Curetis Announces Positive Top Line Data from U.S. FDA Trial

- *Primary endpoint for Unyvero LRT product for lower respiratory tract infections shows overall weighted average sensitivity of 90.2% and overall weighted average specificity of 99.3%*
- *U.S. FDA submission being prepared*

Amsterdam, the Netherlands, and Holzgerlingen, Germany, October 25, 2016 -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced top line data from its successfully completed Unyvero U.S. FDA trial. The trial was designed to compare the performance of the Unyvero Instrument Platform and the Unyvero LRT Lower Respiratory Tract Cartridge in detecting lower respiratory tract infections to microbiology culture, the current diagnostic standard of care. Additionally, the trial compared Unyvero results to a composite of microbiology and independent PCR tests plus sequencing. The prospective and retrospective study met its primary endpoint by demonstrating an overall weighted average sensitivity of 90.2% and an overall average weighted specificity of 99.3%.

The trial included a total of 2,203 prospective and retrospective samples and has run 5,694 Unyvero Cartridges, including daily positive and negative controls at each site as well as reproducibility tests. Tracheal aspirate and bronchoalveolar lavage samples were collected at nine participating sites across the U.S., namely Beaumont Health, Columbia University, Johns Hopkins, Mayo Clinic, Northwestern University, Summa Health, UCLA, University of Rochester, and University of Washington. Of these samples, 1,654 were prospectively and 549 were retrospectively tested with the Unyvero LRT Lower Respiratory Tract Cartridge, with standard of care microbiology culture and with additional molecular diagnostic assays.

Furthermore, the study will be complemented with data from more than 400 contrived samples from well-characterized pathogen strains obtained from several international strain providers. These strains were spiked into negative patient samples and are currently undergoing testing with Unyvero at several clinical trial sites in order to provide additional data points for certain rare pathogens.

Overall, more than 1,100 samples tested positive for one or more pathogens on the LRT panel. Data were available from Unyvero cartridges, from microbiology culture and from independent molecular testing using PCR and sequencing, resulting in a total of more than 350,000 data points. These data are fully consistent and in line with the performance evaluation previously conducted by Curetis for CE IVD marking in Europe, as well as published data from various European KOLs and customer sites.

Based on these data, Curetis is now preparing its final package for a *510(k)* submission for the Unyvero Platform and the LRT Cartridge to the U.S. FDA in due course. The company is expecting feedback from the FDA in the first half of 2017.

“We are truly excited about completing the study on time and as planned and generating a strong and very comprehensive data set,” said Dr. Oliver Schacht, CEO of Curetis. “We have now started compiling the final submission documents and are looking forward to receiving

feedback from the FDA. We will be working closely with the agency in the coming months."

"This is a very broad molecular panel for diagnosis of lower respiratory tract infection," said Principal Investigator 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. "It includes numerous bacteria and resistance genes as well as one fungus. Beyond panel breadth, the test yields faster results than those achieved using traditional culture."

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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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