



## Curetis Joins European Prosthetic Joint Infection Cohort Study (EPJIC)

- *Unyvero i60 ITI cartridges to be run on 500 prospectively collected patient samples from multi-center study across Europe*
- *All Unyvero testing to be conducted in central reference lab under the auspices of the PRO-IMPLANT Foundation and Prof. Andrej Trampuz*

**Holzgerlingen, Germany, Oct. 9, 2014** -- Curetis AG, a developer of next-level molecular diagnostic solutions, today announced it has joined the European Prosthetic Joint Infection Cohort Study (EPJIC). EPJIC is an initiative of the PRO-IMPLANT Foundation to improve the management of Prosthetic Joint Infection (PJI) and to develop consensus guidelines across Europe. PJI is one of the leading causes of joint implant failure. Treatment often requires multiple surgical interventions and prolonged antibiotic therapy and is associated with a failure rate of 10 to 20 percent.

The investigator-initiated study has started in September 2014 and will enroll up to 5,000 PJI patients from up to 100 study centers across Europe. As part of the study, 500 patient samples will be measured by the Unyvero i60 ITI multiplex PCR cartridge system to identify pathogens involved in prosthetic joint infection, a key indication area of the Unyvero i60 ITI cartridge. The data will help build the body of evidence especially in PJI diagnosis using sonication fluid samples. As already demonstrated in the CE performance evaluation study of the i60 cartridge, the Unyvero system is able to detect pathogens frequently missed by microbiology culture. Also, Unyvero i60 results are available within about 5 hours compared to classical microbiological culture methods that can take up to 14 days with PJI samples.

The study's Unyvero arm is expected to be completed by the end of 2015, with initial data anticipated in the first half of 2015. Data will be published at major conferences and in peer-reviewed scientific journals.

"We are very much looking forward to starting the Unyvero arm of our EPJIC study," said Prof. Dr. Andrej Trampuz, Professor at Charité - Universitätsmedizin Berlin, Germany, and a member of the Executive Board of the PRO-IMPLANT Foundation. "The data will be important in assessing the potential benefits of adding rapid molecular testing to today's standard of care for patients as well as hospitals and their health economics."

“We are excited to participate in this prospective multi-center trial,” said Dr. Anne Thews, Medical Director of Curetis. “We have joined forces with a strong laboratory team at Charité that will run the entire Unyvero testing as central reference lab for all 500 patient samples. The data will be an important cornerstone in our future positioning and value proposition of the Unyvero i60 ITI cartridge towards clinicians, orthopedic surgeons and microbiologists as well as hospital finance and purchasing teams across Europe.”

The Unyvero i60 cartridge, which is jointly marketed by Curetis and Heraeus Medical GmbH, covers a broad range of infections common after abdominal as well as bone and joint surgery, trauma (e.g. burns) or skin and soft tissue infections, including diabetic foot disease. Its multiplex panel covers a total of 114 targets - 91 pathogens (gram-negative & gram-positive bacteria and fungi) and 23 resistance markers - relevant for eight clinical indications.

In combination with the unique Unyvero L4 Lysator, it can process biofilm samples, an important prerequisite for the fast and reliable diagnosis of implant infections (catheters, joints etc.).

Further details are available at the new Unyvero product website [www.unyvero.com](http://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](http://www.unyvero.com/en/service/downloads/literature/abstract-list.html) and [www.unyvero.com/en/service/downloads/literature/posters.html](http://www.unyvero.com/en/service/downloads/literature/posters.html).

#### Disclaimer

**CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use. The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on the Curetis Unyvero technology is currently available for sale in the United States of America or Canada. The analytical and clinical performance characteristics of any Curetis Unyvero product which may be sold at some future point in time in the U.S. have not yet been established.**

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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 <https://www.clinicaltrials.gov/> NCT01922024.

The platform enables the DNA-based testing of all clinically relevant

## Press Release Curetis AG

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](http://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 €49.1 million (~ USD 65 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 more than 20 countries.

**For further information, please visit [www.curetis.com](http://www.curetis.com).**

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