Press Release Curetis AG

Curetis Presents First Data on Novel Unyvero™ i60 ITI Application for Implant and Tissue Infections

- *New cartridge detects 114 targets*
- *Roll-out in collaboration with Heraeus Medical expected in early 2014*

Holzgerlingen, Germany, October 22, 2013 -- Curetis AG today announced first details on its new Unyvero™ i60 ITI application for the diagnosis of implant and tissue infections. The cartridge has been developed in close collaboration with Heraeus Medical GmbH, a company focused on orthopedic biomaterials. The data were presented at this year´s *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.

The new Unyvero™ System 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 is also possible to process biofilm samples, an important prerequisite for the fast and reliable diagnosis of implant infections (catheters, joints etc.).

The multiplex panel of the novel i60 application covers a total of 114 targets - 91 pathogens (gram-negative & gram-positive bacteria and fungi) and 23 resistance markers - relevant for eight clinical indications. At the conference, Curetis presented data from first evaluation studies demonstrating that the panel is able to detect pathogens in orthopedic and surgically relevant fresh and frozen samples, such as synovial and sonication fluids, swabs, and tissue material. All results were confirmed by standard microbiology culture. Of note, the i60 application also detected additional pathogens not covered by standard methods, e.g. anaerobic bacteria known to be involved in biofilm-formation on orthopedic implants.

Following the successful completion of assay development, Curetis is now running validation and verification tests. The company aims to run a clinical CE performance evaluation study this fall with a goal of obtaining CE-IVD marking for the Unyvero™ i60 ITI cartridge by the end of 2013.

“We have put a lot of effort into the panel development,” said Dr. Gerd

Luedke, Director Bio-Assay Development of Curetis AG. “We have teamed up with leading specialists for selecting the markers and collected hundreds of patient samples for the various clinical indications covered by the i60 ITI cartridge. The broad spectrum also includes anaerobic pathogens which are difficult to identify by standard microbiology and are therefore frequently overlooked in clinical routine.”

“We are very pleased to contribute to a patient-specific joint replacement based on conclusive diagnostic evidence,” said Dr. André Kobelt, CEO of Heraeus Medical GmbH. “This approach will result in a better cost-effectiveness for the payor, clarity for the orthopedic surgeon and a minimized exposure for the patient – in short, a better sleep for all stakeholders. The new cartridge provides health care professionals with a cutting-edge, superior diagnostics solution to detect infections and antibiotic resistances much faster. As this will allow for a more efficient application of antibiotics, our solution will reduce costs, among others, for the healthcare systems.”

“The new Unyvero™ i60 ITI application, our second high-multiplex cartridge, will considerably leverage our current, growing international network,” said Oliver Schacht, CEO of Curetis AG. “In close collaboration with our strategic development and commercialization partner Heraeus Medical, we expect to launch and roll-out the new application in early 2014.”

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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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