Press Release Curetis AG

Curetis and Acumen to Collaborate on Unyvero Sepsis Test and ASEAN Distribution

- *Curetis licenses Acumen's proprietary sepsis biomarker panel for use with Unyvero Platform*
- *Diagnostics Development (DxD) Hub in Singapore to support Acumen in development and clinical validation of the panel*
- *Acumen to distribute Unyvero product line in ASEAN countries*

Holzgerlingen, Germany and Singapore, October [5], 2015 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced that it has obtained a world-wide, non-exclusive license to AcuSept, a proprietary biomarker panel from Acumen Research Laboratories Pte Ltd. (Singapore). The panel is in advanced clinical development and will be used by Curetis and Acumen for the joint development and clinical validation of a sepsis host response test on the Unyvero Platform. Acumen's activities in Singapore will be supported by NUS Enterprise and the Diagnostics Development (DxD) Hub, a national initiative led by the Agency for Science, Technology and Research (A*STAR), which aims to accelerate diagnostics innovations into market-ready products.

Separately, Curetis and Acumen have signed an exclusive, multi-year distribution agreement for the Unyvero product line in ASEAN markets, which will initially include Singapore, Malaysia, Thailand and Indonesia. The agreement, effective immediately, comprises Unyvero Systems and P55 and i60 ITI Application Cartridges. Acumen will seek product registration in these markets. This agreement, through which Acumen will act as a commercial hub for Curetis in the ASEAN markets, will complement the recently announced Greater China distribution partnership between Curetis and Beijing Clear Biotech, giving Curetis a strong sales and marketing presence in Asia.

The AcuSept biomarker panel is designed to accurately detect changes in a patient's immune system indicative of pathogens in the blood stream and of a systemic inflammatory response syndrome (SIRS) caused by these microorganisms. The presence of both SIRS and infections are the medical criteria for sepsis, a severe disease with poor prognosis and an often fatal outcome: approximately 50% of people with severe sepsis and 80% of people with septic shock die. With an estimated incidence of 26 million cases worldwide per year, sepsis is among the most frequent severe medical conditions and a significant economic burden to the

healthcare systems. A fast and clear distinction between patients with sepsis and those who only have either infections or SIRS by appropriate tests is key to an effective therapy and survival.

“We are very impressed with Acumen’s work on the AcuSept biomarker panel for sepsis host response,” said Oliver Schacht, PhD, CEO of Curetis. “We believe that the panel has the potential to address shortcomings of other approaches for the early detection of sepsis, and believe that a sepsis host response test on our Unyvero Platform will ideally complement our Unyvero Blood Culture test, which is currently in development.”

“We are pleased to have won Acumen as an exclusive distributor of our Unyvero Platform with currently marketed Application Cartridges in pneumonia and implant and tissue infections for the ASEAN markets,” added Achim Plum, Chief Commercial Officer of Curetis. “With its in-depth understanding of the clinical needs and the healthcare systems in these markets, Acumen is optimally positioned to develop the ASEAN markets for us and help us establish an ASEAN commercial hub.”

“Sepsis progresses rapidly and frequently comes with non-specific symptoms at an early stage. Accurate, quick and early diagnosis of a developing sepsis, however, is an important prerequisite for fast and effective treatment,” said Siew Hwa Ong, PhD, CEO of Acumen, who is also an Adjunct Professor at the National University of Singapore (NUS) Yong Loo Lin School of Medicine. “Unyvero is ideally suited for the AcuSept sepsis host response panel to enable the early and reliable segregation of patients who have sepsis from those who have infections or inflammation only. Moreover, the distribution of Unyvero creates great synergies for us in building a market for Unyvero that can be leveraged later for the fast adoption of the AcuSept test on the Unyvero Platform. This partnership is made possible partly due to the DxD Hub’s support to Acumen in refining the technical and commercial strategy for the test, as well as its continued commitment to support the subsequent clinical validation.”

“We are delighted that Acumen is embarking on the next stage of its commercialization journey for its AcuSept technology,” said Sidney Yee, PhD, CEO of the DxD Hub. “The strategic partnership between Acumen and Curetis underscores DxD Hub’s role as a critical enabler for diagnostics solutions to reach the market quickly to deliver effective treatment outcomes for patients.”

Curetis expects to launch a sepsis host response test in Europe in late 2017 at the earliest. The registration process for the current Unyvero Systems and Application Cartridges in ASEAN countries is expected to take up to one year.

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About the Unyvero Platform

The CE-marked Unyvero System is a versatile hardware platform for the detection of a broad panel of bacteria, fungi and antibiotic resistance genes from a single sample in one run. It processes a disposable Application Cartridge providing the necessary reagents to complete the analysis from sample to result. It is marketed in Europe, Russia, the Middle East and various other non-European countries. In the U.S., Curetis is running a prospective multi-center clinical trial aimed at achieving FDA clearance registered here.

The platform enables the DNA-based testing of all clinically relevant samples in a fully automated, unsupervised analysis process requiring only a few, quick manual preparation steps. The analysis thus can be performed with minimal operator time and without the need of skilled staff or special infrastructure.

Thereby, clinically relevant information is available within about four to five hours to support an informed therapy decision as early as possible.

The CE-marked Unyvero P55 Application Cartridge focuses on pneumonia testing and simultaneously analyzes 40 DNA targets. The second CE-marked Unyvero i60 ITI Application Cartridge for implant and tissue infections is also commercially available in Europe and is currently being evaluated in a prospective European multi-center cohort study in prosthetic joint infections (EPJIC).

Application Cartridges for additional indications are in various stages of development and preparation.

For further information, please visit www.unyvero.com.

About Curetis AG

Founded in 2007, Curetis AG 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 AG enable rapid multi-parameter pathogen and antibiotic resistance 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 total funds of over EUR 63.5 million (>US$ 70 million). The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical and Cempra Inc. as well as several international distribution agreements covering many countries across Europe, Russia, the Middle East and various other non-European countries.

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

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 funding from SPRING Singapore and is supported by NUS Enterprise and the Diagnostics Development (DxD) Hub, a national initiative for innovation in medical technology led by the Agency for Science, Technology and Research (A*STAR).

For further information, please visit www.acumen-research.com.

About the Diagnostics Development (DxD) Hub

The Diagnostics Development (DxD) Hub is a national initiative in Singapore, led by the Agency for Science, Technology and Research (A*STAR). The DxD Hub aims to accelerate the transformation of innovations into clinically validated diagnostic devices that are ready for market adoption. Through impactful products, empowering local enterprises and anchoring global companies in Singapore, the DxD Hub contributes to the development of an effective diagnostic devices ecosystem in Singapore.

For further information, please visit www.etpl.sg

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