Curetis Accelerates 510(k) Submission Preparation for Unyvero LRT in BAL Specimen Based on Positive FDA Feedback

- ***U.S. FDA and Curetis agree on 510(k) requirements for clearing BAL as additional sample type for Unyvero LRT***
- ***U.S. commercial roll-out gaining traction, with first dozen Unyvero Analyzers placed and first commercial evaluation agreements signed***

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, USA, November 23, 2018, 07:00 am CET - Curetis N.V. (the "**Company**" and, together with its subsidiaries, **"Curetis**"), a developer of next-level molecular diagnostic solutions, today announced that following a recent meeting, the U.S. FDA has confirmed the suitability of the 510(k) clearance pathway for Curetis' Unyvero LRT Application Cartridge specifically optimized for the detection of microbial pathogens in bronchoalveolar lavage ("BAL") samples.

The U.S. FDA confirmed that data required for the submission can largely be based on clinical samples previously collected during the original Curetis U.S. FDA trial for the Unyvero LRT Application Cartridge. Overall, the Company believes that U.S. FDA feedback has substantially de-risked the planned submission of the Unyvero LRT Application Cartridge for BAL and that the requirements agreed upon with the Agency should allow Curetis to accelerate generating the required data and prepare for an early submission, with an expected clearance decision in 2019.

BAL is another common method for the diagnosis of lower respiratory tract infections, in which the lower airways are flushed with saline solution. The lavage fluid is then analyzed for the presence of pathogens. Sensitivity of the Unyvero LRT Application Cartridge for BAL has been further optimized for this more diluted sample type. It is estimated that half of the samples obtained for the diagnosis of lower respiratory tract infections are BALs, and Curetis believes that a clearance for this additional sample type would increase the total addressable market for the Unyvero LRT Application Cartridge in the U.S. accordingly.

As part of the 510(k) submission, Curetis also plans to include data on an assay for one additional pathogen, *Pneumocystis jirovecii*. This fungus is particularly relevant in lower respiratory tract infections in patients with compromised immune status, such as transplant recipients or AIDS patients.

The Company also reported that the U.S. commercial roll-out of the Unyvero LRT Application Cartridge for tracheal aspirates launched in June 2018 is gaining traction. Since the launch, the U.S. commercial team has qualified about 140 accounts in the top 1,000 hospitals initially

targeted with about 80 being deeply vetted. Several accounts have entered into clinical and commercial evaluation agreements and with a dozen Unyvero Analyzers placed beyond FDA trial sites have since then started the on-site evaluation of the Unyvero System and LRT Application Cartridge. These and many further of these vetted accounts are expected to be converted to commercial accounts over the next several quarters with about a dozen accounts constituting near-term opportunities currently at the contract negotiation stage. These initial accounts on average are expected to have Unyvero LRT cartridge volumes of 700 to 800 annually once they become commercial customers with some accounts having significantly higher total potential annual testing volumes. The Company expects to provide an update on target placement numbers for Unyvero Analyzers in the U.S. market around the J.P. Morgan Healthcare Conference in early 2019.

“We are very pleased with the feedback we received during our recent meeting with the FDA,” said Johannes Bacher, COO of Curetis. “With the confirmation of the 510(k) regulatory pathway and valuable feedback on the data requirements, we have considerably de-risked this commercially important extension of Unyvero LRT utility to bronchoalveolar lavage samples.”

“Our commercial campaign for introducing Unyvero LRT in the U.S. market is gaining momentum, with several accounts having entered into commercial evaluation agreements and a strong pipeline of further near-term commercial opportunities,” commented Chris Emery, CEO & President of Curetis USA Inc. “Once the addition of BAL specimen usage is cleared by the FDA, the Unyvero LRT Application Cartridge for use with these samples will strengthen our position as one of the first movers in syndromic testing for lower respiratory tract infections.”

###

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 what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARES*db*, with advanced bioinformatics and artificial intelligence.

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

Legal Disclaimer

This document constitutes neither an offer to buy nor to subscribe securities and neither this document nor any part of it should form the basis of any investment decision in Curetis.

The information contained in this press release has been carefully prepared. However, Curetis bears and assumes no liability of whatever kind for the correctness and completeness of the information provided herein. Curetis does not assume an obligation of whatever kind to update or correct information contained in this press release whether as a result of new information, future events or for other reasons.

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”, “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.

Contact Details

Curetis GmbH
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 7031 49195-10
pr@curetis.com or ir@curetis.com
www.curetis.com

International Media & Investor Inquiries
akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68

U.S. Media & Investor Inquiries
The Ruth Group
Lee Roth
lroth@theruthgroup.com
Tel. +1 646 536 7012