



Curetis' Unyvero Application Cartridges Receive Regulatory Approvals in Malaysia and Thailand

- ***HPN Cartridge approved in Malaysia; HPN, BCU Cartridges approved in Thailand***
- ***Further commercial roll-out of Unyvero in ASEAN region by partner Acumen Research Laboratories facilitated***
- ***Near-term Chinese NMPA submission of Unyvero HPN expected***

Amsterdam, the Netherlands, and Holzgerlingen, Germany, January 30, 2019; published at 08:00 a.m. CET -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced that its partner for the commercialization of Unyvero in the ASEAN region, Acumen Research Laboratories Pte Ltd. (Acumen), has received first approvals by the respective regulatory authorities to market the Unyvero HPN Hospitalized Pneumonia Application Cartridge in Malaysia and Thailand. Thailand also approved the Unyvero BCU Blood Culture Application Cartridge.

With these additional approvals in Asia, Unyvero HPN for the diagnosis of pneumonia in hospitalized patients is now fully registered as an IVD medical device in Singapore, Malaysia, and Thailand – a milestone that allows for broader commercial roll-out and adoption in ASEAN countries with a total combined population of more than 630 million people. Acumen and Curetis intend to submit additional Unyvero Application Cartridges for regulatory approval in the ASEAN markets to further progress the commercial roll-out of Unyvero in the region.

"In only four to five hours, the Unyvero HPN and BCU tests enable the detection of a very broad panel of pathogens and antibiotic resistance markers that are highly relevant for the diagnosis of hospitalized patients with suspected pneumonia and blood stream infections, respectively. This will not only help to improve clinical outcomes for these patients, but also enable better antibiotic stewardship to help mitigate the growing antimicrobial resistance challenge," said Siew Hwa Ong, PhD, CEO of Acumen.

"The further regulatory approval of several Unyvero Application Cartridges in Asian markets beyond the Singapore bridgehead have the potential to contribute to further growth of our Unyvero business in the entire ASEAN region. This marks an important milestone in our Asian expansion strategy," said Oliver Schacht, PhD, CEO of Curetis. "With an expected near-term regulatory submission to the Chinese National Medical Product Administration for the Unyvero HPN Application by our partner Beijing Clear Biotech and with further clinical studies supporting market access in China and beyond already planned, we are preparing for a significant commercial expansion of our Unyvero portfolio in Asia in the coming years."

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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 Enterprise 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.'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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