Positive T-Track® CMV Study Results With New Guidance Strategies For Anti-viral Treatment Decisions Following Stem Cell Transplantation

Continued Validation of Lophius' Development Capabilities Bode Well as Company Advances in Tuberculosis as Next Focus Area

Regensburg, Germany, February 07, 2019 – Lophius Biosciences GmbH today announced successful top-line results from its multicenter AlloProtect CMV clinical study. Results show the ability of Lophius' CE-marked *in vitro* diagnostic test T-Track® CMV to transform treatment paradigms and patient management: in patients receiving an allogeneic hematopoietic stem cell transplantation - a procedure regularly performed to treat leukemia and lymphoma - the immune monitoring assay opens up novel approaches to risk assessment and stratification, leading to a better guidance in antiviral treatment decisions, due to the reliable identification of patients with freedom from recurrent treatment-requiring CMV reactivation.

"Following positive results in a kidney transplant setting last year, today's results once more highlight the potential of our novel approach to assess the risk of CMV-related complications after transplantation in a reliable fashion. Applied broadly in clinical practice, our test could guide clinicians in their decision to start, discontinue or adjust antiviral treatment, potentially avoiding unnecessary treatments and saving costs for the healthcare system," said Bernd Merkl, CEO & Managing Director of Lophius Biosciences GmbH. "Beyond the positive results of T-Track® CMV as such, today's news once more underlines Lophius' capabilities to successfully develop and establish novel diagnostic solutions, from inception to the market, handling complex clinical studies along the way. This expertise is essential for our running core development program addressing an unmet clinical need in a new indication, tuberculosis, with a proprietary blood-based multi-marker solution."

Study Results of the AlloProtect CMV Study

In the prospective, longitudinal, observational, multicenter AlloProtect CMV study, 175 intermediate- and high-risk HSCT recipients were followed up to 7.5 months post-transplantation for the occurrence of recurrent CMV reactivation. The primary goal was to evaluate whether T-Track® CMV applied following a first treatment-requiring CMV reactivation post-transplantation can predict freedom from recurrence of future CMV reactivation. Remarkably, patients with a positive T-Track® CMV test result after resolution of the first CMV reactivation, as well as at day 100 post-transplantation (when patients are usually discharged from the hospital), remained free from future recurrent CMV reactivation, with a specificity in diagnostic accuracy greater than 90%. Overall, this study demonstrates that T-Track® CMV allows an improved risk stratification of CMV-related clinical complications and can support clinicians in the identification of patients free from future recurrent CMV reactivation, thus allowing an improved management of HSCT patients.

More information on the trial design is available on www.clinicaltrials.gov.

Background on CMV, CMV-specific cell-mediated immunity and T-Track® CMV

The Cytomegalovirus (CMV) is highly present in the human population with an estimated seroprevalence of approximately 30-90% but efficiently controlled in healthy individuals by the immune system, primarily via cell-mediated immunity. In immunosuppressed patients like transplant recipients, however, reactivation of CMV replication may require treatment with antiviral medication either prophylactically in the first months after transplantation or preemptively based on CMV viral load measurement. Nevertheless, optimal duration of either antiviral therapy or virological monitoring is not well defined and assessment of CMV-specific immunity and the ability of immunosuppressed patients to control virus replication via their immune system are not taken into consideration. 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 and empowering clinicians in their decision to start, discontinue or adjust antiviral treatment.

About Lophius Biosciences

Lophius Biosciences' mission is to transform treatment paradigms and patient management with novel molecular diagnostic solutions for life threatening and highly-contagious infectious diseases. The core program addresses an unmet clinical need in tuberculosis (TB), a global epidemic affecting hundreds of millions of people. Lophius has developed a proprietary blood-based multi-marker solution, run on widely available platforms, to deliver a significant improvement on TB infection detection over existing approaches. Lophius is advancing biomarker combinations which would disrupt the field by being able to differentiate between active TB disease and latent TB infection. In addition, the company is commercializing a clinically validated CE-marked diagnostic kit to individualize transplant patient management by personalized CMV disease risk stratification.

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