



Curetis AG Initiates Prospective Clinical Trial for Rapid Pneumonia Diagnostics

Expected CE-marking and launch in Europe in 2012

Holzgerlingen, Germany, February 16, 2012 -- Curetis AG, an innovative molecular diagnostics company focusing on the development and commercialization of in-vitro diagnostic products for infectious diseases, today announced the start of a prospective clinical trial of its Unyvero™ System and the Unyvero™ P50 Pneumonia Cartridge in the European Union.

The prospective, international, multicenter trial will enroll up to 1,000 hospitalized patients suspected with a lower respiratory tract infection. Patient samples such as sputa, aspirates or bronchial lavages will be pre-processed by the Unyvero™ Lysator and transferred to the Unyvero™ P50 Pneumonia cartridge, which is analyzed by the Unyvero™ Analyzer.

Primary endpoint of the study will be assay performance defined as clinical sensitivity and specificity compared to today's diagnostics standard of care, microbiology culture. Trial sites include the University Hospital Tuebingen, Germany, the Heart and Diabetes Center Bad Oeynhausen, Germany, the Hospital Clinic of Barcelona in Spain, the Erasme Hospital in Brussels/Belgium, and the University Hospital Jena, Germany. Principal investigator is Prof. Dr. Ingo B. Autenrieth of the University Hospital Tuebingen. Interim topline data are expected for spring 2012.

"The start of the clinical trial is the next important milestone for Curetis after the opening of our clean room cartridge production facility in Bodelshausen, the signing of our Sanofi Pasteur collaboration agreement and our most recent financing with Forbion and Roche," said Oliver Schacht, CEO of Curetis. "If successful, it will further strengthen the data package for our market launch, in addition to the CE mark for the Unyvero™ System and the Unyvero™ P50 Pneumonia Cartridge. Furthermore, the data may be used to augment the planned prospective trial in the US to also obtain FDA clearance. This trial is expected to start later this year."

"At present, medical doctors often cannot make informed therapy decisions in a timely manner in patients with severe, life-threatening diseases, because pathogen identification takes too much time," said Prof. Dr. Ingo Autenrieth, Medical Director of the Institute for Medical Microbiology and Hygiene of the University Hospital Tuebingen, Germany, and principal investigator of the study. "Moreover, there is no technology on the market that allows for the rapid characterization of a pathogen's antibiotic resistance spectrum. I am therefore looking forward to testing the Un-

yvero™ System. If successful, it may not only enable doctors to provide patients with targeted treatments in time, but also save a lot of money in terms of unnecessary antibiotics prescriptions and duration of patients' hospital stays."

The Unyvero™ P50 Cartridge is the first cartridge developed by Curetis AG and focuses on pathogen as well as antibiotic resistance testing for pneumonia. Each cartridge handles one patient sample and analyzes 39 DNA targets simultaneously. Results are available within less than 4 hours.

The pathogen panel has been selected for clinical relevance based on current international clinical guidelines and has been reviewed by clinical experts in Europe and the USA. Resistance genes were chosen by frequency and clinical significance. Further cartridges for the diagnosis of surgical site infections, blood stream infections and tuberculosis are in preparation.

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 less than four 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.

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.



Press Release Curetis AG

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