Curetis Establishes Medical Advisory Board with Internationally Renowned Experts

- U.S. FDA trial enrolment on track -

Amsterdam, The Netherlands, and Holzgerlingen, Germany, January 11, 2016 – Curetis N.V., a developer of next-level molecular diagnostic solutions for syndromic infectious disease testing, today announced the establishment of its Medical Advisory Board (MAB). Initially, it will consist of four leading experts in their respective fields: Dr. Reno Frei (former Head of the Division of Clinical Microbiology, University Hospital Basel, Switzerland), Prof. Mathias Pletz, MD (Jena University Hospital, Germany), Prof. Jean-Louis Vincent, MD, PhD (Hôpital Universitaire Erasme, Brussels/Belgium), and Prof. Robin Patel, MD (Mayo Clinic, USA), who also serves as Principal Investigator of Curetis' ongoing U.S. FDA trial.

The newly established MAB is expected to meet several times per year and chair roundtables with further key opinion leaders in the field to advise the company on important trends and issues in clinical microbiology as well as novel product concepts addressing high medical need questions in the diagnosis of severe infections in hospitalized patients. The company expects the MAB to provide valuable insight and guidance along the entire value chain of innovative molecular diagnostics products including concept, definition, clinical validation, and positioning.

"We are very proud to have won these outstanding, seasoned experts for our Medical Advisory Board," said Dr. Anne Thews, Medical Director of Curetis. "They combine tremendous experience in the areas of severe infectious diseases including sepsis and prosthetic joint infections, in critical care, clinical microbiology, and further relevant areas. All of them have been working with Curetis over the past couple of years in various roles and functions, in particular in clinical evaluations and studies for our Unyvero product line, such as the ongoing U.S. study to support product clearance for our LRT55 lower respiratory tract application by the FDA."

She explained further that by bringing together these key opinion leaders in a dedicated medical advisory board, the company expects to synergistically leverage the complementary expertise and experience represented in the board.

On the progress of the Unyvero LRT55 U.S. study, Dr. Thews added: "The trial is progressing well and on schedule with more than 900 patient samples already enrolled and tested with Unyvero."

Prof. Jean-Louis Vincent of Brussels's Hôpital Universitaire Erasme commented: "As rising antibiotic resistance has become an enormous threat for modern medicine, we as critical care clinicians demand faster pathogen identification and resistance detection in order to optimize our treatment for each patient. Modern, patient-near molecular testing solutions like the Unyvero System have the potential to significantly improve patient care. Therefore, I am pleased to contribute my thirty years of experience in this field to help further expand the Unyvero Solution."

Biographical sketches and achievements of Curetis' Medical Advisors are as follows:

Reno Frei, MD, was Head of the Division of Clinical Microbiology, University Hospital Basel, Switzerland, for more than 25 years. His research focuses on antibiotic resistance, microbiological diagnostics, and healthcare-associated infections including prosthetic device infections and sepsis. He has published 250 peer-reviewed articles and book chapters. Dr. Frei received his medical degree from the University of Basel Faculty of Medicine in 1980. He completed his training in infectious diseases and laboratory medicine with a research fellowship at the University of Iowa College of Medicine, Iowa City, USA.

Mathias Pletz, MD, Professor of Infectious Diseases, is Director of the Center for Infectious Diseases and Infection Control at the Jena University Hospital, Germany. Prior to that, he worked at the Department for Respiratory Medicine at Hannover Medical School (Hannover, Germany), the Respiratory Diseases Branch of the Center for Disease Control and Prevention (Atlanta, USA) and at the Chest Hospital Heckeshorn (Berlin, Germany). His research focuses on respiratory tract infections and strategies against difficult to treat bacterial infections. This includes rapid tests for antimicrobial resistance and novel approaches to eradicate biofilms. Dr. Pletz has received numerous grants and scientific awards, such as the Honor Award Certificate from the CDC, and has published more than 130 peer-reviewed publications.

