

Lophius Biosciences Press Release, Next Generation of T-Track® CMV**September 1, 2017 – Launch of the Next Generation T-Track® CMV Immune Monitoring Tool**

Regensburg, Germany, September 1, 2017 – **Lophius Biosciences GmbH** today announced the launch of the next generation of its *in vitro* diagnostic test T-Track® CMV for the risk stratification of human cytomegalovirus (CMV)-related clinical complications in transplant recipients. The new version of the CE-marked immune monitoring tool substantially increases user convenience by reducing required blood volumes, extending blood storage time and supporting fast and easy software-supported test result evaluation.

“With the next generation of our T-Track® CMV immune monitoring tool Lophius Biosciences addresses key customer requests while offering the same high quality of results: The increased blood storage time from eight to twenty-four hours makes it significantly easier for diagnostic labs to integrate the test into their daily routine, while the new evaluation software enables fast and easy result assessment with an enhanced evaluation algorithm. The reduction by 50% in the required blood volume considerably increases the convenience for patients and usability for clinicians, in particular in the pediatric area. With these improvements, we expect to markedly broaden the applicability of our test” comments Bernd Merkl, CEO & Managing Director of Lophius Biosciences.

Background:

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 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 expose patients with delayed immune reconstitution to higher risk for CMV disease. On the other hand it 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.

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 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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