

Curetis, Beijing Clear Biotech expand strategic collaboration

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Exclusive Unyvero A50 distribution agreement extended to eight years



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

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.

"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."