Jean-Louis Vincent, MD, PhD, is Professor of Intensive Care at the University of Brussels and Intensivist in the Department of Intensive Care at the Erasme University Hospital in Brussels, Belgium. He has published more than 900 peer-reviewed articles, some 400 book chapters and review articles, 950 original abstracts, and has edited 101 books. Among others, he is the Editor-In-Chief of *Critical Care*, *Current Opinion in Critical Care* and *ICU Management* and a member of the editorial boards of about 30 other journals. Jean-Louis Vincent received numerous awards, including the prestigious Prix Scientifique Joseph Maisin - Sciences biomédicales cliniques. Prof. Vincent is a Past-President of the European Society of Intensive Care Medicine and presently President of the World Federation of Societies of Intensive and Critical Care Medicine.

Robin Patel, MD, Professor of Medicine and Professor of Microbiology, is Director of the Clinical Bacteriology Laboratory and the Infectious Diseases Research Laboratory and Chair of the Division of Clinical Microbiology, Mayo Clinic, USA. Prior to taking a staff position at Mayo in 1996, she completed residencies in Internal Medicine and Microbiology in Rochester, Minnesota, and a fellowship in Infectious Diseases at the College of Medicine, Mayo Clinic. Robin Patel's research focuses on clinical bacteriology diagnostic testing, antimicrobial resistance, and microbial biofilms. She has published over 250 peer-reviewed manuscripts and has delivered numerous national and international presentations. She graduated from Princeton University with a BA in Chemistry in 1985 and from McGill University in Montreal, Canada, with an MD (C.M.) in 1989.

Product 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 Platform

The CE-marked Unyvero System is a versatile hardware platform for the detection of a broad panel of bacteria, fungi and antibiotic resistance genes from a single sample in one run. It processes a disposable Application 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 here.

The platform enables the DNA-based testing of all clinically relevant samples in a fully automated, unsupervised analysis process requiring only a 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 CE-marked Unyvero P55 Application Cartridge focuses on pneumonia testing and currently simultaneously analyzes 39 DNA targets. The second CE-marked Unyvero i60 ITI Application Cartridge for implant and tissue infections is also commercially available in Europe and is currently being evaluated in a prospective European multi-center cohort study in prosthetic joint infections (EPJIC).

Application Cartridges for additional indications such as blood culture testing, intra-abdominal / gastrointestinal infections and sepsis host response are in various stages of development and preparation.

For further information, please visit www.unyvero.com.

About the LRT55 U.S.-FDA Trial

The primary endpoint of the multicenter U.S. study that aims at achieving FDA clearance is the performance of Curetis' second generation Unyvero Lower Respiratory Tract (LRT) cartridge, LRT55, in detecting lower respiratory tract infections as compared to microbiology culture – which is currently considered the diagnostic standard of care. In addition, Unyvero results will be compared to an independent molecular composite comparator based on pathogen DNA analysis by PCR and sequencing. Nine trial sites across the U.S. participate in the study.

The prospective arm of this trial includes at least 1,500 hospitalized patients with suspected lower respiratory tract infections to determine the clinical specificity of the Unyvero LRT55 cartridge. In another arm of the study, around 1,000 retrospective blinded patient samples will be analyzed for clinical sensitivity endpoints. All pathogens and resistance markers featured on the Unyvero LRT55 Cartridge are included in the study. All retrospective samples will have been tested positive for pathogens on the LRT55 panel by standard microbiology culture.

LRT55 is a second-generation cartridge based on the design of the CE- IVD marked P55 cartridge marketed outside the U.S. It features 40 markers and a novel control concept with live bacteria in the control material and improved coverage of pathogens in the panel. As a result, it provides the most comprehensive molecular marker panel for LRT infections marketed today. P55 has demonstrated superior performance in the CE performance evaluation study and additional investigator-initiated clinical studies.

The study is registered here.

About Curetis

Founded in 2007, Curetis 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 enable rapid multi-parameter pathogen and antibiotic resistance marker 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 EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 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 many countries across Europe, the Middle East and Asia.

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For further information, please visit www.curetis.com.

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