# Curetis' Unyvero System Selected for Global Phase III Antibiotics Trial

– *Unyvero to be used for pathogen identification and patient inclusion at several clinical sites across Europe*

**Holzgerlingen, Germany, June 24, 2015** -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced that Curetis' Unyvero System will be used in a Phase III trial of a novel formulation of the antibiotic Amikacin. Unyvero was chosen as a platform to detect pathogens and antibiotic resistances in patients to be enrolled at intensive care units at several clinical trial sites across multiple European countries. Unyvero will be used to support patient identification and help boost enrollment rates at these sites.

Amikacin is an aminoglycoside antibiotic marketed for the treatment of severe, hospital-acquired infections with multidrug-resistant Gram-negative bacteria. The trial is evaluating the efficacy of a novel drug-device combination as an adjunctive therapy for Gram-negative pneumonia in the treatment of intubated and mechanically ventilated adult patients with Gram-negative pneumonia receiving standard of care intravenous antibiotics. The trial is recruiting approximately 650 patients at trial sites worldwide.

Under the terms of the agreement with the sponsor of the trial, Curetis will deliver Unyvero systems and CE-IVD marked P55 cartridges to the trial sites as well as install the systems and provide training and technical support at these sites. The sponsor will fully reimburse Curetis for systems, training, services and consumables. Further financial details were not disclosed.

"We are delighted that Unyvero was selected as the system of choice for this important Amikacin trial," said Oliver Schacht, Ph.D., CEO of Curetis. "This is the third partnership of Curetis with a global pharmaceutical company to use Unyvero in support of a clinical trial. This increase in big pharma adoption of Unyvero for trials clearly demonstrates the value these companies see in our platform. We are proud that major pharmaceutical companies increasingly rely on Unyvero for the fast and reliable identification of pathogens and antibiotic resistance markers – a value our system already provides on a daily basis in the clinic of many leading European hospitals. Clinical trial support, like that we are providing under this agreement, adds further momentum to the expansion we already see in the hospital market."

Dr. Schacht added that major pharmaceutical companies select Unyvero

to support clinical trials because the system is easy to use and already clinically validated and CE-IVD marked in Europe. Curetis' Unyvero P55 Pneumonia cartridge is especially appealing to these clients because of its unparalleled breadth of pathogens and resistance markers in many different relevant native clinical sample types.

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

**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 here.

The platform enables the DNA-based testing of all clinically relevant samples in a fully automated, unsupervised analysis process requiring only a 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 analyzes 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 a prospective multi-center EPJIC study.

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 companywhich 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.**

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