Curetis Receives U.S. FDA *De Novo* Clearance of Unyvero System and Unyvero LRT Lower Respiratory Tract Infection Cartridge

- ***First ever multiplex MDx test to be granted clearance by the FDA for this indication***
- ***Commercial launch in the U.S. expected this quarter***

Amsterdam, the Netherlands, San Diego, CA, USA, and Holzgerlingen, Germany, April 03, 2018, 15:45 am EDT - Curetis N.V. (the "**Company**" and, together with Curetis USA Inc. and Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, announced today that the Company has been granted a *De Novo* clearance by the U.S. Food and Drug Administration (FDA) to market the Unyvero System and Lower Respiratory Tract Infection (LRT) Application Cartridge in the U.S.

The sample-to-answer Unyvero System together with the Unyvero LRT Application Cartridge provides rapid infectious disease testing directly from aspirate samples in under five hours. It covers more than 90% of infection cases of hospitalized patients with pneumonia and provides clinicians with a comprehensive overview on genetic antibiotic resistance markers detected. As the first-in-class molecular test for lower respiratory tract infections with no direct MDx competition, it addresses a high unmet medical need that generates over $10bn in annual costs for the U.S. healthcare system.[1, 2] It is also the first time the FDA has granted an automated molecular diagnostic test for the atypical microorganism *Legionella pneumoniae*. In sum, Unyvero is expected to impact clinical outcomes, support antibiotic stewardship and create health economic benefits.

The Company has a team of more than 20 seasoned experts already in place at its Curetis USA Inc. subsidiary in San Diego, CA. These experts include the U.S. executive leadership, regional sales directors, clinical application specialists, and field-based territory sales managers and service engineering and logistics support. Commercial roll-out will start early in the second quarter, with initial placement opportunities expected in the same quarter. Curetis targets to place 60 to 80 Unyvero Analyzers in the U.S. within the first full year of commercial availability.

“The launch of our Unyvero System and LRT Application Cartridge in the United States will address a pressing unmet medical need as it delivers results much faster than current standard

[1] CDC (2015) ‘New CDC study highlights burden of pneumonia hospitalizations among US adults’, available at: https://www.cdc.gov/media/releases/2015/p0714-pneumonia-hospitalizations.html
[2] American Thoracic Society (2015) ‘Top 20 pneumonia facts – 2015’, available at: https://www.thoracic.org/patients/patient-resources/resources/top-pneumonia-facts.pdf

of care microbiology culture", said Curetis' co-founder and Chief Operating Officer Johannes Bacher.

"We expect that the LRT panel will transform our approach to the diagnosis of lower respiratory tract infections", said Dr. Donna Mildvan, Infectious Diseases Physician and Clinical Professor of Medicine at Icahn School of Medicine at Mount Sinai, New York, NY. "Having the opportunity to characterize pneumonia by knowing the causative organism as well as relevant antibiotic resistance markers in 4 to 5 hours has great clinical implications – it is game changing and exciting."

Data from a clinical trial, which included more than 2,200 patient samples at nine participating U.S. hospitals, were submitted to the FDA in early 2017. Curetis' clinical trial operations team has worked in close collaboration with the FDA's review team to evaluate the study data set and develop relevant statistics and reports, as well as a benefit-risk analysis which was compiled with input and support from several renowned U.S. clinical experts.

"The LRT application is the first cartridge for our Unyvero System that has been approved in the U.S. Preparations for another prospective multi-center clinical trial for a second Unyvero application are already underway", said Oliver Schacht, PhD, Chief Executive Officer of Curetis.

As disclosed previously, Curetis intends to submit an application for a label claim extension following this initial clearance of the LRT application, which would include the bronchial lavage (BAL) sample types, as well as several additional diagnostic targets. In addition, further to the already significant investments in its U.S. operations in anticipation of the FDA approval, Curetis will make additional and accelerated investments in the U.S. Therefore, Curetis will continue to explore and prepare for strategic and tactical options to finance its commercial roll-out in the U.S. and its other operations.

"We have assembled a team of high-caliber talent here at Curetis USA, and we will continue to expand our commercial organization in support of the Unyvero product launch in Q2/2018. We are truly excited to bring the innovative Unyvero Solution to clinicians, microbiologists in clinical laboratories, and above all to patients in the Unites States", commented Chris Bernard, President and CEO of Curetis USA Inc. and Executive Vice President Global Sales.

Investor Update Conference Call and Webcast

Curetis will host a public investor conference call and webcast tomorrow, April 04, 2018, at 03:00 pm CEST / 09:00 am EDT to provide an overview on the Unyvero System and LRT Cartridge for the U.S. market, the FDA *De Novo* clearance decision and the underlying U.S. clinical evaluation data, and the planned U.S. launch and market development activities.

Dial-in details for this investor update conference call and webcast will be published in an additional press release tomorrow.

###

About the Unyvero System

The Unyvero System with the Unyvero LRT Cartridge is the first, most comprehensive molecular diagnostics (MDx) product for lower respiratory tract infections that has been granted clearance by the FDA. With 29 multiplexed PCR assays it can detect more than 30 Gram-positive and Gram-negative bacterial organisms known to cause lower respiratory tract infections, as well as 10 genetic markers for antibiotic resistance, including carbapenem and 3rd generation cephalosporins. Preparations for a future submission of bronchoalveolar lavage (BAL) sample types for use with the LRT Cartridge are progressing, and the Company intends to request a pre-submission meeting in due course. The Company also is already collecting patient samples for a multi-center FDA study for its Unyvero IJI Cartridge for the detection of invasive joint infections. Further Unyvero Cartridges with unique panels designed for the rapid diagnosis of microbial and viral infections are in preparation.

About Curetis

Curetis N.V. (Euronext: CURE) is a leading provider of innovative solutions for molecular microbiology designed to address the global challenge of diagnosing 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, and thereby facilitates 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 in the U.S.

Curetis' wholly-owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. ARES' technology platform combines the world's most comprehensive database on the genetics of antimicrobial resistances with advanced bioinformatics and artificial intelligence.

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

Legal Disclaimer

This announcement contains inside information. This is a public announcement pursuant to article 17 paragraph 1 of the European Market Abuse Regulation (596/2014).

This document constitutes neither an offer to buy nor to subscribe for 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