

# Curetis Receives Clearance for Unyvero™ System and Pneumonia Application in Russia and Serbia

- First Unyvero™ Systems installed for clinical evaluation
- Presentation at 23rd National Congress on Lung Diseases in Kazan

Holzgerlingen, Germany, October 30, 2013 -- Curetis AG today announced that its Unyvero™ System and its Unyvero™ P50 Application have been registered and cleared by the Russian and Serbian Ministry of Health, respectively.

The first Unyvero™ System has already been installed for approbation at the Central Clinical Hospital of the Presidential Administration of the Russian Federation in Moscow and another will be tested at one of the major hospitals in St. Petersburg.

Curetis' distribution partner, BioLine LLC, is currently presenting the Unyvero™ System at major clinical and scientific events in Russia. Likewise, Curetis' distribution partner Ako med d.o.o. is demonstrating the Unyvero™ System at major hospitals in Serbia, Bosnia Hercegovina, Croatia and Slovenia.

"We are very pleased that the Russian Ministry of Health has registered and cleared Curetis' Unyvero System and P50 Pneumonia Application," said Olga Solntseva, Director Sales and Marketing for Diagnostic Products at BioLine LLC. "With the successful registration, we can now begin to promote and broadly market the product in Russia. To that end, we participated in the 23rd National Congress on Lung Diseases in Kazan from October 23 to 25."

"At Ako med, we are really happy with the recent regulatory clearance of the Unyvero product range in Serbia," stated Stojan Radakovic, Director of Ako med. "We have received excellent feedback from a recent road show where we presented Unyvero to major hospitals and key opinion leaders in several cities across Serbia and Bosnia Hercegovina and we are planning to broaden the campaign to other countries in the region."

"With the growing number of installed Unyvero Systems worldwide, we are excited to see that the product is very successful in all regions we

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currently cover," said Oliver Schacht, CEO of Curetis AG. "The fact that Unyvero receives excellent feedback in different, heterogeneous markets underlines the quality and maturity of the system. Therefore, we are convinced that we are in a good position to access new markets with Unyvero and to quickly expand our market share in existing distribution areas."

#### Disclaimer

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 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

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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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