Curetis Files for U.S. FDA 510(k) Clearance of Unyvero LRT for BAL Specimens

- Final LRT BAL panel demonstrates overall weighted average sensitivity of up to 94.7% and overall weighted average specificity of up to 98.4%

- Unyvero provides results after approximately five hours, compared to an average of several days for standard-of-care methods

Amsterdam, the Netherlands, San Diego, CA, USA and Holzgerlingen, Germany, July 23, 2019, 08:00 am CEST - Curetis N.V. (the "**Company**" and, together with Curetis USA Inc. and 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 LRT Lower Respiratory Tract Cartridge for use with BAL (bronchoalveolar lavage) specimens. The submission is for use of Unyvero LRT BAL for the diagnosis of lower respiratory tract infections such as pneumonia. The LRT BAL panel covers 50 diagnostic targets with 30 assays for the most clinically relevant pathogens and antibiotic resistances in this indication area.

The submission is based on clinical data from a cohort of patient samples collected at nine sites during the Company's U.S. FDA LRT trial as well as a cohort of additional retrospective samples known to be positive for one or more pathogens, comparing the performance of the Unyvero LRT BAL Lower Respiratory Tract Cartridge in detecting respiratory pathogens to the current diagnostic standard of care, i.e. microbiology culture. The trial also compared Unyvero results to a composite comparator of microbiology and independent PCR tests plus DNA sequencing. In total, the study included more than 1,400 patient samples from the combined prospective and retrospective cohorts and demonstrated an overall weighted average sensitivity of 90.1% and 94.7% and an overall average weighted specificity of 98.4% and 97.9% across all pathogens in the prospective and retrospective cohorts, respectively. The Unyvero application delivered microorganism and resistance marker results in approximately 5 hours, whereas the standard-of-care based on microbiology culture methods required several days on average to complete microorganism identification and antibiotic susceptibility testing of a patient sample.

The study was complemented by an additional set of 240 contrived samples, which successfully confirmed performance of LRT BAL with negative patient samples that were spiked with rare pathogens and resistance markers at known concentrations. All in all, more than 5,500 LRT BAL cartridges were run as part of the comprehensive analytical and clinical performance evaluation.

Furthermore, independent clinical evaluation data for the Unyvero LRT BAL Application Cartridge from an investigator-initiated study has recently been presented at the ASM Microbe 2019 conference in San Francisco, CA, USA, confirming the excellent sensitivity and specificity of the panel.

“With the submission of our FDA filing for the Unyvero LRT BAL Application Cartridge, we have met another key milestone laid out for mid-2019,” said Johannes Bacher, COO of Curetis. “The clinical validation has resulted in a very comprehensive and strong data package to support a clearance decision by the FDA later in 2019 and has once again shown the substantial reduction in time-to-result that can be achieved with Unyvero.”

“With this second FDA submission filed, we are well on track towards expanding the utility of our Unyvero LRT panel in the USA to also include BAL specimens in addition to tracheal aspirates,” added Oliver Schacht, CEO of Curetis. “We will continue to drive evaluations and adoption of our Unyvero Application Cartridges, and we also look to further menu expansions and conducting clinical trials e.g. in support of a U.S. FDA submission of our IJI Invasive Joint Infection Application Cartridge as additional funding becomes available.”

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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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