Press Release

Prospective multi-center trial enrolls 800 patient samples

Curetis Completes Enrollment for its EU Trial As Planned

(Holzgerlingen, Germany, October 9, 2012) -- Curetis AG today announced it has completed enrollment for the European clinical trial of its Unyvero™ Pneumonia Application on schedule. More than 800 patient samples were collected until September 30, 2012 in just 7 months. Data analysis will be completed in early 2013. Subsequently, results will be published in a major, peer-reviewed journal.

The trial will compare the performance of the Unyvero™ P50 Pneumonia Cartridge with conventional microbiology culture, the current standard of care. Primary endpoint will be clinical sensitivity and specificity for the identification of 17 pathogens covered by the Unyvero™ P50 panel. Secondary endpoints include time to result and correlation of resistance marker detection with phenotypic antibiograms. Curetis will conduct systematic discrepant results resolution by PCR and sequencing to confirm the clinical truth in samples where Unyvero results differ from microbiology culture.

The study complements the previously completed CE performance evaluation study, in which the Unyvero P50 Cartridge identified a significant number of additional pathogens not detected by microbiology culture. These findings were confirmed by PCR analysis.

“We are happy to announce the successful completion of another major clinical project milestone,” said Oliver Schacht, CEO of Curetis. “Together with the more than 200 samples analyzed earlier this year, we now have data collected from over 1,000 samples tested, which will form a substantial body of clinical evidence around the Unyvero Solution and our Pneumonia Application.“

“While data analysis for the multicenter study will be ongoing for some time, we have already seen some rather exciting case studies of patients who might have benefited substantially from the rapid and comprehensive diagnostic solution offered by Curetis´ Unyvero Solution,” said Dr. Peter Keller of Friedrich-Schiller University in Jena. “With the testing completed on beta-prototypes of the Unyvero systems, we are now intrigued by the availability of fully CE-marked series-production instruments and look forward to a growing body of clinical data. We will continue working with the Curetis team to make the solution available to microbiologists and clinicians for routine use

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and to the benefit of our patients."

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. To date, Curetis has raised total funds of over € 36.6 million (~ USD 50 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.

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