Curetis Files for U.S. FDA Clearance for Unyvero Platform and LRT Application Cartridge

- Final panel demonstrates overall weighted average sensitivity of 91.4% and overall weighted average specificity of 99.5% across all lower respiratory tract panel pathogens

- Unyvero results available after approximately five hours only, compared to three to four days on average for microbiology culture based methods

Amsterdam, the Netherlands, and Holzgerlingen, Germany, January 05, 2017 - Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced it has submitted a *510(k)* application to the U.S. Food and Drug Administration for its Unyvero Platform and the Unyvero LRT Lower Respiratory Tract Cartridge. The submission is for the use of Unyvero for the diagnosis of lower respiratory tract infections. The LRT panel includes up to 36 analytes for all key pathogens and antibiotic resistances in this indication area

The submission is based on clinical data of the Company's U.S. FDA trial comparing the performance of the Unyvero LRT Lower Respiratory Tract Cartridge in detecting respiratory pathogens to microbiology culture, the current diagnostic standard of care. The trial also compared Unyvero results to a composite of microbiology and independent PCR tests plus sequencing. The study included a total of 2,202 prospective and retrospective samples and met its primary endpoints by demonstrating an overall weighted average sensitivity of 91.4% across all pathogens of the final panel definition as well as an overall average weighted specificity of 99.5%, which increased to 99.8% after discrepant result resolution. The Unyvero application delivered microorganism and resistance marker results in approximately 5 hours, whereas microbiology culture methods required three to four days on average until microorganism identification and antibiotic susceptibility testing of a sample has been completed.
The study was complemented by a set of contrived samples, i.e. negative patient samples spiked with rare pathogens and analytes at known concentrations. This part was successfully completed at four trial sites with data showing an overall weighted average positive percent agreement (PPA) for all tested pathogens of 87.6%. All in all, more than 10,000 LRT cartridges were run in the trial, including comprehensive analytical and pre-clinical testing.

Together with the participating study centers, Curetis is preparing a publication of the clinical trial data. An abstract will be submitted for peer review and for presentation at one of the major upcoming U.S. medical diagnostics conferences.

"With the timely submission of our FDA filing for Unyvero and the LRT Application Cartridge, we have met yet another key milestone as laid out during our IPO," said Johannes Bacher, COO of Curetis. "The trial resulted in a very comprehensive and strong data package that will hopefully allow for getting a clearance decision in 2017 and has confirmed the

substantial reduction in time-to-result that can be achieved with Unyvero."

"With the first FDA trial completed, we are well on track towards launching our Unyvero Platform in the USA in 2017," added Dr. Oliver Schacht, CEO of Curetis. "To that end, we have recently completed recruitment of a core team at our San Diego office with the hires of Rick Betts as our Director Marketing from Abaxis and Faranak Atrzadeh as Director Scientific Affairs, who was most recently at GenMark. Once we have clarity on the FDA process and timelines, we will start building a field-based sales and service organization and a back-office support team of around 20 additional staff during 2017. In addition, we will continue to drive additional Application Cartridges and Menu expansions by conducting further U.S. FDA trials."

Curetis has already started preparations for another FDA trial with its Unyvero ITI Application Cartridge for the diagnosis of joint infections, including periprosthetic joint infections. The Company expects to launch this trial in 2017 with the aim of completion in 2018.

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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. Furthermore, Curetis has entered into a debt financing facility with EIB for up to EUR 25 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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