Curetis' Unyvero BCU Blood Culture Application Receives Approval from Singapore Health Sciences Authority

- ***Second market authorization for Unyvero Cartridges this year in Singapore***

Amsterdam, the Netherlands, and Holzgerlingen, Germany, April 04, 2018; published at 11:30 am CEST -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced that Acumen Research Laboratories Pte. Ltd. (Acumen), its partner for the commercialization of Unyvero in the ASEAN region, earlier today has received approval by the Singapore Health Sciences Authority (HSA) to market the Unyvero BCU Cartridge for bloodstream infections in Singapore. The Application Cartridge is now fully registered as a Class C IVD medical device with the Singapore Medical Device Register (Device Registration No: DE0501464). The HSA in February this year already approved the Unvyero HPN Cartridge for pneumonia. The Unyvero BCU approval by the HSA earlier this morning follows yesterday's decision by the U.S. FDA to clear the Company's Unyvero System and Unyvero LRT Cartridge for lower respiratory tract infections for the U.S. market.

The Unyvero BCU Cartridge, which was launched as a CE-IVD marked product in Europe in April 2016, is designed for the diagnosis of infections spreading through the blood stream, analyzing positively flagged blood culture samples. The BCU cartridge allows detecting 103 diagnostic targets, i.e. microorganisms and genetic markers of antibiotic resistances. With this panel, it is currently believed to be the most comprehensive molecular diagnostic test having received approval by the HSA.

The approval is based on data from a CE-IVD performance evaluation study which tested a total of 609 samples using the BCU Cartridge: more than 200 samples from blood culture bottles flagged positive for microbial growth in the routine work-up of patients, blood cultures that were flagged negative in clinical routine as well as 59 additional blood culture bottles inoculated with one of the different microbial strains covered by the panel.

The results demonstrated

- a weighted average sensitivity for all pathogens of 96.2%,
- a weighted average specificity of 99.4%,
- a positive predictive value (PPV) of 90.1% and
- a negative predictive value (NPV) of 99.8%.

"With two Unyvero Cartridges approved in Singapore, we are now in an excellent position to expand the market for our Unyvero System in the ASEAN region with our partner Acumen", said Oliver Schacht, PhD, CEO of Curetis. "The approval of Unyvero BCU by the HSA in Singapore

comes on the heels of yesterday's *De Novo* clearance decision by U.S. FDA for our Unyvero System and the Unyvero LRT Cartridge for the U.S. market. With these two regulatory milestones in the last 24 hours, we have made major progress in bringing our Unyvero Solution into two strategically very important markets, the U.S. and Asia", he explained.

"We are very pleased with the HSA's approval of the second Unyvero Cartridge this year", said Siew Hwa Ong, PhD, CEO of Acumen. "As a next step, we are now planning to submit the Unyvero ITI Implant and Tissue Infection and Unyvero IAI Intra-Abdominal Infection Application Cartridges for HSA approval."

Dr. Achim Plum, CBO of Curetis added: "We also completed development of the Unyvero SHR Cartridge for the rapid identification of patients with sepsis. Sepsis is a major medical challenge due to difficulty to detect it early and a very complex disease. The healthcare burden is further exacerbated by aging populations, co-morbidities such as cancer and diabetes, as well as increasing antimicrobial drug resistance. The Unyvero SHR Cartridge will be a completely new addition to our portfolio and is based on a proprietary gene expression biomarker panel licensed by Curetis from our partner Acumen in 2015. We will also work closely with the team at Acumen in the clinical validation of this product."

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About Acumen Research Laboratories

Acumen Research Laboratories, based in Singapore, was founded in 2010. The company has strong capabilities in translational research for developing molecular diagnostics using gene-based biomarkers, with approaches that focus on in-depth clinical validation early in the development process. Acumen is one of the few industry leaders in host-based, gene expression sepsis diagnostics. Acumen has received strong support from several Singapore government agencies such as SPRING Singapore, the country's enterprise development agency, the National University of Singapore Enterprise Centre and the Diagnostics Development (DxD) Hub, of the Agency for Science, Technology and Research (A*STAR).

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.

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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