Curetis Prepares Launch of Second Unyvero™ Application

- *Final clinical performance evaluation study for Unyvero™ i60 ITI application ongoing*
- *Study data expected by the end of Q1/2014*

Holzgerlingen, Germany, March 4, 2014 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced that it has completed development of its second Unyvero™ application. The new Unyvero™ i60 ITI cartridge rapidly identifies more than 90 pathogens and more than 20 resistance markers common in implant and tissue infections. After successfully manufacturing several lots and completing initial verification testing of the cartridge, the Company has initiated a pivotal study using approximately 500 cartridges to validate analytical, technical and clinical performance for CE marking.

Following the completion of the study scheduled for end of Q1/2014, commercialization of the Unyvero™ i60 ITI is expected to begin in Q2/2014. Curetis will jointly market the cartridge with Heraeus Medical GmbH, the development and commercialization partner for this cartridge. Both companies have already received pre-orders from key opinion leaders and hospitals across central Europe.

“We are delighted to have successfully completed development of this highly multiplexed Unyvero assay,” said Dr. Gerd Lüdke, Director BioAssay Development of Curetis. “Our ITI cartridge combines up to 114 analytes which can be diagnosed in a broad spectrum of highly diverse, native clinical samples obtained from patients with prosthetic joint infections, diabetic foot ulcers, catheter infections, surgical site infections, and many other complex implant and tissue infections.”

“It is gratifying to see the development phase of our collaboration with the Curetis team to be accomplished soon. Our commercial teams are already cooperating closely to prepare for the launch,” added Katharina Apitius, Head of Sales Central & Eastern Europe of Heraeus Medical. “The Unyvero solution and the i60 cartridge are a key element of our strategy to provide a comprehensive infection management solution to our customers across Europe.”

The study will use frozen patient specimens – watery/swabs, viscous/purulent, sonication and synovial fluids, and biopsy material – for

diagnosis. The study will compare the molecular test with conventional microbial culture techniques. Discrepant or unexpected results will be resolved by additional tests. The study will also test assay repeatability and reproducibility and establish limit of detection.

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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 i60

The Unyvero™ i60 cartridge covers a broad range of infections common after abdominal as well as bone and joint surgery, trauma (e.g. burns) or skin and soft tissue infections, including diabetic foot disease. In combination with the unique Unyvero™ L4 Lysator it can process biofilm samples, an important prerequisite for the fast and reliable diagnosis of implant infections (catheters, joints etc.).

The i60 multiplex panel covers a total of 114 targets - 91 pathogens (gram-negative & gram-positive bacteria and fungi) and 23 resistance markers - relevant for eight clinical indications.

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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