



## **Curetis' Partner Beijing Clear Biotech Submits Filing for Unyvero Approval in China**

- ***Submission for Unyvero HPN Cartridge to Chinese regulatory authority NMPA includes U.S. and EU data***
- ***Leverages recent changes in regulation allowing submission of foreign data***
- ***Further collection of clinical data in China planned to support market access and adoption***

**Amsterdam, the Netherlands, and Holzgerlingen, Germany, February 04, 2019, 08:00 am CET** - Curetis N.V. (the "**Company**" and, together with its subsidiaries, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced that Beijing Clear Biotech (BCB) has filed for regulatory approval of the Unyvero A50 HPN Application Cartridge for pneumonia with the Chinese National Medical Products Administration (NMPA; formerly Chinese Food and Drug Administration). BCB is Curetis' exclusive distribution partner for the Unyvero A50 platform and product line in Greater China and has filed the submission to the NMPA in the name and on behalf of Curetis.

The submission is based on comprehensive data from Curetis' U.S.-FDA trial as well as from European CE-IVD validation studies comprising data sets from close to 1,400 patient samples in total, combined with analytical validation data of the Unyvero HPN Application Cartridge that were generated under the auspices of the Beijing Institute of Medical Technologies. The use of foreign data in submissions to the newly formed NMPA became possible in October 2017 when a respective new regulation was issued by the Chinese government.

BCB has already generated clinical data from several hundred patient samples at a Chinese hospital and further intends to collect additional clinical data on the performance of Unyvero HPN in China under appropriate protocols to augment the submission, if required, and to support future market access and adoption in Greater China.

Assuming a potential regulatory approval by NMPA in late 2019 or early 2020, Curetis anticipates initial revenues from commercial sales through BCB in China starting in 2020.

In the light of the progress made toward gaining market access in China, BCB and Curetis in October 2018 expanded their exclusive distribution agreement from five to eight years post

NMPA approval with total minimum purchasing commitments by BCB that may generate more than EUR 150 million in revenues for Curetis over the entire duration of the contract, i.e. an increase by about EUR 90 million compared to the original agreement between the parties.

“The filing for our Unyvero A50 System and our HPN pneumonia panel by our partner BCB is an important milestone in our strategic approach to the Chinese market,” said Dr. Achim Plum, Chief Business Officer of Curetis. “With pneumonia being a major health threat in China and a leading cause of death particularly in children, we believe that Unyvero, once approved, can support ongoing public health initiatives to improve rapid diagnosis and treatment of this often fatal disease.”

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### **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](http://www.curetis.com) and [www.ares-genetics.com](http://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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### **Contact Details**

#### **Curetis GmbH**

Max-Eyth-Str. 42

71088 Holzgerlingen, Germany

Tel. +49 7031 49195-10

[pr@curetis.com](mailto:pr@curetis.com) or [ir@curetis.com](mailto:ir@curetis.com)

[www.curetis.com](http://www.curetis.com)

### **International Media & Investor Inquiries**

akampion

Dr. Ludger Wess / Ines-Regina Buth

Managing Partners

[info@akampion.com](mailto:info@akampion.com)

Tel. +49 40 88 16 59 64

Tel. +49 30 23 63 27 68