Curetis Completes Sample Enrollment in Unyvero U.S. FDA Trial in Lower Respiratory Tract Infections

- Last patient enrolled in prospective arm of IVD trial

- More than 2,250 prospective and retrospective samples enrolled in study

- Data to be complemented with up to 500 additional contrived samples with focus on rare pathogens

Holzgerlingen, Germany, June 28, 2016 -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the completion of patient enrollment in its Unyvero U.S. FDA trial. The primary endpoint of the prospective and retrospective study is the performance of the Unyvero LRT55 Lower Respiratory Tract cartridge in detecting lower respiratory tract infections as compared to microbiology culture, the current diagnostic standard of care.

In less than a year, a total of 2,254 tracheal aspirate and bronchoalveolar lavage samples have enrolled at nine participating sites across the US, including Mayo Clinic, Northwestern University, Johns Hopkins Hospital, UCLA and Columbia University Medical Center. 1,698 samples were prospectively tested, and 556 were retrospectively tested with the LRT55 Unyvero Lower Respiratory Tract Cartridge as well as using standard of care microbiology culture. The Principal Investigator of the trial is Dr. Robin Patel, Director of the Clinical Bacteriology Laboratory and Infectious Diseases Research Laboratory, and Chair of the Division of Clinical Microbiology at Mayo Clinic.

“Our Clinical Trial Operations team would like to thank all of the participating sites, as well as our Principal Investigator Robin Patel, for their dedicated support during the study,” said Johannes Bacher, Chief Operating Officer of Curetis. “We are proud to conclude patient enrollment this month as planned, after running more than 5,650 Unyvero LRT55 Cartridges in a study with complex sample management logistics.”

“We are very pleased to have finished enrolment of our U.S. study on schedule and according to plan,” said Dr. Oliver Schacht, CEO of Curetis. “In preparing for our IPO during the second half of last year, we outlined a number of anticipated near- and mid-term milestones for the Company. Following the commercial launch of our blood culture (BCU) application cartridge earlier this year, the completion of enrollment in our U.S. trial represents another important accomplishment from that list. I am proud of what our teams have accomplished since becoming a public company, and we look forward to the release of initial top-line data from the study later this year.”

After completion of all molecular comparator testing, data will be unblinded and Unyvero results will be compared against an independent molecular composite comparator based on pathogen DNA analysis by PCR and sequencing. Completion of the analysis is expected in the second half of 2016. Subsequently, a statistical analysis based on more than 350,000 data points combined from microbiology, Unyvero runs, additional molecular testing and bidirectional sequencing will be prepared. FDA submission is anticipated before the end of the year, with a goal of securing FDA clearance for Unyvero and commercialization of the technology in the first half of 2017.

In order to provide additional data points for certain rare pathogens, e.g. *Legionella*, *Mycoplasma*, *Pneumocystis*, up to 500 contrived samples from well characterized pathogen strains from several international strain providers will be spiked into negative matrix and tested with Unyvero at several clinical trial sites. It is expected that this phase will add approximately 1,500 cartridge runs, as double testing will be performed on two systems in parallel for software validation, including daily controls and a number of sample repeats.

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, a novel control concept and provides the most comprehensive molecular marker panel for lower respiratory tract infections available today.

Further details about the Unyvero platform are available at the Unyvero product website – www.unyvero.com.

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.

###

About Curetis

Founded in 2007, Curetis 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 enable rapid multi-parameter pathogen and antibiotic resistance marker 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 EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 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 countries across Europe, the Middle East and Asia.

For further information, please visit www.curetis.com.

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, with three CE-marked Unyvero Application Cartridges currently available: The Unyvero P55 Cartridge focuses on pneumonia testing, the ITI Cartridge is designed for the diagnosis of implant & tissue infections and the BCU Cartridge is designed to analyze positively flagged blood culture samples from bottles inoculated with blood from patients with suspected blood stream infections. Cartridges for additional indications are in various stages of development and preparation.

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.

For further information, please visit www.unyvero.com.

Legal Disclaimer

This document constitutes neither an offer to buy nor to subscribe securities and neither this document nor any part of it should form the basis of any investment decision in Curetis.

The information contained in this press release has been carefully prepared. However, Curetis bears and assumes no liability of whatever kind for the correctness and completeness of the information provided herein. Curetis does not assume an obligation of whatever kind to update or correct information contained in this press release whether as a result of new information, future events or for other reasons.

This press release includes statements that are, or may be deemed to be, “forward-looking statements”. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes”, “estimates”, “anticipates”, “expects”, “intends”, “may”, “will”, or “should”, and include statements Curetis makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Curetis’ actual results may differ materially from those predicted by the forward-looking statements. Curetis undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

According to §§ 190 ff. German Reorganization Act (UmwG) and by way of enrolment in the commercial register at district court Stuttgart on March 15, 2016 Curetis plc (AG) changed its legal form into Curetis Ltd. (GmbH).

Contact
Curetis GmbH
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 7031 49195-10
pr@curetis.com
www.curetis.com - **www.unyvero.com**

International 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

U.S. Media Inquiries
The Ruth Group
Lee Roth
lroth@theruthgroup.com
Tel. +1 646 536 7012