Curetis to Launch Next-Generation Pneumonia Application at ECCMID 2015

- *Company Successfully Completes Clinical CE Performance Evaluation of Unyvero P55 Pneumonia Application*
- *Clinical sensitivity across 40-marker panel averages 94% at 99.4% specificity*

Holzgerlingen, Germany, April 16, 2015 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced the successful completion of the clinical and analytical CE performance evaluation of its next-generation Unyvero P55 Pneumonia Application. The upgraded cartridge will launch at the 25th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID, April 25 – 28, 2015 in Copenhagen, Denmark) and is supported by more than 800 cartridge runs and over 400 patient samples.

Unyvero P55, which is replacing the current P50 cartridge, identified a total of 127 additional pathogens compared to microbiology culture. Discrepant results have been resolved by independent PCR and sequencing and validated 93 cases as true positives, e.g. cases where traditional microbiology culture missed the pathogen.

The Unyvero P55 Pneumonia Application demonstrates superiority over culture and key enhancements compared to the P50 cartridge, evidenced by pathogen and resistance expansions and improved sensitivity proven in the CE clinical performance study. Specific upgrades include:

- Expansion to detect 21 pathogens, including new targets *Mycoplasma pneumoniae, Citrobacter freundii*, *Enterobacter aerogenes* and *Klebsiella variicola*
- Addition of critical antibiotic resistance markers (now a total of 19), including genes coding for carbapenem (*imp, ndm, vim, oxa-23, oxa-24, oxa-48,* and *oxa-58* markers) and oxacillin (*mecC*) resistance
- Improvements to sensitivity for several analytes, i.e.
    - Greater than 90% for most pathogens on the P55 panel, including *Pseudomonas aeruginosa*
    - Greater than 92% for *Staphylococcus aureus*
    - Near 100% for *Pneumocystis, E. coli and Moraxella catharralis.*

Comprehensive data supporting the next-generation Pneumonia Application will be presented at ECCMID.

The European and international roll out (excluding North America) commences in April 2015. Pricing for the P55 Pneumonia Application remains unchanged from the P50 cartridge. In the U.S., the P55 is being used under the label LRT55 as a Lower Respiratory Tract (LRT) Application in a U.S. FDA clearance trial, which is expected to be completed in 2016.

“The successful completion of the CE performance evaluation study demonstrates significant performance improvements over our previous P50 Pneumonia cartridge,” said Dr. Gerd Lüdke, Director Bio-Assay Development of Curetis AG. “It also underscores our commitment to evolving our multiplex panels according to the changing landscape of antibiotic resistance and pathogens. We believe the Unyvero P55 cartridge offers an unparalleled panel of pathogen detection and antibiotic resistance marker analysis from any native respiratory clinical sample type within four to five hours.”

“The addition of critical carbapenem resistance markers as well as several important pathogens underlines the unique multiplexing offered by the Unyvero Solution,” said Prof. Dr. Brigitte König, Institute of Medical Microbiology and Infection Epidemiology, University Hospital Leipzig. “We are looking forward to seeing the clinical data and to introducing this enhanced and expanded application cartridge into our clinical routine.”

Further details on the Unyvero platform are available at the new Unyvero product website, www.unyvero.com. The new site details the Unyvero range of products and hosts key Unyvero scientific and clinical publications and posters for download.

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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 CE-marked Unyvero P55 Cartridge focuses on pneumonia testing and simultaneously analyses 40 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