



Curetis Launches CE-IVD Marked Unyvero Urinary Tract Infection (UTI) Cartridge at ECCMID 2018

- ***UTI panel covers 103 diagnostic targets***
- ***443-patient multi-center study demonstrates overall weighted average sensitivity of 95.6% at an overall weighted average specificity of 99.3%.***

Amsterdam, the Netherlands; San Diego, CA, USA; and Holzgerlingen, Germany; April 19, 2018, 01:00 EDT -- Curetis N.V. (the "Company" and, together with Curetis USA Inc. and Curetis GmbH, "Curetis"), a developer of next-level molecular diagnostic solutions, today announced the successful completion of clinical performance evaluation and CE-IVD marking of its novel Unyvero Application Cartridge, UTI, for the diagnosis of severe urinary tract infections. Unyvero UTI will be launched during the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) taking place in Madrid, Spain, from April 21 to 24, 2018.

The Unyvero UTI Cartridge covers 103 diagnostic targets. The 88 pathogens that can be detected with Unyvero UTI include a broad range of Gram-positive, Gram-negative species as well as difficult to culture anaerobic bacteria and *Candida auris*, a multi-drug resistant pathogenic fungus that is of increasing concern, particularly in immunocompromised hospitalized patients. Unyvero UTI also detects 15 genetic markers of antibiotic resistances including the *mcr-1* antibiotic resistance gene, which results in resistance to colistin, one of the few last-resort antibiotics for Gram-negative infections. Similar to other Unyvero Applications, Unyvero UTI allows the rapid detection of pathogens and genetic resistance markers in a broad range of routinely available patient sample types, such as midstream urine, catheter urine, suprapubic aspiration, and tissue.

The prospective, multi-center clinical performance evaluation study for CE-IVD marking was conducted at Curetis and three clinical centers in France and Germany. The study, which analyzed a total of 443 patient samples, validated the excellent performance of Unyvero UTI: overall weighted average sensitivity for the pathogens specifically targeted by the test panel was 95.6% at an overall weighted average specificity of 99.3%. The Positive Predictive Value (PPV) was 95.8%, and the Negative Predictive Value (NPV) 99.2%.

The novel Unyvero UTI Cartridge primarily targets urinary tract infections in patients with complicated and severe UTIs. This includes pregnant woman, pediatric patients, and hospitalized patients with anatomical, structural and functional alterations, renal impairments and impaired immune status, as well as catheter-associated urinary tract infections (CAUTI), patients failing to respond to therapy, and urosepsis.

"The UTI Cartridge is a highly comprehensive tool for the diagnosis of urinary tract infections," said Prof. Cattoir, University Hospital of Rennes, France, one of the sites participating in the performance evaluation study. "We have been eagerly awaiting a diagnostic solution with such fast time-to-result and broad coverage, including numerous pathogens that are difficult to culture as well as pathogens that are of increasing clinical

concern such as *Candida auris*, a multi-drug resistant pathogenic yeast that was only recently discovered in Japan. It is becoming increasingly prevalent in Europe and other regions, and requires special attention by physicians. Unyvero UTI's ability to detect the *mcr-1* antibiotic resistance gene is also significant, given that it confers plasmid-mediated resistance to colistin, a last-resort antibiotic for treating Gram-negative infections."

"This new product further enhances our portfolio of Unyvero cartridges for hospital-acquired infections," said Dr. Achim Plum, CBO of Curetis. "With the launch of Unyvero UTI, clinicians now have access to Unyvero cartridges that cover all primary infections which may lead to sepsis, still the number one cause of morbidity and mortality worldwide and the most significant cause of death in non-coronary intensive care units."

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About Urinary Tract Infections

Urinary tract infections (UTIs) account for a large portion of hospital-acquired infections. The European point prevalence survey 2016 conducted by the European Center for Disease Prevention and Control (ECDC) revealed that healthcare-associated UTI accounted for 25.2% of all healthcare associated infections, followed by pneumonia/LRT (24.4%) and surgical site infections (15.4%). In urology clinics, nearly 10% of hospitalized patients develop UTIs, often due to multi-drug resistant uropathogens.

Among hospital-acquired UTIs, about 75% are associated with a urinary catheter, which is received by between 15-25% of hospitalized patients. In the U.S., there are an estimated 1 to 1.5 million catheter-associated UTIs per year. Although most catheter-associated UTIs are not serious, complications can increase the patient's length of hospital stay, and results in higher morbidity and mortality and increased healthcare costs.

The most serious complication of an UTI is increasingly urosepsis, which accounts for 9 to 31% of all cases of sepsis and has a mortality rate of 20–40%.

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 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 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 the world's most comprehensive database 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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