Curetis Launches Unyvero System and LRT Cartridge for Lower Respiratory Tract Infections in the U.S.

- ***Multiple scientific conference contributions at ASM Microbe highlight benefits of Unyvero LRT***
- ***First commercial evaluation agreements expected in the coming weeks***

Amsterdam, the Netherlands, Holzgerlingen, Germany and San Diego, CA, USA, June 7, 2018, 1:00 a.m. EDT - Curetis N.V. (the "**Company**" and together with its subsidiaries "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the U.S. commercial launch of its Unyvero sample-to-answer molecular diagnostic system and the Unyvero LRT Application Cartridge for lower respiratory tract infections at the *ASM Microbe 2018* Congress in Atlanta, GA, USA (June 7-11). Curetis obtained regulatory clearance for the Unyvero System and Unyvero LRT from the U.S. FDA in April this year.

The Unyvero System, together with the Unyvero LRT Application Cartridge, provides rapid infectious disease testing directly from aspirate samples in less than five hours. It covers more than 90% of infection cases of hospitalized pneumonia patients and provides clinicians with a comprehensive overview of genetic antibiotic resistance markers detected. As the first-in-class molecular test for lower respiratory tract infections with no direct molecular diagnostic competition, it addresses a significant unmet medical need that causes over $10bn in annual costs for the U.S. healthcare system (see references 1, 2 below). It is also the first time that the U.S. FDA has granted clearance for an automated molecular diagnostic test for the atypical microorganism *Legionella pneumoniae*.

The potential of the Unyvero System and LRT Application Cartridge to positively impact clinical outcomes, support antibiotic stewardship, and create health economic benefits is substantiated by several key contributions to the scientific program of ASM Microbe 2018:

Dr. Chiagozie I. Pickens, MD, and colleagues from the Northwestern Memorial Hospital, Chicago, IL, USA show data demonstrating that delays in the transport time of LRT specimens to the microbiology laboratory result in loss of viable pathogens, including virulent nosocomial pathogens. They conclude that “molecular technologies, such as Unyvero PCR, are less affected and identified causative agents even after long transport times.”

Dr. Matthew D. Sims, MD, PhD, and his group at William Beaumont Hospital, Royal Oak, MI, USA, evaluated Unyvero LRT with regard to clinical impact and antibiotic stewardship and conclude that “the Unyvero Platform and the LRT Cartridge have significant potential to improve the management of lower respiratory tract infections and can improve antibiotic stewardship at the same time.” This poster is also featured in an oral presentation by Dr. Sims during the Lounge & Learn Session “Outcomes Impacting Income: Cost Effective Clinical Diagnostics.”

In addition, in an Industry and Science Workshop hosted by Curetis USA, Dr. Joseph M.

Campos, PhD, D(ABMM), F(AAM), Director of Microbiology Laboratory, Infectious Disease Molecular Diagnostics Laboratory, and Laboratory Informatics at Children's National Medical Center, Washington, DC, USA, will share early results from the evaluation of the Unyvero System and the Unyvero LRT Application at his institution.

"ASM Microbe is an ideal platform to launch the Unyvero System and the LRT Application Cartridge in the U.S.," commented Chris Bernard, President and CEO of Curetis USA Inc. and EVP Global Sales. "The advantages of Unyvero, highlighted by Dr. Pickens and Dr. Sims in the congress' scientific program, are also recognized by many clinicians and laboratory directors at those hospitals we have been actively reaching out to following the FDA clearance decision. We are making very good progress in getting Unyvero Systems installed in several of those accounts short-term and expect to have signed multiple commercial evaluation agreements in the coming weeks. We also received the first commercial Unyvero cartridge order from a U.S. customer."

To drive the commercial roll-out of the Unyvero System and Unyvero LRT as a first application cartridge in the U.S., the Company has completed the U.S. commercial operations setup and has a dedicated team of about 25 seasoned commercialization experts at its Curetis USA Inc. subsidiary in San Diego, CA. With the commercial team in place and the roll-out initiated, Curetis is targeting the placement of 40 to 50 Unyvero Analyzers by year-end 2018 and 60 to 80 Analyzers within the first full year of commercial availability in the U.S.

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Unyvero Posters and Presentations at ASM Microbe 2018

Poster 263: Impact of Specimen Transport Time on Identification of Pathogens: Comparison of a PCR-Based Diagnostic Platform to Routine Microbiological Cultures
***C. Pickens**, C. Qi, H. Donnelly, M. Breganio, R. Wunderink; Northwestern Univ., Chicago, IL, USA*

Session 221 - CPHM03 - Diagnostic Bacteriology: Pre-Analytical Methods and Automation; June 9, 11:00 a.m. - 1:00 p.m. EDT, Exhibit and Poster Hall, Building B, Halls B2-B5
http://www.abstractsonline.com/pp8/#!/4623/presentation/12015

Poster 367: Evaluation of a Rapid Highly Multiplexed Molecular Diagnostic Lower Respiratory Panel for Clinical Impact and Antibiotic Stewardship
*H. Mopuru, K. Powell, **M. SIMS**; Beaumont Health, Royal Oak, MI, USA*

Session 225 - CPHM12 - Molecular Diagnostic Microbiology: The Future of Diagnostics is Here; June 9, 11:00 a.m. - 1:00 p.m. EDT, Exhibit and Poster Hall, Building B, Halls B2-B5
http://www.abstractsonline.com/pp8/#!/4623/presentation/12392

Session 501 - Outcomes Impacting Income: Cost Effective Clinical Diagnostics; June 10, 2018, 4:55 p.m. - 5:00 p.m. EDT, Lounge and Learn 2, Building A, Level 3
http://www.abstractsonline.com/pp8/#!/4623/presentation/16632

Industry and Science Workshop - Curetis USA: Microbial Analysis of Lower Respiratory Tract Specimens with the Curetis Unyvero LRT Multiplex PCR Assay
J. M. Campos; Children's National Medical Center, Washington, DC, USA

June 7, 1:00p.m. - 1:45p.m. EDT, Room B313, Georgia International Convention Center,
http://www.abstractsonline.com/pp8/#!/4623/session/1740

References

(1) CDC (2015) 'New CDC study highlights burden of pneumonia hospitalizations among US adults', available at: https://www.cdc.gov/media/releases/2015/p0714-pneumonia-hospitalizations.html

(2) American Thoracic Society (2015) 'Top 20 pneumonia facts – 2015', available at: https://www.thoracic.org/patients/patient- resources/resources/top-pneumonia-facts.pdf

About Curetis

Curetis N.V.'s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting 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, thereby facilitating 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 the U.S.

Curetis' wholly owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARES*db*, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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