

# Curetis, Beijing Clear Biotech Expand Strategic Collaboration for Unyvero in Greater China

- Exclusive Unyvero A50 distribution agreement extended to eight years
- Significant further contractual minimum purchase commitments by Beijing Clear Biotech for additional contract years
- Good progress in regulatory process for gaining market access for Unyvero A50 in China

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, USA, October 11, 2018, 09:00 am CET - Curetis N.V. (the "Company" and, together with its subsidiaries, "Curetis"), a developer of next-level molecular diagnostic solutions, today announced that it has significantly expanded its strategic collaboration with Beijing Clear Biotech (BCB) for the exclusive distribution of the Unyvero A50 Platform and Unyvero A50 Application Cartridges in Greater China.

The parties have amended their exclusive international distribution agreement (the "Agreement"), originally signed in September 2015, to expand the term of the Agreement from five to eight years from the first regulatory approval in China. The amended agreement has also expanded the total commitment of BCB for cumulative minimum purchases to more than 360 Unyvero A50 Systems from 260 Systems previously and over 1.5 million Unyvero Application A50 Cartridges from about 550,000 Cartridges previously for the duration of the Agreement. This minimum commitment would indicate potential revenues to Curetis of over EUR 30 million annually in years six to eight of commercialization in China in addition to potential cumulative revenues of more than EUR 60 million for years one to five of commercialization in China as agreed upon previously.

Further, the parties agreed to waive certain milestone payments otherwise payable by Curetis to BCB for the initiation of clinical trial sites and the future regulatory approvals by the China Food and Drug Administration (CFDA) for the Unyvero A50 System and the first two Unyvero A50 Application Cartridges. These waivers represent a total saving to Curetis of EUR 600,000 over the next one to three years.

BCB has made significant progress in preparing the CFDA submission for approval of the Unyvero A50 System and the Unyvero HPN Application Cartridge. For example, BCB has successfully completed the analytical validation of the Unyvero HPN Application Cartridge under the auspices of the Beijing Institute of Medical Technologies with all 40 assays of the HPN panel now cleared for clinical trials in China. Further, BCB has successfully completed a first clinical evaluation with approximately 500 patient samples at the Sino-Japanese

Friendship Hospital in Beijing, China, generating a data set that will become a further element in the submission to the CFDA. The parties also intend to use the comprehensive data from Curetis' U.S. FDA trial for the Unyvero LRT Application Cartridge to bolster the submission of data to the CFDA to potentially accelerate market access in China. The use of foreign data in submissions to the CFDA became possible after October 2017 when a respective new regulation was issued by the Chinese government.

The Company expects that BCB will initiate clinical trials in China, which may be required to support the final submission for CFDA approval, swiftly after feedback from the CFDA on the regulatory pathway and the data requirements for a final submission. Assuming a final submission in 2019 and a CFDA approval were obtained in late 2019 or early 2020, Curetis anticipates that it would generate initial revenues from commercial sales in China starting in 2020.

"With the amendment of our strategic agreement with BCB, we further limit our short-term cash exposure in gaining market access to China, while creating a much more attractive medium to longer term business prospect for our partner and ourselves", said Dr. Achim Plum, Chief Business Officer of Curetis. "The expansion of a strategic collaboration with BCB is timely as we believe we are making very good progress with the preparation of a submission for the approval of the Unyvero A50 System and HPN Application Cartridge in China. We are also excited about the prospect of accelerating access to this strategically important market by potentially leveraging our comprehensive data set from our U.S. FDA trial in a submission to the CFDA."

## **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 what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARES db, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

**About Beijing Clear Biotech** 

Founded in 2001 in Beijing, Beijing Clear Biotech Co., Ltd ("Beijing Clear Biotech") 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 sells POCT devices and supplies to hospitals, physician office laboratories and other primary care settings.

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This press release includes statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "expects", "intends", "may", "will", or "should", and include statements Curetis makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Curetis' actual results may differ materially from those predicted by the forward-looking statements. Curetis undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

### **Contact Details**

#### **Curetis GmbH**

Max-Eyth-Str. 42 71088 Holzgerlingen, Germany Tel. +49 7031 49195-10 pr@curetis.com or ir@curetis.com www.curetis.com

## **International Media & Investor Inquiries**

akampion Dr. Ludger Wess / Ines-Regina Buth Managing Partners info@akampion.com Tel. +49 40 88 16 59 64 Tel. +49 30 23 63 27 68

## **U.S. Media & Investor Inquiries**

The Ruth Group Lee Roth Iroth@theruthgroup.com Tel. +1 646 536 7012