Curetis Unyvero HPN Application Receives Singapore Health Sciences Authority Approval; Updates on Sepsis Host Response Test

- ***Market authorization paves way for broader Unyvero commercial roll-out in ASEAN region through partner Acumen Research Laboratories***
- ***Near-term clinical validation study of first cartridge-based molecular test for Sepsis Host Response panel licensed from Acumen in preparation***

Amsterdam, the Netherlands, and Holzgerlingen, Germany, February 06, 2018; published at 11:00 EST -- 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, has received approval by the Singapore Health Sciences Authority (HSA) to market the Unyvero HPN Hospitalized Pneumonia Application Cartridge in Singapore.

With this approval, Unyvero HPN is now fully registered as a Class C IVD medical device with the Singapore Medical Device Register (Device Registration No: DE0501196). After the initial placement of Unyvero Systems under the GN-27 exemption at early adopter sites such as Raffles Hospital, Farrer Park Hospital, and Parkway Laboratories, the HSA approval now allows for a more comprehensive roll-out in Singapore as a bridgehead to the ASEAN region. Acumen expects that the approval in Singapore will facilitate market entry into other countries of the region including Malaysia, Indonesia, and Thailand going forward.

The HSA review and approval process for the Unyvero BCU Blood Culture Application Cartridge as a second application for the Singaporean and ASEAN markets is ongoing. Acumen and Curetis further intend to submit the Unyvero ITI Implant and Tissue Infection and Unyvero IAI Intra-Abdominal Infection Application Cartridges for HSA approval.

Curetis and Acumen also announced that the development of the Unyvero SHR Sepsis Host Response Application Cartridge for the rapid identification of patients with bloodstream infections and sepsis has been completed. The cartridge is based on a proprietary gene expression biomarker panel licensed by Curetis from Acumen in 2015. In the coming months, the Companies expect to initiate clinical validation work on this first cartridge-based rapid molecular test for sepsis alongside a laboratory-developed test (LDT) based on the same biomarker panel already offered by Acumen to hospitals in Singapore. The validation work will focus on demonstrating concordance of the analytical and clinical performance of two tests in the same patient population.

“In only four to five hours, the new Unyvero HPN test enables detection of 21 pathogens and 19 antibiotics resistance markers that are highly relevant for the diagnosis of hospitalized patients with suspected pneumonia. This will not only help to improve outcomes for these patients, but also facilitate the more prudent use of antibiotics and thereby help mitigating the

growing antimicrobial resistance challenge," commented Siew Hwa Ong, PhD, CEO of Acumen. "We are also pleased with the progress of the Unyvero SHR Application Cartridge building on our biomarker panel, as this rapid and easy-to-use molecular test bears great potential in addressing the diagnostic challenges clinicians are facing in treating sepsis."

"This first approval of a Unyvero Application in an Asian market serves as a bridgehead to the entire ASEAN region and marks an important milestone in the commercial growth strategy of Curetis," said Oliver Schacht, PhD, CEO of Curetis. "With an expected near-term clearance decision from the U.S. FDA for the Unyvero Lower Respiratory Tract Application and the solid progress we are making with our partner Beijing Clear Biotech with regulatory studies in China, we are setting the stage for significant commercial expansion of Unyvero in the years to come."

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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

Founded in 2007, Curetis is a molecular diagnostics company which focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases. The diagnostic solutions of Curetis enable rapid multi-parameter pathogen and antibiotic resistance marker detection in only a few hours, a process that today can take up to days or even weeks with other techniques.

To date, Curetis has raised EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 million. Furthermore, Curetis has entered into a debt financing facility with EIB for up to EUR 25 million. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis collaborates with Heraeus Medical, pharmaceutical companies, and has entered into several international distribution agreements covering many countries across Europe, the Middle East and Asia.

In 2017, Curetis established Ares Genetics GmbH, a wholly-owned subsidiary of Curetis GmbH in Vienna, Austria. Ares Genetics is dedicated to maximize the R&D and related scientific and business opportunities of the GEAR assets acquired in 2016 for the entire Curetis Group.

For further information, please visit www.curetis.com**.**

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