions QuantiFERON®-CMV (73%) and iTAg™ MHC Tetramers (77%). Thus, T-Track® CMV represents a superior immune monitoring tool to identify candidate transplant recipients potentially at increased risk for CMV-related clinical complications.

"The recent publications clearly demonstrate the technical capabilities of our assay T-Track® CMV and give an outlook toward its ability to support personalized CMV therapy management. We are looking forward to the results of on-going clinical studies in allogeneic hematopoietic stem cell and solid-organ transplant recipients to confirm the full clinical potential and the health-economic benefit of our test", said Bernd Merkl, CEO & Managing Director of Lophius Biosciences GmbH.

1) Barabas, S., Spindler, T., Kiener, R., Tonar, C., Lugner, T., Batzilla, J., Bendfeldt, H., Rascle, A., Asbach, B., Wagner, R., and Deml, L. An optimized IFN-γ ELISpot assay for the sensitive and standardized monitoring of CMV protein-reactive effector cells of cell-mediated immunity (2017) BMC Immunology. **18**:14.

2) Banas, B., Böger, C.A., Lückhoff, G., Krüger, B., 3, Barabas, S., Batzilla, J., Schemmerer, M., Köstler, J., Bendfeldt, H., Rascle, A., Wagner, R., Deml, L., Leicht, J., and Krämer, B. K. Validation of T-Track® CMV to assess the functionality of cytomegalovirus-reactive cell-mediated immunity in hemodialysis patients (2017) BMC Immunology. **18**:15.

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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