Curetis to Launch CE-IVD Unyvero Blood Culture Application Cartridge at ECCMID 2016

- Successful completion of CE Performance Evaluation Study

- Covers 103 diagnostic targets with 87 pathogens and 16 resistance markers

Amsterdam, the Netherlands and Holzgerlingen, Germany, March 23, 2016 -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the successful completion of the CE Performance Evaluation study of the new Unyvero BCU Blood Culture Application Cartridge (Unyvero BCU). Unyvero BCU, which will be launched in early April as a CE-IVD-marked product, is designed for the diagnosis of infections spreading through the bloodstream. The cartridge is compatible with most standard blood culture systems. Its comprehensive assay panel covers a broad range of diagnostic targets including 87 of the the clinically most relevant pathogenic microorganisms, among them Gram positive and Gram negative bacteria, several fungi and atypical pathogens, as well as 16 related antibiotic resistance markers. Sold as a consumable for Curetis' Unyvero System, the product analyzes samples from blood culture bottles inoculated with blood or punctates from patients with suspected bloodstream infections that were flagged positive for microbial growth during incubation in an automated blood culture system. It is the third Application Cartridge for the Unyvero System following the P55 Pneumonia Application launched in 2015 and the ITI Application for implant and tissue infections launched in 2014.

In the performance evaluation study, a total of 609 samples were tested with the BCU Cartridge. These include more than 200 samples from blood culture bottles flagged positive for microbial growth in the routine work-up of patients, blood cultures that were flagged negative in clinical routine as well as 59 additional blood culture bottles inoculated with one of the different microbial strains covered by the panel.

The results demonstrated

- an average sensitivity for all pathogens of 96.2%,
- an average specificity of 99.4%,
- a positive predictive value of 90.1% and
- a negative predictive value of 99.8%.

To ensure compatibility with commonly used blood culture systems, the two most common systems and bottle types in the industry by Becton Dickinson and bioMérieux were used in the study and performance has been uniformly positive across the range of systems and bottles tested. Moreover, Curetis has demonstrated that other blood culture systems and bottles such as products by Oxoid, Thermo and VersaTREK can also be used with the Unyvero BCU cartridge.

The Unyvero BCU Blood Culture Application Cartridge will be launched during the 26th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Amsterdam, The Netherlands (April 8-12, 2016). Three customer sites at renowned hospitals in Austria and Germany have already agreed to further evaluate the CE-IVD-marked Unyvero BCU product in clinical routine. Following the launch, Curetis expects to roll out the product via its direct selling markets in Europe and its distribution partner network in other

European countries, the Middle East and Asia.

“We are excited to start marketing the third Application Cartridge for our Unyvero Platform,” said Dr. Achim Plum, Chief Commercial Officer of Curetis. “With over 100 diagnostic targets covered by the Unyvero BCU cartridge, we believe to have the broadest available panel for suspected blood stream infections that can be used with a wide range of routine blood culture systems. The new Unyvero application will provide physicians with timely, comprehensive and actionable information in situations where every hour counts for the patient.”

Curetis´ CEO Oliver Schacht, PhD, added: “One of our key priorities after the IPO has been the expansion and acceleration of our product development pipeline. With the successful validation and launch of the BCU product, significant progress with a second generation ITI cartridge, the upcoming IAI Intra-Abdominal Application Cartridge and our Sepsis Host Response program, we continue to deliver on key aspects of our equity story outlined to the market at our IPO.”

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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.

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

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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).

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