



## Curetis Enters into Distribution Agreement to Expand Commercial Activities into Greater China

- *Exclusive Unyvero distribution agreement with Beijing Clear Biotech Co., Ltd. for Mainland China, Hong Kong and Taiwan*
- *Clinical trials for CFDA regulatory approval in preparation*

**Holzgerlingen, Germany, September 25, 2015** -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced that it has signed an exclusive distribution agreement (the "Agreement") for China, Hong Kong and Taiwan (collectively "Greater China") with Beijing Clear Biotech Co. Ltd. The Agreement, effective from September 25, 2015, comprises the Unyvero Systems and P55 and i60 ITI Application Cartridges. Based in Beijing and founded in 2001, Beijing Clear Biotech is an experienced and prominent distributor of prime medical technology brands throughout Greater China. In the *in vitro* diagnostics market, Beijing Clear Biotech focuses on the distribution of point-of-care diagnostics, in particular European products and PCR devices.

Under the terms of the Agreement, Beijing Clear Biotech will conduct and fully fund all prospective multi-center clinical trials required for approval of the Unyvero System and its P55 and i60 ITI Application Cartridges by the China Food and Drug Administration ("CFDA"), including funding the systems and application cartridges required for the trials. Beijing Clear Biotech's responsibilities also include leading the registration and approval process, inclusive of paying all fees, on behalf of Curetis. The anticipated CFDA license will be owned by Curetis. Curetis will pay Beijing Clear Biotech certain milestone payments upon clinical trial initiation and CFDA approval, respectively, and grant a commercial exclusivity for distribution in China, Hong Kong and Taiwan. Under the terms of the Agreement, Beijing Clear Biotech has agreed to certain minimum purchase numbers of Unyvero Systems as well as P55 and i60 ITI Application Cartridges per year.

Upon CFDA approval, Curetis will support commercialization through Chinese-language marketing materials and regular product training for the distributor's sales force. Beijing Clear Biotech will be responsible for managing all local marketing and sales activities as well as handling storage and logistics support. Marketing in Taiwan will start earlier than in

China and Hong Kong, as specific trials are not required for product registration there.

For the commercialization of the Unyvero i60 implant and tissue infection (“ITI”) Application Cartridge, Beijing Clear Biotech will partner with LandMover Medical Technologies Co. Ltd. (Beijing, China), the exclusive Chinese distributor of Heraeus Medical, one of the leading companies in the field of bone cement and biomaterials for elective orthopedic and trauma surgery. The i60 ITI Application Cartridge was co-developed by Curetis with Heraeus Medical to improve the management of patients with implant and tissue infections, including prosthetic joint and other orthopedic infections, to support an early and informed decision on the choice of antibiotic-supplemented bone cement in revision surgery.

“Beijing Clear Biotech is a well-established distributor with an impressive management team and a strong product portfolio,” said Dr. Achim Plum, Chief Commercial Officer of Curetis AG. “As it is also distributing Heraeus Medical’s products in China via its strategic partner LandMover, we see a number of commercial synergies, given that our Unyvero i60 ITI Application Cartridge was co-developed with Heraeus Medical.”

“We became interested in the Unyvero products on being introduced to the Unyvero i60 ITI Application Cartridge,” said Zeeman Zhang, Director of Beijing Clear Biotech. “The speed and accuracy of the Unyvero System is impressive and it is a great addition to our portfolio. Pending approval, we see great potential in the Greater China market. We are particularly excited about the near-term opportunity in Taiwan, where we will launch the Unyvero product line while pursuing the CFDA registration process for marketing approval in Mainland China and Hong Kong.”

The clinical trials are expected to enroll several thousand patients at a minimum of three trial sites. The trial, approval and registration process are expected to be completed in 2017 at the earliest.

#### Disclaimer

**CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use. The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on the Curetis Unyvero technology is currently available for sale in the United States of America or Canada. The analytical and clinical performance characteristics of any Curetis Unyvero product which may be sold at some future point in time in the U.S. have not yet been established.**

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#### About the Unyvero System

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

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 application, the Unyvero i60 ITI Application Cartridge for implant & tissue infections, is also commercially available in Europe and is currently being evaluated in a [prospective multi-center EPJIC study](#).

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

**For further information, please visit [www.unyvero.com](http://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 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 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 Cembra Inc. as well as several international distribution agreements covering many countries across Europe and the Middle East.

**For further information, please visit [www.curetis.com](http://www.curetis.com).**

#### **About Beijing Clear Biotech Co., Ltd.**

Founded in 2001 in Beijing, Beijing Clear Biotech Co., Ltd (“Beijing Clear”) is a privately held distributor of POCT products in China with a particularly strong geographic focus on north China. Beijing Clear is known for its industrial expertise and marketing experience in the POCT segment and

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sells POCT devices and supplies to hospitals, physician office laboratories and other primary care settings. For additional information, please visit the company's website at [www.clear-bj.com](http://www.clear-bj.com).

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