Press Release Curetis AG

New Favorable Clinical Evaluation Data for Unyvero™ P50 Pneumonia Application

– *Dutch study demonstrates excellent sensitivity of Unyvero™ cartridges*

Holzgerlingen, Germany, April 23, 2014 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced positive clinical data from an independent study conducted by researchers from the Department of Medical Microbiology of Maastricht University Medical Center (MUMC), Maastricht, the Netherlands. The data demonstrate the high clinical sensitivity of the Unyvero™ P50 Pneumonia application in detecting pathogens, including samples with low pathogen concentrations.

The researchers compared the performance of the Unyvero™ P50 cartridge with conventional microbiology culture in broncho-alveolar lavage fluid (BALF) samples for the diagnosis of ventilator-associated pneumonia (VAP), a common complication in intensive care patients. The most frequent causes are *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Enterobacteriaceae*.

Using the quantitative culture standard, Unyvero™ P50 Pneumonia correctly detected 8 different important pathogens in all VAP samples (n=44) at 100% sensitivity. The overall sensitivity of the Unyvero™ P50 panel was 88.6% at clinically relevant pathogen concentration. Unyvero™ P50 was also able to detect 8 different clinically relevant pathogens in 12 patient samples where conventional microbiology culture failed. This data confirms previous results where Unyvero™ had consistently detected pathogens missed by conventional culture.

“Our Unyvero application exhibited exceptional sensitivity, even at low concentrations. Importantly, P50 was able to detect pathogens in 12 samples where conventional microbiology failed," said Dr. Gerd Luedke, Director Bio-Assay Development of Curetis. “Within four hours, our application identified close to 90% of all pathogens within the specified cutoff and even 60% with concentrations below this threshold.”

The data were presented at the Scientific Spring Meeting of the Koninklijke Nederlandse Vereniging voor Microbiologie (Royal Dutch Society for Microbiology) KNVM and Nederlandse Vereniging voor Medische Milieukunde (Dutch Association for Environmental Medicine) NVMM 2014 in Arnhem, The Netherlands.

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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, fungi 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. It is marketed in Europe, Russia, the Middle East and various other non-European countries. In the U.S., Curetis is running a prospective multi-center clinical trial aimed at achieving FDA clearance registered under http://www.clinicaltrials.gov NCT01922024.

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 application, the Unyvero™ i60 ITI cartridge for implant & tissue infections, is in final stages of clinical validation. Cartridges for additional indications are in various stages of development and 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 enable rapid multi-parameter 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.

To date, Curetis has raised total funds of over €49.1 million (~ USD 65 million). The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical, Sanofi Pasteur and Cempra Inc. as well as several international distribution agreements covering more than 20 countries.

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