Press Release

Prospective Multi-Center Trial to Enroll Over 2,000 Clinical Samples

Curetis AG Initiates Clinical Trial in the U.S. Towards FDA Clearance

Holzgerlingen, Germany, December 6, 2012 -- Curetis AG today announced the start of a clinical trial of its Unyvero™ System and the corresponding LRT (lower respiratory tract) application in the U.S. The company expects enrollment completion within the next 12-15 months, followed by a 510(k) submission to the FDA in 2014.
The prospective, multicenter trial will include samples collected from more than 2,000 hospitalized patients suspected to have a lower respiratory tract infection and several hundred retrospective samples with known microbiology culture results for rare pathogens. Samples will be processed by the Unyvero™ Lysator, transferred to the LRT cartridge, and tested by the Unyvero™ Analyzer.

Primary endpoint of the study will be assay performance defined as clinical sensitivity and specificity compared to microbiology culture (today's diagnostics standard of care) and to a composite reference diagnosis that incorporates PCR and sequencing to determine clinical truth whenever microbiology culture results are negative.

Trial sites include Northwestern University (Chicago, IL) and North Shore-LIJ Health System (Lake Success, NY), among others. The Principal Investigator is Prof. Christine C. Ginocchio, Senior Medical Director and Chief, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System. Curetis has contracted Aptiv Solutions as its CRO and Neil Mucci of GlobalBioclinical as project manager in the US.

"With shipment of instruments and cartridges and training of the first sites completed, we expect the first three sites to be initiated during the next few weeks," said Oliver Schacht, CEO of Curetis. "Based on an intensive and engaged dialog with the FDA and our regulatory affairs advisors over the past 24 months, we have designed a study protocol to meet FDA requirements. We are very happy that we were able to effectively establish a path forward for our highly multiplexed, PCR-based cartridge."

"With current standard microbiology, it takes up to 72 hours to provide the clinician with initial information on the types of organisms causing a life-threatening infection and also the appropriate antibiotics that can be used as treatment," said Christine Ginocchio. "This can delay appropriate therapy and if a patient is not treated with an appropriate antibiotic regimen from the beginning, this can result in increased morbidity and mortality. We are therefore very much looking forward to test the Unyvero System.

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Faster, accurate and reliable testing will be of tremendous clinical benefit and greatly improve the quality of patient care."

The LRT application analyzes 39 DNA targets simultaneously from a single patient sample. Results are available within about 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. A similar product, the Unyvero™ P50 pneumonia cartridge is CE-marked and currently marketed in Europe and the Middle East.

Disclaimer

Caution - Investigational Device, Limited by Federal (or US) Law to Investigational Use. Not available for sale in the United States. Performance characteristics for this device have not yet been established and the U.S. FDA has not yet cleared the device.

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 about 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. The second Unyvero™ application for implant & tissue infections is already in product development. Cartridges for additional indications, such as blood stream infections and tuberculosis, are in preparation.

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 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. Curetis has signed collaboration agreements with Heraeus Medical, Sanofi Pasteur and Cempra Inc. as well as several international distribution agreements.

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