Press Release

Curetis AG Achieves CE-Marking for Unyvero™ Solution and Initiates Commercialization

Successful completion of performance evaluation study; CE Mark for Unyvero™ instrument system and pneumonia application

Holzgerlingen, Germany, May 14, 2012 -- Curetis AG, an innovative molecular diagnostics company focusing on the development and commercialization of in-vitro diagnostic products for infectious diseases, today announced that the company has achieved the CE marking for its Unyvero™ suite of instruments and the P50 Pneumonia Cartridge and that is has already initiated national and international commercialization activities. The performance evaluation of Curetis´ Unyvero™ System and the Unyvero™ P50 Pneumonia cartridge was successfully completed just recently.

The evaluation has demonstrated excellent performance characteristics of the Unyvero™ pneumonia application in terms of sensitivity and specificity. Overall sensitivity in 186 tested fresh and frozen clinical sputum, aspirate and lavage samples was above 75% sensitivity with a better than 95% specificity. The Unyvero™ P50 pneumonia application cartridge identified 74 additional pathogens missed by standard microbiology culture, which was used as gold-standard comparator in terms of performance. If confirmed with independent methods this might demonstrate that the Unyvero™ pneumonia test offers significant improvements in terms of sensitivity over current clinical standards. This analysis is ongoing.

Cartridge and instrument system have also passed other important criteria, such as repeatability, reproducibility, interference testing, and cross-reactivity. The complete performance evaluation study included 318 Unyvero™ P50 cartridge runs between January and April 2012.

“We are very happy that the Unyvero System successfully demonstrated its high sensitivity, specificity and reliability using real-world clinical patient samples,” said Oliver Schacht, CEO of Curetis AG. “The CE mark is a major corporate milestone for Curetis and prerequisite for our commercialization activities in Europa and in many other countries around the globe that accept CE marking for IVDs. Our commercial team, which we have built in the preceding months, has already started direct marketing of the Unyvero System to hospitals in Germany, Austria and Switzerland.”

Based on positive feedback from many potential distribution partners during the 22nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) earlier this year, Curetis has also begun establishing its international distributor network and expects to target an even broader international market than originally anticipated beginning in 2012/13 already

About the Unyvero™ System

The CE-marked Unyvero™ System is a versatile hardware platform for the detection of a broad panel of bacteria 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.

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 less than four 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. Cartridges for further applications, e.g. for surgical site infections, blood stream infections and tuberculosis, are in preparation.

About Curetis (Germany)

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 will enable rapid multiparameter 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 € 36.6 million (~ USD 50 million). The company is based in Holzgerlingen near Stuttgart, Germany. In 2011, Curetis signed a collaboration agreement with Sanofi Pasteur for the potential use of the Unyvero™ platform in a future global clinical trial.

Contact

Curetis AG
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 (0) 7031 49195-10
pr@curetis.com
www.curetis.com

Media Inquiries
akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68