Curetis Expects Near-Term FDA Decision on *De Novo* Request

- Review of the Unyvero System and Lower Respiratory Tract (LRT) Cartridge is nearing completion

- U.S. commercial team and operational infrastructure in place

Amsterdam, the Netherlands, San Diego, CA, USA, and Holzgerlingen, Germany, January 08, 2018, 01:00 am EST - Curetis N.V. (the "**Company**" and, together with Curetis USA Inc. and Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today provided a status update on the FDA *De Novo* filing for the Company's Unyvero System and LRT Cartridge for the diagnosis of lower respiratory tract infections.

The FDA and Curetis have agreed on software results screens and disclaimer language in the fourth quarter of 2017 and software implementation of the final reporting format is already underway. In December 2017, the FDA and Curetis also agreed on the format and scope of reporting of clinical and resistance marker data (incl. resistance marker statistics) as part of the labelling (package insert / handbook).

"We are in very close interaction with the FDA's review team," said Oliver Schacht, CEO of Curetis. "We are now expecting a near-term decision on our *De Novo* request for the Unyvero System and Unyvero LRT Cartridge."

Preparations for a future submission of bronchoalveolar lavage (BAL) sample types for use with the LRT Cartridge are also progressing, and the Company intends to request a pre-submission meeting in due course.

As the FDA review is nearing completion and in anticipation of the FDA decision, the Company has continued to build its U.S. commercial organization in San Diego, CA with the recent hiring of highly experienced key regional sales and commercial support staff.

###

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**.**

Legal Disclaimer

This document constitutes neither an offer to buy nor to subscribe securities and neither this document nor any part of it should form the basis of any investment decision in Curetis.

The information contained in this press release has been carefully prepared. However, Curetis bears and assumes no liability of whatever kind for the correctness and completeness of the information provided herein. Curetis does not assume an obligation of whatever kind to update or correct information contained in this press release whether as a result of new information, future events or for other reasons.

This press release includes statements that are, or may be deemed to be, “forward-looking statements”. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes”, “estimates”, “anticipates”, “expects”, “intends”, “may”, “will”, or “should”, and include statements Curetis makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Curetis’ actual results may differ materially from those predicted by the forward-looking statements. Curetis undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

Contact Details

Curetis GmbH
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 7031 49195-10
pr@curetis.com or ir@curetis.com
www.curetis.com

International Media & Investor Inquiries

akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68

U.S. Media & Investor Inquiries

The Ruth Group
Lee Roth
lroth@theruthgroup.com
Tel. +1 646 536 7012