Curetis Initiates Next Phase of Unyvero U.S. FDA Trial in Lower Respiratory Tract Infections

- *First patient enrolled in prospective arm of IVD trial*
- *Study to include a total of at least 2,500 patient samples*
- *Milestone triggers payment of EUR 6.8 million financing tranche*

Holzgerlingen, Germany, July 8, 2015 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced the enrollment of the first patient in the prospective phase of its Unyvero U.S. FDA trial.

The primary endpoint of the multicenter U.S. study will be the performance of Curetis' second generation Unyvero Lower Respiratory Tract (LRT) cartridge, LRT55, in detecting lower respiratory tract infections as compared to microbiology culture – which is currently considered the diagnostic standard of care. In addition, Unyvero results will be compared to an independent molecular composite comparator based on pathogen DNA analysis by PCR and sequencing. At least eight trial sites across the U.S. will participate in the at least 2,500-patient study.

The new trial phase is based on an augmented study design and an enhanced product. This phase of the U.S. trial incorporates two new elements: the latest FDA guidelines for diagnostic trials, and modifications resulting from outcomes of the first phase of this trial. Enrollment completion is anticipated in mid-2016 with FDA submission targeted for the second half of 2016. The Company aims for FDA clearance for Unyvero and subsequent commercialization in early 2017.

The continuation of the trial triggers a EUR 6.8 million financing tranche supported by current Curetis investors.

"We look forward to resuming our work on the trial with the Unyvero System," said Robin Patel, M.D., Chair, Division of Clinical Microbiology, Mayo Clinic and principal investigator of the study. "Unyvero offers the possibility of identifying a panel of pathogens and antibiotic resistance genes in LRT infections within a few hours – compared to days when using standard methods."

"We are very happy about the progress of the trial," said Johannes Bacher, COO of Curetis. "It's an important milestone for us in expanding

our already fast-growing market in Europe, Asia and other regions to the U.S. The financing tranche triggered by the milestone will fund us well through the study and will also further commercial operations in Europe. For building a commercial organization in the U.S., which is expected to start in late 2016, we are considering several financing options, including accessing the public capital markets."

LRT55 is a second-generation cartridge based on the design of the CE-IVD marked P55 cartridge marketed outside the U.S. It features 40 markers and a novel control concept with live bacteria in the control material and improved representation of pathogens in the panels. As a result, it provides the most comprehensive molecular marker panel for LRT infections marketed today. P55 has demonstrated superior performance in the CE performance evaluation study and additional investigator-initiated clinical studies.

In the U.S. FDA trial, tracheal aspirates and bronchial lavages will be pre-processed by the Unyvero Lysator and transferred to the Unyvero LRT55 cartridge, which is subsequently analyzed by the Unyvero Analyzer. Results are available within four-to-five hours.

The prospective arm of this trial includes at least 1,500 hospitalized patients with suspected lower respiratory tract infections to determine the clinical specificity of the Unyvero LRT55 cartridge.

In another arm of the study, at least 1,000 retrospective blinded patient samples will be analyzed for clinical sensitivity endpoints. All pathogens and resistance markers featured on the Unyvero LRT55 Cartridge will be included in the study. Already, Curetis has collected more than 500 retrospective patient samples across its clinical trial network. All retrospective samples have been tested positive for pathogens on the LRT55 panel by standard microbiology culture.

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.

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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 resistance genes 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 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.

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