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Curetis AG Opens Unyvero™ Cartridge Production Facility

Manufacturing capacity scalable to up to 1 Mio. cartridges per year

Holzgerlingen, Germany, October 18, 2011 -- Curetis AG, an innovative molecular diagnostics company focusing on the development and commercialization of in-vitro diagnostic products for infectious diseases, today announced the opening of its state-of-the-art production facility for disposable Unyvero™ cartridges in Bodelshausen (near Tuebingen, Germany).

The fully automated manufacturing line in a clean room environment is designed to be fully cGMP compliant and offers scalability and flexibility to meet the growing demands of clinical trials and commercialization with the scheduled 2012 EU launch of the Unyvero P50™ pneumonia cartridge.

Initial production capacity is 100,000 p.a. which may be easily expanded to an annual production capacity of 1 mio. cartridges. First product is the Unyvero™ P50 pneumonia cartridge for the identification of 17 pneumonia pathogens and 22 of their clinically most relevant antibiotic resistance markers.

“From the very beginning Curetis was determined to build its own cartridge production facility in order to have full control over the entire manufacturing process and the production conditions,” said Oliver Schacht, CEO of Curetis. “After two years of intense planning and designing with our partners we now have a manufacturing line for an optimal product and are very well prepared for a market entry next year.”

“Politics is already taking proactive measures to tackle the spread of antibiotic-resistant pathogens,” said Annette Widmann-Mauz, Member of the German Parliament und Parliamentary Secretary of State in the German Federal Health Ministry. “In this context it is very important to not only amend hygiene in hospitals and medical institutions but also to improve the rapid identification of bacteria and antibiotic resistances and the prescription of antibiotics.”

“Bacterial pneumonia is an important and often fatal medical condition with increasing incidence and - because of the spread of multiple resistances - narrowing treatment options,” added Prof Dr. Cornelius Knabbe, Director of the Institute for Laboratory and Transfusion Medicine at the Heart and Diabetes Center North Rhine-Westphalia. “The Unyvero system for the first time enables medical doctors to rapidly obtain an overview on the infection and to switch from a calculated therapy in which the antibiotic is chosen based on statistics, to a personalized, matching therapy. This offers significant benefits for the patient and also helps to contain costs.”

About the Unyvero™ System

The 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 three hours to support an informed therapy decision as early as possible.

The first 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.

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