Curetis Presents New Clinical Validation Data on its Unyvero™ P50 Pneumonia / LRT Application

- *Clinical studies from U.S. and Switzerland confirm previous performance data*
- *Findings presented at DGHM/DGI 2013 and ICAAC 2013*

Holzgerlingen, Germany, October 9, 2013 -- Curetis AG today announced the presentation of additional clinical validation data on its Unyvero™ P50 / LRT application at two international conferences. The cartridge is designed to detect 16 respiratory bacteria and one fungus responsible for about 80% of severe non-viral pneumonia cases. In addition, it is able to simultaneously identify 22 antibiotic resistance markers.

At this year's *53rd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC 2013)* in Denver, CO, researchers from the Northwestern Memorial Hospital (Chicago, IL) and Curetis presented data generated during the initial familiarization and training phase for the FDA trial of the Unyvero™ LRT application, an investigational device. It is based on the panel of the P50 cartridge, which is already marketed outside the U.S. In the small cohort using native clinical samples, the Unyvero™ LRT application achieved an overall sensitivity of 89% and an overall specificity of 98% for pathogen identification. Moreover, it detected 6 additional pathogens not discovered by routine microbiological culture. The resistance markers showed an overall sensitivity of 87% at an overall specificity of 97%. The authors conclude that "this data indicates that the system can significantly contribute to patient management by providing rapid pathogen identification and antimicrobial resistance profiling."

At the *65th Joint Annual Meeting of the German Society for Hygiene and Microbiology and the German Society for Infectious Diseases (DGHM/DGI 2013)* in Rostock, Germany, clinicians from the University Hospital Basel, Switzerland, presented data comparing the Unyvero™ P50 cartridge with standard microbiological culture, including anti-microbial susceptibility testing. While in 104 cases microbiology culture detected 96 pathogens evaluable by the Unyvero™ P50 cartridge, P50 detected 73 pathogens (76%). However, Unyvero™ P50 detected 68 microorganisms that were not listed in the culture report. Of these, 46% were S. pneumoniae and 10% were H. influenzae - pathogens difficult to culture or part of the oral

flora for which clinical significance is not yet determined. The discrepancies are still under investigation. Phenotypic antimicrobial susceptibility or resistance was predicted correctly in 82% of cases by Unyvero™ P50. While standard culture and anti-microbial susceptibility testing took 2 to 4 days, the Unyvero™ results were obtained in less than 4.5 hours. The Basel microbiology team concluded that the “Unyvero™ Pneumonia P50 assay is able to provide fast and clinically useful results on the most prevalent pathogens causing pneumonia and their antibiotic resistance genes.”

“We are very pleased about these novel data,” said Dr. Anne Thews, Medical Director of Curetis AG. “Early effective antimicrobial therapy is crucial for the successful management of severe infections such as lower respiratory tract infections or pneumonia. In both studies, data gained by clinicians confirm that our Unyvero solution is significantly contributing to achieving this goal.”

A previous study testing more than 1,000 samples in Europe showed an overall sensitivity of 81% and an overall specificity of 96%.

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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 www.ClinTrials.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 late-stage product development. It covers 114 targets from many native clinical sample types and 8 distinct clinical indications. Cartridges for additional indications 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 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 already.

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