

Lophius Biosciences Achieves Development Milestone in Establishing High-Performance Tuberculosis Infection Detection Test

Test Meets Performance Goals and Outperforms Benchmark Solutions, Lophius Continues Usability Optimization Including Evaluation of Technology Platforms for Automation

Regensburg, Germany, May 7, 2019 – [Lophius Biosciences GmbH](https://www.lophius.com) today announced that the company has achieved an important development milestone for its proprietary, blood-based, multi-marker tuberculosis (TB) infection detection assay. During a clinical study, Lophius' novel test system outperformed predefined performance goals for detecting the presence of a tuberculosis infection among more than 190 study participants, comparing active and latent TB to non-infected control subjects. Lophius will continue tailoring the optimal assay design and currently evaluates the transfer of the assay to broadly used automation platforms to enable fast market penetration. The company anticipates the start of a clinical validation study with the final assay design for 2020.

The Lophius solution is suitable for infection detection in diverse patient subpopulations, also including extrapulmonary and sputum smear-negative TB cases. Using this solution, more than 95% of patients with active tuberculosis disease were correctly classified as infected in the Lophius study. In this regard, the assay clearly outperformed an Interferon Gamma Release Assay, which Lophius used as a benchmark. In addition, the Lophius solution has shown the potential to complement PCR tests for direct pathogen detection by correctly classifying active TB cases previously missed by PCR analysis. Overall, the Lophius TB infection detection assay has shown the potential to close the performance gap for identification of active TB subjects described in literature.

“We are very pleased with the interim results of our study, which shows that we are on track with our program for a truly next-generation tuberculosis infection detection test. We expect that our blood-based assay will set a new standard for the early detection of a TB infection to improve patient management and save healthcare costs,” commented Dr. Bernd Merkl, CEO of Lophius Biosciences. “These initial results combined with Lophius' expertise and network also provide a solid basis to tackle



the even bigger hurdle for a breakthrough solution: The ability to consistently differentiate between latent tuberculosis and treatment-requiring active TB.”

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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