



Curetis Initiates Prospective Multicenter Unyvero™ Study in Europe

- Study to demonstrate added value of Unyvero™ P50 pneumonia application in clinical routine -

Holzgerlingen, Germany, July 9, 2013 -- Curetis AG today announced the start of an additional prospective, multicenter clinical trial of its marketed Unyvero™ P50 Pneumonia Application to demonstrate its clinical and health economic value.

The CE performance evaluation completed last year already demonstrated 81% sensitivity at 99% specificity for detecting pneumonia-causing pathogens. Following the market launch in April 2012, Curetis in 2013 presented data from more than 1,000 patient samples showing overall sensitivity of its pathogen panel of 80.6% at a specificity of 96% (ECCMID European Conference of Clinical Microbiology and Infectious Diseases, Berlin).*

The new multicenter study aims to establish real-world data on the health economic impact of fast, patient-near molecular testing and subsequent therapy adjustments (if necessary). It will be conducted in five leading European centers and will involve several hundred critically ill patients with pneumonia requiring mechanical ventilation. The study is designed to first evaluate the current pneumonia treatment and clinical outcome situation by detailed chart reviews comparing patients having received initial adequate, respectively inadequate treatment. Data will be used to fine tune endpoints for the interventional, randomized second part of the study, which aims to investigate the potential clinical and economic benefit of the Unyvero™ system. Parameters analyzed will be, e.g. type of antibiotic regimen and costs, length of stay in the ICU, etc.

Participating clinicians are world-renowned intensive care, pulmonology and microbiology specialists: Prof. Manfred Quintel (University of Goettingen), Prof. Tobias Welte (MHH University Clinic Hanover), Prof.s Philippe Eggimann and Gilbert Greub (CHUV University Hospital of Lausanne), Prof. Mathias Pletz (Jena University) and Prof. Antoni Torres (University Hospital Clinic Barcelona).

* Abstract Nr. 2360: M. Klein et al., First clinical validation of a rapid molecular test (Unyvero™ P50 Pneumonia Application) detecting microorganisms and antibiotic resistances in patients suspected with severe pneumonia.

„A substantial number of medical studies demonstrate that initial inadequate empirical antibiotics treatment in pneumonia prolongs hospital stays, adds more than €5,000 in costs per patient and greatly increases mortality,” said Oliver Schacht, CEO of Curetis. “This suggests that early diagnosis can be very beneficial for patients and clinics. However, we are well aware that in today’s cost-sensitive healthcare systems the benefit of an innovative, fast diagnostic system needs to be proven in controlled studies. We are therefore very pleased to have won internationally renowned centers to participate in this study.”

„The Unyvero system is a breakthrough in the very fast, easy and reliable diagnosis of pneumonia,” said Prof. Tobias Welte. “We are therefore very much looking forward to the study and the data it will generate.”

Preliminary results of the study are expected by the end of this year.

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About the Unyvero™ System

The CE-marked Unyvero™ System is a versatile hardware platform for the detection of a broad panel of bacteria and antibiotic resistances from a single sample in one run. It processes a disposable cartridge providing the necessary reagents to complete the analysis from sample to result.

The platform enables the DNA-based testing of all clinically relevant samples in a fully automated, unsupervised analysis process requiring only few, quick manual preparation steps. The analysis thus can be performed with minimal operator time and without the need of skilled staff or special infrastructure.

Thereby, clinically relevant information is available within about four hours to support an informed therapy decision as early as possible.

The first CE-marked Unyvero™ Cartridge, Unyvero™ P50, focuses on pneumonia testing and simultaneously analyses 39 DNA targets. The second Unyvero™ application for implant & tissue infections is already in product development. Cartridges for additional indications, such as blood stream infections and tuberculosis, are in preparation.

About Curetis AG

Founded in 2007, Curetis AG is a molecular diagnostics company which focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases. The diagnostic solutions of Curetis AG will enable rapid multiparameter pathogen and antibiotic resistance detection in only a few hours, a process that today can take up to days or even weeks with other techniques.



Press Release Curetis AG

To date, Curetis has raised total funds of over € 49.1 million (~ USD 64 million). The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical, Sanofi Pasteur and Cemptra Inc. as well as several international distribution agreements.

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