



## **Curetis Establishes U.S. Scientific Advisory Board**

- ***U.S. Scientific Advisory Board formed with five renowned infectious disease specialists***
- ***Expands Curetis' scientific network and clinical expertise to support U.S. adoption of recently cleared Unyvero System and LRT Cartridge***

**Amsterdam, the Netherlands; San Diego, CA, USA; and Holzgerlingen, Germany; April 11, 2018;** published at 02:45 EDT -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH and Curetis USA Inc., "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced that it has established a dedicated U.S. Scientific Advisory Board. The board was founded to support the clinical adoption of Curetis' Unyvero System and Unyvero LRT Application Cartridge for lower respiratory tract infections, which were recently granted FDA *de novo* clearance for the U.S. market. Five renowned U.S. infectious disease experts have been appointed to the board: Debra Goff, Pharm.D. (The Ohio State University Wexner Medical Center, OH, USA), Donna Mildvan, M.D. (Icahn School of Medicine at Mount Sinai, NY, USA), Melissa Miller, Ph.D. (University of North Carolina at Chapel Hill School of Medicine, NC, USA), Frederick Nolte, Ph.D. (Medical University of South Carolina, SC, USA), and Robin Patel, M.D. (Mayo Clinic, MN, USA).

"I am extremely pleased that such a distinguished group of infectious disease experts has agreed to join Curetis' newly established U.S. Scientific Advisory Board," said Faranak Atrzadeh, Director of Scientific Affairs, Curetis USA Inc. "They are deeply experienced and highly regarded within the infectious diseases, clinical microbiology and molecular diagnostics communities. Following the recent *de novo* clearance of Unyvero by the U.S. FDA, their insight and advice will be invaluable as we introduce the solution into the clinical routine in the U.S."

"I am pleased to be a part of the Curetis U.S. Scientific Advisory Board," said Dr. Donna Mildvan, a recognized specialist in infectious diseases. "Curetis' focus on novel diagnostic solutions is important and exciting, with promise to address critical unmet needs in infectious diseases and improve patient outcomes. Delivering diagnostic information significantly earlier than current standard microbiologic methods can serve to optimize empiric clinical treatment decisions, improve the management of difficult-to-diagnose infections, and enhance the utility of antimicrobial stewardship."

"The Unyvero System developed by Curetis holds much promise as a simple, rapid and comprehensive diagnostic tool for critical infectious diseases. I welcome the opportunity to work with the team at Curetis to identify new diagnostic applications for this exciting, emerging technology," added Dr. Frederick Nolte.

### **Resumes of Curetis' U.S. Scientific Advisory Board Members**

**Dr. Debra Goff** is an associate professor at the College of Pharmacy working with the One Health Antibiotic Stewardship team at The Ohio State University, and she is an infectious

diseases specialist at Wexner Medical Center (OSUWMC) in Columbus, Ohio. She also is a founding member of the Antimicrobial Stewardship Program at OSUWMC. Prior to her current position, she was program director of the Infectious Diseases Residency program at OSUWMC. She has received numerous awards and, among others, is a faculty member of the World Health Organization (WHO) Pathogens Priority List Working Group. Her interests include antimicrobial resistance; the application of rapid diagnostic tests with stewardship interventions; use of Twitter to increase global engagement; and cross collaboration with surgeons, oncologists, veterinarians, and patient advocate organizations in antibiotic stewardship. Dr. Goff lectures nationally and internationally as an antimicrobial stewardship advocate.

**Dr. Donna Mildvan** is a clinical professor of medicine at Icahn School of Medicine at Mount Sinai in New York. Prior to her current position, she was chief, Division of Infectious Diseases/AIDS at Mount Sinai Beth Israel, and co-principal/principal investigator, AIDS Clinical Trials Group. Dr. Mildvan is widely recognized for her significant contributions to science, including early descriptions of AIDS and its complications. She is the recipient of several awards of excellence in medical research and chair of numerous study protocols and a member of NIH review committees, the National Pneumonia Technical Expert Panel, and served as a consultant to the U.S. Centers for Disease Control and Food and Drug Administration (FDA). Dr. Mildvan has a long-standing interest in community-acquired pneumonia and studies addressing antimicrobial prescribing and its impact on the emergence of drug resistance. Her research focus includes innovative trial design and drug development, biomarker research, and championing minority representation in clinical trials. She has co-authored more than 200 peer-reviewed publications.

