Curetis N.V. (the "Company" and, together with Curetis GmbH, "Curetis"), a developer of next-level molecular diagnostic solutions, today announced the broad commercial roll-out of its new Unyvero BCU Blood Culture Application Cartridge, which was introduced during ECCMID in April 2016. The roll-out has been initiated in Europe, the Middle East and Asia via Curetis' internal sales force and the company’s distribution partner network.

The market launch is supported by excellent interim data from an external, prospective, multicenter evaluation comparing the performance of the BCU Application Cartridge against the performance of conventional microbiology work-up of positive blood cultures that is ongoing at three European hospitals.

The interim analysis on approximately 100 patient samples demonstrated a 98% concordance with conventional microbiology. Additional pathogens that escaped detection by conventional microbiology were found in several cases. On average, Unyvero results were available 24 hours earlier and in some cases up to two days earlier than results obtained by routine diagnostic methods. The data also confirm compatibility with most commonly used blood culture systems, namely BacT/ALERT® (BioMérieux) and BD BACTEC™ (Becton Dickinson).

Curetis expects to finalize the prospective evaluation during the third quarter of 2016 and is planning to submit a joint publication with the clinical investigators of the study to a peer-reviewed medical journal.

“The new Unyvero Application for blood cultures has truly proven its worth in our microbiology laboratory, thanks to its broad coverage of pathogens, the identification of antibiotic resistances and its easy handling,” said Dr. Monika Huber, senior physician and private lecturer of the Institute of Pathology and Bacteriology, at SMZ Otto Wagner Spital in Vienna, Austria, one of the clinical investigators of the study. “Even with mixed infections, excellent results are obtained within a few hours – a very valuable time gain for bringing adequate therapy to the patient.”

“We are very pleased with these first data from the prospective evaluation of our BCU Blood Culture Application,” said Dr. Achim Plum, CCO of Curetis, “They demonstrate the versatility and utility of our new BCU Application Cartridge in the rapid and reliable identification of pathogens and antibiotic resistance markers in positively flagged blood cultures. The results also indicate its significant potential to improve the management of critically ill patients with blood stream infections.”
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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 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 many countries across Europe, the Middle East and Asia.

On a separate note, the Company has announced for the purposes of article 2(1)(i) of Directive 2004/109/EC (as amended by Directive 2013/50/EU) and as implemented in the Netherlands in section 5:25a of the Dutch Financial Supervision Act (Wet financieel toezicht) that the Netherlands is the home member state of Curetis N.V.

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

About the BCU Application Cartridge
The BCU Application Cartridge features a unique and differentiated test panel covering more than 100 diagnostic targets, including tests detecting Gram-positive and Gram-negative bacteria, fungi and mycobacteria, as well as tests for up to 16 antibiotic resistance biomarkers. The Application Cartridge is used for samples from positively flagged blood culture samples from bottles inoculated with blood from patients with suspected blood stream infections. The BCU Application Cartridge delivers comprehensive results within four to five hours and requires just a few minutes of hands-on time. The cartridge is compatible with the most common commercial blood culture systems (e.g. BioMérieux BacT/ALERT® and BD BACTEC™). The BCU Application Cartridge was CE-IVD marked prior to its market introduction based on a clinical CE performance evaluation study demonstrating a sensitivity of 96% and a specificity of 99%.

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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.

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