Curetis Provides Update on Unyvero LRT FDA *510(k)* Submission

- Curetis reiterates that it expects FDA to provide decision on clearance of Unyvero LRT in the second half of 2017

Amsterdam, the Netherlands, and Holzgerlingen, Germany, May 24, 2017 - Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today provided an update regarding the ongoing interactive review by the U.S. Food and Drug Administration (FDA) of its *510(k)* application for clearance of the Unyvero Platform and Lower Respiratory Tract Infection (LRT) Application Cartridge.

On April 21, 2017, Curetis participated in a Meeting with a team of FDA reviewers, discussing the FDA's request for additional information communicated to the Company in March 2017. Meeting minutes have been drafted and confirmed by Curetis and FDA as of May 23, 2017.

Based on the outcome of this meeting and further discussions with the reviewers, FDA is moving forward with review of the Unyvero Platform and LRT Application Cartridge for use initially with tracheal aspirate samples. Curetis believes that clearance of the Unyvero System and LRT Cartridge with one of the most relevant sample types initially could give Curetis a time advantage, being the only provider of a diagnostic solution of this kind. Following clearance of Unyvero LRT with tracheal aspirate samples, Curetis plans to submit data for clearance of the LRT Cartridge for bronchial lavage (BAL) sample types. Originally, Curetis filed for both bronchial lavage (BAL) and tracheal aspirate sample types in its De Novo submission. By making the strategic decision to move forward in this phased approach, Curetis aims to pursue the fastest and least risky regulatory pathway. This decision should render unnecessary a possible Advisory Committee Panel meeting that the FDA has brought up for moving forward with aspirate and BAL sample types at the same time.

Curetis plans to continue working closely with the FDA reviewers to identify an appropriate path to develop or augment the BAL data package, which shall be submitted as part of a proposed future label claim expansion following the potential initial clearance of Unyvero LRT for tracheal aspirates.

"In light of our ongoing discussions with the reviewers, we believe that our request to exclude the BAL sample type from the initial label claims provides the most expeditious path forward for Unyvero in the U.S., and we are pleased that the FDA might issue an initial clearance decision for tracheal aspirates. We look forward to continuing to work closely with the FDA through the interactive review while determining the optimal process through which to file a label claim extension following potential clearance," said Johannes Bacher, Chief Operating Officer of Curetis. "Apart from additional data on the BAL sample type, we are planning to generate data from the interventional use of the Unyvero LRT product in the routine clinical setting once approved, and to further assess its potential impact on antibiotic

stewardship. We strongly believe in the unique, paradigm-shifting potential of Unyvero to inform better, more actionable treatment decisions and promote more efficient antibiotic use in critically ill patients."

The FDA has requested additional data (e.g. stability data of fresh vs. frozen samples, additional contrived sample testing and adding some reproducibility data) that will require Curetis to conduct incremental wet lab testing at the Company's facilities in Germany. The total number of additional Unyvero LRT Application Cartridge runs is expected to be around 500 to 1,000 (i.e. 5% to 10% of the total number of more than 10,000 cartridges already run for the LRT clinical studies) and will likely be completed in the coming 3 to 4 months.

"We are working diligently to provide this additional information to the FDA in the coming weeks and months, and still expect that a decision on the initial clearance of the Unyvero platform and LRT Application Cartridge could be issued in the second half of this year," added Dr. Oliver Schacht, CEO of Curetis.

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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 maximizing 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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