Curetis Reports Positive Results from Clinical Validation Study for U.S. FDA 510(k) Submission of Unyvero LRT for BAL Samples

- Test shows overall weighted average sensitivity of 90.1% (94.7%) and overall weighted average specificity of 98.4% (97.9%) in prospective (retrospective) sample cohort

- U.S. FDA 510(k) submission for Unyvero LRT BAL Application Cartridge in preparation

Amsterdam, the Netherlands, and Holzgerlingen, Germany, May 23, 2019 -- Curetis N.V. (the "Company" and, together with Curetis GmbH, "Curetis"), a developer of next-level molecular diagnostic solutions, today announced key data from its successfully completed Unyvero LRT clinical performance evaluation study for BAL samples. The study was designed based on U.S. FDA feedback to demonstrate enhanced performance of the Unyvero LRT Application Cartridge for detecting lower respiratory tract infections such as pneumonia in BAL specimens. BAL samples, together with tracheal aspirates, for which Unyvero LRT was already cleared by the U.S. FDA in April 2018, are the most common sample types used in the diagnosis of these infections.

The performance of Unyvero LRT BAL was evaluated against standard of care microbiology culture in a prospective sample cohort comprising more than 1,000 patient samples previously collected at nine clinical trial sites in the U.S. With a significant performance improvement in sensitivity compared to 2016 clinical trial data in a similar cohort, the Unyvero LRT BAL Application Cartridge demonstrated an overall weighted sensitivity of 90.1% and an overall weighted specificity of 98.4% with BAL samples.

This study was complemented by additional testing of almost 400 archived BAL samples that were positive according to standard of care and verified by molecular testing. With an overall weighted sensitivity of 94.7% and an overall weighted specificity of 97.9%, the results fully confirmed the prospective BAL sample cohort data.

In total, over 4,500 Unyvero LRT BAL Application Cartridges were used by Curetis to perform the analytical and clinical performance evaluation studies for the validation in BAL specimens.

Based on these data, Curetis is preparing a 510(k) submission for the Unyvero LRT Cartridge for use with BAL specimens to the U.S. FDA in the coming weeks. The Company expects feedback from the FDA shortly after such submission.

“We are truly excited about successfully completing the Unyvero LRT clinical performance evaluation studies in BAL samples on time and with such strong performance data. This should bode well for the intended clearance of a Unyvero LRT Application Cartridge for BAL specimens, complementing Unyvero LRT for tracheal aspirate samples for which we have FDA clearance already,” said Johannes Bacher, Chief Operating Officer of Curetis. “We are currently preparing the final submission documents and are looking forward to receiving feedback from the FDA in due course.”

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About Curetis

Curetis N.V.'s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis' Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis' wholly owned subsidiary Ares Genetics GmbH is developing next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines the presumably most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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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," "targets," "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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