Curetis Presents Product Updates at Intensive Care Conference

- *Multiple Unyvero product launches planned for 2015*
- *Clinical trial aimed at US FDA clearance of Unyvero adapted to reflect most recent FDA guideline issued in Q3-2014*

Holzgerlingen, Germany, Feb. 17, 2015 -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced the presentation of its product range at Germany's biggest congress on intensive medicine and intensive care, *Symposium Intensivmedizin + Intensivpflege*, in Bremen from February 18-20, 2015. Curetis will be exhibiting the Unyvero Solution at booth #N27, hall 4 at Messe & Congress Centrum Bremen. Curetis is also providing an update on its pipeline of new products to be launched in 2015.

By the end of 2014, the installed base of Curetis´ Unyvero Solution has grown to more than 60 systems world-wide. Unyvero is a versatile hardware platform for the detection of a broad panel of bacteria, fungi and antibiotic resistances from a single sample in one run. At present, cartridges for pneumonia testing (Unyvero P50) and for implant & tissue infections (Unyvero i60 ITI) are available in Europe. The company is expecting the European launch of its enhanced and expanded Unyvero P55 Pneumonia application in the spring of 2015.

By mid 2015, Curetis also anticipates data from an updated i60 ITI application Cartridge. Moreover, the company is planning the launch of a comprehensive blood culture panel combining Gram-positive and Gram-negative pathogen markers as well as resistance markers by the end of 2015 in Europe.

The company also announced an update on its US trial of the Unyvero LRT lower respiratory tract infection application. Curetis has adapted its FDA trial design to reflect the new guidelines issued by the FDA for multiplexed infectious diseases tests and will re-initiate prospective sample measurement once the enhanced and expanded P55 Pneumonia Cartridge is available as LRT-labeled test cartridges for the US FDA trial. Patient sample collection with the updated LRT application based on the P55 assay is expected to start mid-2015.

Curetis has decided to un-blind all data generated in its FDA trial to date and has engaged its network of US trial sites to continue collecting retrospective specimen. Data from the previous LRT study based on the P50 panel will be analyzed and published in a peer-reviewed format.

The new FDA guideline reduces the minimum number of required prospective patient samples to 1,500, limits requirements for prospective samples to only specificity endpoints, allows testing of retrospectively collected patient samples for sensitivity endpoints, and provides clarity on positive and negative control samples. Based on the adapted design and a start of patient sample collection with the new LRT55 application, which is anticipated by mid-2015, Curetis is expecting completion of patient enrolment in the first half of 2016, with subsequent filing with the FDA.

Further details on the Unyvero platform are available at the new Unyvero product website www.unyvero.com. In addition to details of the Unyvero range of products, the site offers downloads of all scientific and clinical publications using Unyvero. Please visit: www.unyvero.com/en/service/downloads/literature/abstract-list.html and www.unyvero.com/en/service/downloads/literature/posters.html.

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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 resistances 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 under http://www.clinicaltrials.gov/ct2/results?term=NCT01922024 .

The platform enables the DNA-based testing of all clinically relevant samples in a fully automated, unsupervised analysis process requiring only 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 first CE-marked Unyvero Cartridge, Unyvero P50, focuses on pneumonia testing and simultaneously analyses 39 DNA targets. The second CE-marked application, the Unyvero i60 ITI cartridge for implant &

tissue infections, is also commercially available in Europe and is currently being evaluated in the prospective multi-center EPJIC study http://www.epjic.org/ .

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

For further information, please visit 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 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 Cempra 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.

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