Curetis initiates U.S. FDA study for Unyvero Invasive Joint Infections Cartridge

- ***Initial patient samples collected for second U.S. Unyvero Product Study***
- ***Prospective clinical trial expected to start in 2018***

Amsterdam, the Netherlands, and Holzgerlingen, Germany, October 23, 2017; published at 09:00 a.m. EDT -- Curetis N.V. (the "**Company**" together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced it has started collecting patient samples for a multi center FDA study for its Unyvero IJI Cartridge for the detection of invasive joint infections. The cartridge will be a newly developed U.S. version based on the CE IVD marked Unyvero ITI Cartridge already marketed in Europe and other parts of the world. The Unyvero IJI Cartridge is the second Unyvero application to undergo a U.S. FDA study. Clearance decision by the FDA for the Unyvero LRT (Lower Respiratory Tract) Infections Application, Curetis' first Unyvero U.S. product, is expected by the end of 2017.

Following Institutional Review Board (IRB) approvals, the first patient samples were collected in early October. Among the sites that have already entered the trial for sample collection of microbiology-positive synovial fluid patient samples are sites that previously participated in the Unyvero LRT trial (e.g. Beaumont Hospital, Royal Oak, MI), as well as new sites (e.g. Froedtert Hospital and the Medical College of Wisconsin, Milwaukee, WI), med fusion, (Lewisville, TX) and a leading reference lab in the Southwest. The Company is expecting further expansion of the network to include additional sites in the coming months.

The overall trial design is similar to the Unyvero LRT study. Following FDA guidance, the IJI clinical trial is expected to enroll more than 1,500 prospective test samples, complemented with archived microbiology-positive specimens to reach significant numbers for each of the analytes in the IJI panel, as well as a comprehensive analytical testing data package.

Development of the Unyvero IJI Application Cartridge has also advanced well. The Company expects availability of the Cartridges and the initiation of the prospective arm of the FDA trial to begin in 2018.

"As interactive review of the Unyvero System and the LRT cartridge application is progressing , we decided to initiate a second U.S. FDA trial program," said Johannes Bacher, COO of Curetis. "Upon FDA clearance, the Unyvero Invasive Joint Infection Cartridge is expected to be yet another first-in-class application and will expand the application options for future U.S. users of the Unyvero Solution.

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About Curetis
Founded in 2007, Curetis is a molecular diagnostics company which focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases. The diagnostic solutions of Curetis enable rapid multi-parameter pathogen and antibiotic resistance marker detection in only a few hours, a process that today can take up to days or even weeks with other techniques.

To date, Curetis has raised EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 million. Furthermore, Curetis has entered into a debt financing facility with EIB for up to EUR 25 million. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis collaborates with Heraeus Medical, pharmaceutical companies, and has entered into several international distribution agreements covering many countries across Europe, the Middle East and Asia.

In 2017, Curetis established Ares Genetics GmbH, a wholly-owned subsidiary of Curetis GmbH in Vienna, Austria. Ares Genetics is dedicated to maximize the R&D and related scientific and business opportunities of the GEAR assets acquired in 2016 for the entire Curetis Group.

For further information, please visit www.curetis.com**.**

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