Curetis Starts Final Validation Study for New Unyvero Blood Culture Application Cartridge

- Data and CE-IVD launch expected in Q2, 2016

- Company also prepares launch of 2nd generation ITI Application Cartridge and novel product for intra-abdominal infections

Amsterdam, the Netherlands and Holzgerlingen, Germany, February 23, 2016 -- Curetis N.V. (the "**Company**" and, together with Curetis AG, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the start of a CE performance evaluation study for its third Unyvero Application Cartridge. The BCU Blood Culture Application Cartridge is designed to diagnose infections that are spreading through the bloodstream and is targeting clinically most relevant microorganisms and related antibiotic resistance markers. Curetis expects data from the study and the subsequent launch of the CE-IVD-marked BCU Application Cartridge in Q2, 2016.

The BCU Application Cartridge features a unique and differentiated test panel covering more than 100 diagnostic targets, including tests to identify Gram-positive and Gram-negative bacteria, fungi and mycobacteria, as well as tests for up to 16 antibiotic resistance markers. The Application Cartridge is using positively flagged blood culture samples from bottles inoculated with blood or punctate. Comprehensive results are delivered within 4 to 5 hours and require just a few minutes of hands-on time.

For the study, the BCU Application Cartridge is being validated in conjunction with the most common commercial blood culture systems, using about 250 blood culture samples. Previous studies testing around 200 BCU cartridges as part of the analytical and pre-clinical performance evaluation were already completed successfully. The data, which are to be published and presented at upcoming conferences, are expected to support the CE-IVD-marking of the BCU Application Cartridge. Three clinical sites in the DACH region already have agreed to further evaluate the Unyvero BCU Application Cartridge in routine clinical settings once it becomes available as a CE-IVD-marked product.

“With the Unyvero BCU Application Cartridge, we are entering the important sepsis market,” said Oliver Schacht, CEO of Curetis. “In Germany, sepsis is the leading cause of death in intensive care units, with 60,000 cases per year. In the US, sepsis has a higher incidence than common cancer types and even heart failure. To complement the BCU cartridge with a sepsis host response test, we have already started the partnered development program with our Singapore-based partner Acumen announced late last year.”

Curetis has also progressed with the development of a second-generation ITI Application Cartridge for implant and tissue infections and has started the development program towards a novel Application Cartridge targeting intra-abdominal infections.

“The second-generation ITI Application Cartridge will be expanded from currently 80 to up to over 100 diagnostic targets, adding further pathogens, among them mycobacteria, and resistance markers that have become clinically relevant in many parts of the world,” Schacht added. "All in all, we expect three product launches this year: the new cartridges for positive blood culture, the expanded ITI cartridge and a novel application for intra-abdominal

infections. Accelerating the product pipeline development is another key element of our post IPO equity story and in line with our guidance to investors."

Further pipeline updates and an outlook of additional future product opportunities will be provided in H2, 2016, including an update on the preparation of Curetis' next US FDA trial for a second Unyvero Application Cartridge for the US market once the ongoing LRT55 FDA trial has been completed.

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About Curetis

Founded in 2007, Curetis 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 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 EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 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, the Middle East and Asia.

On a separate note, the Company has announced for the purposes of article 2(1)(i) of Directive 2004/109/EC (as amended by Directive 2013/50/EU) and as implemented in the Netherlands in section 5:25a of the Dutch Financial Supervision Act (Wet financieel toezicht) that the Netherlands is the home member state of Curetis N.V.

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

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