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ASIA EDITION

Curetis receives regulatory approvals for Unyvero Application Cartridges

January 31, 2019 | News

HPN Cartridge approved in Malaysia; HPN, BCU Cartridges approved in Thailand



Curetis N.V., a developer of next-level molecular diagnostic solutions, has 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.”