Curetis Launches Unyvero LRT Panel for BAL Specimens in the U.S.

- ***Panel also includes atypical pathogens such as Pneumocystis jirovecii***
- ***LRT BAL Panel expected to substantially increase total addressable market for Unyvero System in the U.S.***

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, January 14, 2020, 08:00 am CET -- Curetis N.V. (the "**Company**" and, together with its subsidiaries, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the U.S. launch of its Unyvero LRT BAL Lower Respiratory Tract Application Cartridge for use with bronchoalveolar lavage (BAL) samples to diagnose lower respiratory tract infections such as pneumonia. The Company received 510(k) clearance of Unyvero LRT BAL panel by the U.S. FDA on December 20, 2019, and has taken all necessary steps for an immediate U.S. commercial launch.

The LRT BAL panel will be commercially available to Curetis' U.S. customers from the end of January onwards. Several prestigious medical centers, including a major cancer center and a large academic institution, have already committed to evaluate the Unyvero LRT BAL panel for routine use in patients hospitalized for suspected pneumonia.

The Unyvero LRT BAL application is the first and only FDA-cleared molecular diagnostic pneumonia panel that includes *Pneumocystis jirovecii*. As culture-based diagnosis of *Pneumocystis jirovecii* Pneumonia (PJP) is not possible, identification of this pathogen is often based on morphological detection techniques, which are labor-intensive and time-consuming and lack sensitivity. Rapid diagnosis of PJP, which causes severe and life-threatening symptoms, is crucial in patients with a weak or suppressed immune system. Initiating the appropriate therapy even one day earlier can significantly reduce mortality in this patient group.

"*Pneumocystis jirovecii* is a leading cause of pneumonia in immunocompromised individuals. Several features unique to *Pneumocystis* make its diagnosis difficult. No combination of symptoms, signs, and chest radiographic findings is diagnostic of *Pneumocystis* Pneumonia, the organism cannot be cultured, and its diagnosis currently relies on microscopic visualization of the characteristic cysts and/or trophic forms on stained respiratory specimens," said Richard G. Wunderink, MD, Professor of Medicine, Pulmonary Critical Care, Northwestern University Feinberg School of Medicine, and Medical Director, Medical ICU, Northwestern Memorial Hospital, when the FDA cleared the test in December. "Inclusion of *Pneumocystis jirovecii* in a rapid comprehensive molecular panel for BAL, the preferred diagnostic procedure for *Pneumocystis* Pneumonia, will greatly facilitate our ability to quickly diagnose and treat these patients."

Beyond *Pneumocystis jirovecii*, the LRT BAL panel detects a broad spectrum of clinically relevant causative agents, including atypical pathogens, as well as antibiotic resistance markers. Thereby, it provides clinicians with a valuable diagnostic tool that informs early and supports appropriate antibiotic treatment decisions in this indication.

Infections with atypical pathogens are often associated with community-acquired pneumonia (CAP), but are not considered in the context of hospital-acquired or ventilator-associated pneumonia. Therefore, hospitalized patients usually are not tested for these organisms unless there is a suspicion of infection. Further, empiric treatment of these patients does not normally cover atypical pathogens. Unyvero LRT BAL expands the diagnostic capability of clinicians to routinely identify atypical infections that might otherwise escape detection and hence can prevent prolonged inappropriate treatment of patients.

Indiscriminate overuse and misuse of antibiotics are key drivers of dramatically spreading antibiotic resistance, a substantial global health threat. A report recently issued by the Centers for Disease Control and Prevention (CDC) revealed that drug-resistant bacteria and fungi cause almost 3 million infections and 35,000 deaths a year in the United States, meaning that antibiotic-resistant pathogens cause a serious infection every 11 seconds and a death every 15 minutes (Ref. 1).

By providing a fast and reliable solution for the rapid detection of pathogens and antibiotic resistance markers, Unyvero LRT BAL is an essential, indispensable tool for targeted antimicrobial therapy improving patient outcomes while facilitating stringent antibiotic stewardship.

“Unyvero LRT had already been cleared by the U.S. FDA for tracheal aspirate samples in 2018,” said Johannes Bacher, COO of Curetis. “With our newly launched Unyvero LRT BAL Application Cartridge, clinicians and hospitals can now also test bronchoalveolar lavage samples. This sample type accounts for about half of the samples obtained for the diagnosis of lower respiratory tract infections such as pneumonia. As a result, our Unyvero solution is offering the most comprehensive multiplex molecular panel for the rapid diagnosis of bacteria and fungi associated with severe pneumonia. It not only enables rapid and simultaneous detection of pathogens but also offers the broadest coverage of resistance markers.”

“We are excited about this launch on the heels of the recent FDA clearance decision. We expect that the launch of our LRT panel for BAL samples will significantly increase the total addressable market for our Unyvero System in the U.S.,” said Oliver Schacht, PhD, CEO of Curetis. “It will provide us with substantial opportunities to place Unyvero instruments for rapid testing of patients with suspected lower respiratory tract infections. Moreover, by providing laboratorians and clinicians with a powerful diagnostic tool to identify pathogens in lower respiratory tract infections earlier, faster and more reliably, Unyvero supports antibiotic stewardship efforts to avoid the unnecessary use of antibiotics.”

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Reference

1) CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

   The full 2019 AR Threats Report, including methods and appendices, is available online at www.cdc.gov/DrugResistance/Biggest-Threats.html.

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, ARESdb, with advanced bioinformatics and artificial intelligence.

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

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