**Dr. Melissa Miller** is professor of pathology and laboratory medicine and director, Clinical Molecular Microbiology Laboratory, as well as associate director, Clinical Microbiology Laboratory, at the University of North Carolina at Chapel Hill School of Medicine. In addition, she is the current chair of the ASM Professional Practices Committee, the co-chair of the Pan American Society for Clinical Virology Clinical Practices Committee and a fellow of the American Academy of Microbiology. Dr. Miller has participated in several diagnostic clinical trials and is a current member of the Center of Devices and Radiological Health FDA Microbiology Devices Panel. She received her PhD in Molecular Biology from Princeton University.

**Dr. Frederick (Rick) S. Nolte** is a professor and vice chair for laboratory medicine in the Department of Pathology and Laboratory Medicine, and a medical director of Clinical Laboratories and Molecular Pathology at the Medical University of South Carolina (MUSC). Prior to joining MUSC in 2007, he spent 18 years at Emory University School of Medicine where he was a professor of pathology and laboratory medicine and director of the Clinical Microbiology, Molecular Diagnostic, and Serology Laboratories, Emory Medical Laboratories. Dr. Nolte has experience with FDA clinical trial work and served as a member and consultant to the Center of Devices and Radiological Health FDA Microbiology Devices Panel. He has authored numerous book chapters, practice guidelines and more than 100 peer-reviewed publications in the areas of clinical microbiology and molecular diagnostics. In addition, he served on scientific advisory boards and provided consulting services to many start-up and established diagnostic companies.

**Dr. Robin Patel** is the Elizabeth P. and Robert E. Allen Professor of Individualized Medicine, a professor of medicine and professor of microbiology, co-director of the Clinical Bacteriology Laboratory, director of the Infectious Diseases Research Laboratory, and chair of the Division of Clinical Microbiology at Mayo Clinic in Rochester, Minnesota. Prior to taking a staff position at Mayo over two decades ago, she completed a residency in internal medicine and a fellowship in infectious diseases and clinical microbiology at the Mayo Clinic College of Medicine and Science. Dr. Patel's research focuses on clinical bacteriology diagnostic

testing, antimicrobial resistance, and microbial biofilms. She has published more than 300 peer-reviewed manuscripts and has delivered numerous national and international presentations. Dr. Patel graduated from Princeton University with a bachelor's degree in chemistry and earned her M.D. from McGill University in Montreal, Canada.

The newly formed U.S. Scientific Advisory Board complements the Curetis Medical Advisory Board, now renamed the EU Scientific Advisory Board. Current members of this board include Dr. Reno Frei (Luzerner Kantonsspital, Switzerland), Dr. Mathias Pletz (University Hospital Jena, Germany), Dr. Laurent Poirel (University of Fribourg, Switzerland), and Dr. Jean-Louis Vincent (Erasmus University Hospital, Belgium).

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### **About the Unyvero System in the U.S. Market**

The Unyvero System with the Unyvero LRT Cartridge is the first, most comprehensive molecular diagnostics (MDx) product for lower respiratory tract infections that has been granted clearance by the U.S. FDA. With 29 multiplexed PCR assays, it can detect more than 30 Gram-positive and Gram-negative bacterial organisms known to cause lower respiratory tract infections, as well as 10 genetic markers for antibiotic resistance, including carbapenem and third-generation cephalosporins. Preparations for a future U.S. FDA submission of bronchoalveolar lavage (BAL) sample types for use with the LRT Cartridge are progressing, and the Company intends to request a pre-submission meeting in due course. The Company has also started the collection of patient samples for a multi-center U.S. FDA study for its Unyvero IJI Cartridge for the detection of invasive joint infections. Further, Unyvero Cartridges with unique panels designed for the rapid diagnosis of microbial and viral infections are in development.

### **About Curetis**

Curetis N.V.'s (Euronext: CURE) goal is to become a leading molecular microbiology provider of innovative solutions for molecular microbiology designed to address the global challenge of diagnosing severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis' Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, and thereby facilitates improved patient outcomes, stringent antibiotic stewardship and health economic benefits. Unyvero *in vitro* diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and in the U.S.

Curetis' wholly owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. ARES' technology platform combines the world's most comprehensive database on the genetics of antimicrobial resistances with advanced bioinformatics and artificial intelligence.

**For further information, please visit [www.curetis.com](http://www.curetis.com) and [www.ares-genetics.com](http://www.ares-genetics.com).**

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