New Data on Curetis' Unyvero LRT Panel for Pneumonia to be Presented at ASM Microbe 2019

- Several scientific conference contributions outline benefits of U.S. FDA-cleared Unyvero LRT Application Cartridge in both endotracheal aspirate and bronchoalveolar lavage samples

- Study shows that Unyvero LRT has potential to support antibiotic stewardship and may reduce time to actionable clinical results by more than two days

Amsterdam, the Netherlands, San Diego, CA, USA, and Holzgerlingen, Germany, June 04, 2019 - 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 new data on its Unyvero System and LRT Application Cartridge for pneumonia will be presented at the upcoming ASM Microbe Conference, June 20-24, 2019, in San Francisco, CA, USA.

The potential of Unyvero LRT to support antibiotic stewardship and positively impact clinical outcomes is substantiated by several key contributions to the scientific program of ASM Microbe 2019:

- Dr. Joseph M. Campos, PhD, D(ABMM), F(AAM), Children's National Medical Center, Washington, DC, will present the performance evaluation of the Unyvero LRT panel for pneumonia on bronchoalveolar lavage (BAL) and endotracheal aspirate (ETA) specimens obtained from pediatric patients. The findings highlight that the Unyvero LRT improved the detection of important and difficult-to-treat pathogens such as *Pseudomonas* and *Acinetobacter*. They conclude that 'the qualitative reporting scheme of the Unyvero LRT results was unbiased and straightforward, enabling clinicians to manage patients with early interventions and avoid ineffective antimicrobial therapy.' This poster is also featured as an oral presentation by Dr. Campos during the symposium "Novel Diagnostics for Pneumonia" on Saturday, June 22.

- Dr. Matthew D. Sims, MD, PhD, Beaumont Health, Royal Oak, MI, will present an evaluation of the Unyvero LRT panel on bronchoalveolar lavage (BAL) specimens obtained from patients suspected of pneumonia. The data demonstrated excellent overall sensitivity (93%) and specificity (98%) compared to microbiology culture, and importantly, Unyvero LRT detected pathogens that were missed by culture. Furthermore, Dr. Sims concludes that 'Unyvero reduced the time from specimen arrival in the laboratory to actionable results by more than 2 days, providing significant potential to reduce the time to appropriate diagnosis of pneumonia.'

- In addition, in an Industry and Science Workshop hosted by Curetis USA, Dr. David W. Craft, PhD, D(ABMM), Professor of Pathology and Medical Director of Microbiology at Penn State Hershey Medical Center, will share early results from the evaluation of the Unyvero LRT panel on sputum and tracheal aspirates compared against conventional culture methods and will discuss the implications of the rapid test results

on conventional diagnostic work-ups and the potential impact on the therapeutic management of patients by reporting these results into the electronic medical record.

“We are delighted about the growing amount of excellent clinical and scientific data on our Unyvero System and LRT Cartridge,” said Faranak Atrzadeh, Senior VP of Scientific Affairs of Curetis. “Most importantly, the recent results confirm that Unyvero may lead to a significantly faster diagnosis and enable informed treatment decisions more than two days earlier than standard microbiology culture.”

The Unyvero LRT Application Cartridge for pneumonia was cleared by the U.S. FDA in April 2018 and launched in the U.S. market at ASM Microbe Conference 2018. Initially cleared for use with tracheal aspirates as a sample type, Curetis is currently in the final stages of preparing a U.S. FDA submission for the clearance of the Unyvero LRT Application Cartridge for bronchoalveolar lavages (BAL), another sample type commonly used in the diagnosis of pneumonia. The submission builds on excellent recent performance data from clinical evaluation studies, which will be presented by Dr. Matthew D. Sims, MD, PhD, in his poster presentation at ASM Microbe 2019.

Curetis at ASM Microbe 2019

Curetis invites ASM Microbe 2019 attendees to visit the Curetis booth (#1236) for a demonstration of Unyvero LRT and discussing its clinical benefits supported by the recent study data and wealth of previous studies.

Unyvero LRT Presentations and Posters at ASM Microbe 2019

Industry and Science Workshop: Evaluation of the Curetis Unyvero Lower Respiratory Tract (LRT) Panel for Pneumonia in the Clinical Microbiology Laboratory of a Tertiary Care Teaching Hospital
***D. W. Craft**; Penn State Hershey Medical Center, Hershey, PA*
June 20, 4:00 – 4:45PM PDT, Room 205/206, The George R. Moscone Convention Center

Poster 4617: Use of a Multiplex PCR Pneumonia Panel for the Microbial Analysis of Lower Respiratory Tract Specimens from Children
***J. M. Campos**, C. Guray; Children’s National Medical Center, Washington, DC*
Session CPHM12 – Molecular Diagnostics Using Multiplex Platforms; Poster Board Number CPHM-951
June 22, 11:00AM – 12:00PM and 4:00 – 5:00PM, Exhibit and Poster Hall

Poster 4899: Evaluation of a Rapid Highly Multiplexed Molecular Diagnostic Lower Respiratory Tract Panel for Use with Bronchoalveolar Lavage Specimens
*K. Powell, **M. Sims**; Beaumont Health, Royal Oak, MI*
Session CPHM12 – Molecular Diagnostics Using Multiplex Platforms; Poster Board Number CPHM-953
June 22, 11:00AM – 12:00PM and 4:00 – 5:00PM, Exhibit and Poster Hall

Oral Abstract Presentation: Use of a Multiplex PCR Pneumonia Panel for the Microbial Analysis of Lower Respiratory Tract Specimens from Children
***J. M. Campos**; Children’s National Medical Center, Washington, DC*
Session Symposium – Novel Diagnostics for Pneumonia
June 22, 2:00 – 2:15PM, Room 213/214, The George R. Moscone Convention Center

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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 is developing next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines the presumably most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

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

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