



Curetis Launches Unyvero™ i60 Implant and Tissue Infection Cartridge in Europe

- *Successful completion of CE performance evaluation study covering more than 400 patient samples*
- *Sales and Marketing Program Underway in Germany, Austria and Switzerland*

Holzgerlingen, Germany, May 7, 2014 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced that it has launched its new Unyvero™ i60 Implant and Tissue Infection (ITI) cartridge in Europe. The new cartridge for the Unyvero™ system was developed to rapidly identify more than 90 pathogens and more than 20 resistance markers common in eight clinical indications. Commercial launch and roll-out has already begun in close collaboration with Heraeus Medical GmbH, the development and commercialization partner for the Unyvero™ i60 cartridge. The Company has made first placements at major clinical centers in Germany, Austria and Switzerland (DACH market).

The i60 cartridge has been CE-IVD marked following the successful completion of a CE performance evaluation study involving more than 750 cartridges. Analytical sensitivity testing was conducted in 350 cartridges, while more than 400 cartridges were run with patient samples. Samples of various clinical indications were obtained for the trial, including periprosthetic joint infections, diabetic foot, catheters, surgical sites, skin and soft tissue and cardiology-related infections. The Unyvero™ system analyzed challenging native clinical sample types such as swabs, synovial fluid, sonication fluid, tissue and catheters. Among others, the i60 cartridge detected several key pathogens with sensitivities in the range between 75% to 100% at an overall panel sensitivity of 67% and panel specificity of 97.8% for the 81 analytes that have been successfully validated so far. The i60 cartridge also identified 147 clinically important pathogens not found by standard microbiology culture. In particular, in every second sonication fluid and every third synovial fluid sample, i60 detected pathogens missed by microbiology culture. Pathogens most often overlooked by culture, yet identified by i60, were *Enterococcus* sp., *Fingoldia magna*, *Corynebacterium* sp., *Enterobacter cloacae*, and *Acinetobacter baumannii*. Resolution of these discrepant results is ongoing.

“We are delighted to have delivered the next highly multiplexed Unyvero application,” said Dr. Gerd Luedke, Director Bio-Assay Development of Curetis AG. “It is gratifying to see the clinical value Unyvero can add in the

many cases where classical microbiology culture fails to identify crucial pathogens, addressing a major shortcoming of established methods when pathogens are hard to culture and grow. Furthermore, we are pleased to see that the Unyvero Lysator allows us to process an extremely broad and diverse set of native patient sample types. Unyvero's unique lysis capabilities make the platform impressively versatile, especially in a point of care environment where clinicians might not always have the purest of native samples."

"The launch and commercial availability of the Unyvero i60 ITI Cartridge marks an important milestone in our collaboration with Curetis," said Dr. André Kobelt, CEO of Heraeus Medical GmbH. "In combination with our broad range of Heraeus Medical biomaterials for orthopedics and traumatology, i60 will enable us to offer comprehensive infection management solutions to our customers throughout Europe. This added capability will help foster teamwork in hospital settings between orthopedic surgeons, infectiologists, microbiologists and stakeholders in health economics."

"The i60 launch demonstrates our ability to continuously extend and expand our Unyvero platform to address unmet medical needs with unparalleled multiplexing capabilities and versatility in terms of sample types," said Oliver Schacht, CEO of Curetis. "By detecting not only pathogens, but also key antibiotic resistance markers, i60 for the Unyvero™ system further builds our leading position in the marketplace. Initial customer response has been very positive and demand for this new cartridge has been building steadily over the past few months."

Curetis and its distribution partners will introduce the Unyvero™ i60 ITI cartridge at the 2014 ECCMID conference in Barcelona, Spain (9-13 May 2014 – Booth 39), where the Company will also host the Medical Symposium, "Implant and Tissue Infections - Challenges and Opportunities" (May 10, 2014, from 13:30 - 15:30 in Hall J).

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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 CE-marked application, the Unyvero™ i60 ITI cartridge for implant & tissue infections, is also commercially available in Europe. 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 Cempira Inc. as well as several international distribution agreements covering more than 20 countries.

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