Curetis Initiates Clinical CE Performance Evaluation of Unyvero P55 Pneumonia Application

- *Clinical study to test more than 400 patient samples*
- *Follows successful completion of analytical CE Performance Evaluation in more than 400 cartridge runs*
- *Expected results and product launch in spring 2015*

Holzgerlingen, Germany, March 9, 2015 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced the start of the clinical CE performance evaluation of its next-generation Unyvero P55 Pneumonia Application. The new P55 Cartridge will replace the current P50 Pneumonia Application, which was launched in 2012. P55 will offer an even broader panel of pathogens and antibiotic resistance markers, reflecting global changes in the importance of microorganisms and certain critical resistance mechanisms responsible for pneumonia and other lower respiratory tract infections. Final study data and the P55 product will be presented at the upcoming 25th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) April, 25 – 28 2015 in Copenhagen, Denmark.

The clinical study will evaluate more than 400 already collected native samples from patients suffering from pneumonia. Primary endpoint of the study will be assay performance defined as clinical sensitivity and specificity as compared to microbiology culture, today's diagnostics standard of care. Analytical sensitivity has already been established for all panel analytes in more than 400 P55 cartridge runs.

The P55 Cartridge comes with a panel of up to 21 pathogens and up to 19 antibiotic resistance markers. Additions are expected to include e.g. *Mycoplasma pneumoniae, Citrobacter freundii*, *Enterobacter aerogenes*, and *Klebsiella variicola* as well as clinically relevant resistance genes coding for carbapenem (*imp, ndm, vim* and several *oxa*-markers) and oxacillin (*mecC*) resistance. These enhancements reflect input from clinical and epidemiological findings, key opinion leaders and customers over the past two years and will support Curetis' global product launch activities.

The new cartridge will replace the P50 Application on the European market. Pricing will remain unchanged, with an international roll-out expected to start in the second quarter of 2015. Under the label LRT55, the P55 Cartridge will also be used as a Lower Respiratory Tract (LRT)

Application in the U.S. FDA clearance trial, which is expected to be completed in 2016.

“The landscape of antibiotic resistances and clinically relevant pathogens is quickly changing. The Unyvero P55 Application underlines our commitment to constantly evolve our multiplex panels to meet the latest medical findings,” said Dr. Gerd Lüdke, Director Bio-Assay Development of Curetis. „With P55, we are offering an unparalleled panel of pathogen detection and antibiotic resistance marker analysis suitable to obtain clinically relevant results from any native respiratory patient sample type within 4 to 5 hours.”

“The addition of critical carbapenem resistance markers as well as several microorganisms of increased clinical relevance confirms the unique multiplexing capacity offered by the Unyvero Solution,” said Dr. med. Anne Thews, Medical Director of Curetis. “We are looking forward to the clinical data of the P55 study and we are truly convinced that this enhanced cartridge will add significant value to our customers in daily clinical routine improving the standard of care.”

Further details on the Unyvero platform are available at the new Unyvero product website www.unyvero.com. In addition to details of the Unyvero range of products, the site offers downloads of all scientific and clinical publications using Unyvero. Please visit: www.unyvero.com/en/service/downloads/literature/abstract-list.html and www.unyvero.com/en/service/downloads/literature/posters.html.

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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/ct2/results?term=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 to five 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 and is currently being evaluated in the prospective multi-center EPJIC study http://www.epjic.org/ .

Cartridges for additional indications are in various stages of development and preparation.

For further information, please visit www.unyvero.com.

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 EUR 63.5 million (>US$ 70 million). The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical and Cempra Inc. as well as several international distribution agreements covering many countries across Europe and the Middle East.

For further information, please visit www.curetis.com.

Contact

Curetis AG
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 7031 49195-10
pr@curetis.com
www.curetis.com - www.unyvero.com

Media Inquiries
akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68