



Curetis Presents New Unyvero Pneumonia Data at Major Clinical Microbiology Meetings

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? Presentation of clinical data from a pneumonia study on multi-pathogen infections at ICAAC 2014 and DGHM 2014

? Rapid Multiplex PCR assays confirmed as valuable addition to conventional testing methods

Holzgerlingen, Germany, Sept. 30, 2014 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced new data on the clinical performance of its Unyvero P50 pneumonia cartridge in multi-pathogen infections.

A study conducted by researchers from private laboratory medicine firm MVZ Dr. Eberhard & Partner (Dortmund, Germany) analyzed pneumonia patient samples with both Curetis' Unyvero P50 pneumonia cartridge and with classical microbiology culture. The investigator-initiated study determined >80% sensitivity at >95% specificity for pathogen identification with Unyvero P50. Of note, 54% of all cases had polymicrobial infections, many of them involving between 3 and 6 different pathogens. In the trial, Unyvero P50 found additional polymicrobial infections and detected 17 pathogens, all of which were not identified by microbiology culture. In contrast, in 6 cases classical culture identified a total of 8 pathogens not detected by Unyvero P50.

„The results suggest that combining rapid molecular methods such as the Unyvero solution with traditional microbiology culture can be a huge advantage in assessing the optimum treatment regime,” said Dr. med. Arthur Pranada, a specialist for microbiology, virology and infectious disease epidemiology at MVZ Eberhard and lead author of the study. “This is of great importance in many polymicrobial infections and with challenging native respiratory samples.”

“We are excited to see our laboratory partners and customers conduct clinical studies on important medical questions such as polymicrobial infections,” added Dr. med. Anne Thews, Medical Director of Curetis. “The data show that both methods are synergistic, with Unyvero delivering results after only 4 to 5 hours compared to several days for classical microbiology.”

The data have been presented at the recent Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Washington D.C. (U.S.) and will also be presented at the upcoming conference Microbiology and Infection 2014 in Dresden (Germany), a joint event of the Association for General and Applied Microbiology (VAAM) and the Society of Hygiene and Microbiology (DGHM).

During Microbiology and Infection 2014, Curetis will host a symposium on the “Clinical Relevance of Rapid Infectious Disease Diagnostics”. It will take place on Monday, October 6, from 12:15pm - 1:15 pm CET (Room: Konferenz 1 / International Congress Center Dresden). The symposium will be chaired by Prof. Dr. Helmut Fickenscher (Kiel University). Presentations will be held by Dr. Reno Frei (University of Basel) and Prof. Dr. Maria Déja (Charité - Universitaetsmedizin Berlin).

Further details will shortly be available at the new Unyvero product website www.unyvero.com [1]. 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 [2] and www.unyvero.com/en/service/downloads/literature/posters.html [3].



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CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use. The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on the Curetis Unyvero technology is currently available for sale in the United States of America or Canada. The analytical and clinical performance characteristics of any Curetis Unyvero product which may be sold at some future point in time in the U.S. have not yet been established.

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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/> [4] 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. Cartridges for additional indications are in various stages of development and preparation.

For further information, please visit www.unyvero.com [1].

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 and Cempra Inc. as well as several international distribution agreements covering more than 20 countries.

For further information, please visit www.curetis.com [5].

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Links:

[1] <http://www.unyvero.com>

[2] <http://www.unyvero.com/en/service/downloads/literature/abstract-list.html>

[3] <http://www.unyvero.com/en/service/downloads/literature/posters.html>

[4] <http://www.clinicaltrials.gov/>

[5] <http://www.curetis.com>