Curetis Acquires Patents and Rights to Genetic Antibiotic Resistance and Susceptibility (GEAR) Database and Know-How from Siemens

- Agreement gives Curetis worldwide rights to database and IP based on Next Generation Sequencing
- GEAR significantly enhances Curetis' leading position in the area of genetic antimicrobial resistance biomarker testing

Amsterdam, the Netherlands, and Holzgerlingen, Germany, September 7, 2016 -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the signing of an asset acquisition agreement with the Siemens Technology Accelerator GmbH (STA). Under the terms of the agreement, Curetis has acquired sole commercial rights from STA to the GEAR GEnetic Antibiotic Resistance and Susceptibility platform and database with all its content, numerous GEAR-related patents and patent applications, as well as all corresponding know-how. The deal gives Curetis sole worldwide product development and commercial rights, including the right to sublicense in the fields of human and animal diagnostics as well as food safety testing. Furthermore, Curetis has secured the sole rights to leverage the GEAR assets in collaboration with pharmaceutical companies for the development of novel antimicrobial drugs for human and animal health.

As consideration for these assets, STA will receive an undisclosed upfront payment from Curetis. Furthermore, Curetis will make undisclosed milestone payments for products including GEAR biomarkers upon first CE IVD marking and first FDA approval (or similar regulatory clearance), respectively. Also, there will be royalty payments to STA in industry-typical percentage ranges on future products based on use of the GEAR platform or GEAR biomarkers. Further financial details were not disclosed.

The state-of-the-art GEAR bioinformatics platform and database was developed and compiled in collaboration with two academic partners: The Institute of Clinical Molecular Biology (IKMB) at Kiel University that carried out the next generation sequencing (NGS) of bacterial isolates and the Clinical Bioinformatics Group of Saarland University headed by Prof. Dr. Andreas Keller that developed the bioinformatics platform and performed the computational analysis of 30 Terabyte of data underlying the GEAR database. GEAR allows users to assemble and annotate bacterial genomes from NGS raw data, identify genetic variations in those genomes and correlate those with the response of the respective bacterial strain to antibiotics. Currently, the GEAR database contains the entire DNA sequences as well as sensitivity data for 21 antibiotics of more than 11,000 bacterial strains isolated from patient samples across the world over the last three decades. It will allow Curetis to rapidly identify potential novel biomarkers, biomarker combinations, and algorithms predicting antibiotic resistance, as well as potential novel targets for antimicrobial drugs.

The acquisition of the GEAR database and patent estate adds significantly to the leadership position that Curetis has established in the area of genetic antimicrobial resistance biomarker testing with its Unyvero Application Cartridges. Curetis will further expand and mine the GEAR database in collaboration with leading academic institutions as well as

pharmaceutical and diagnostics companies and leverage those into commercial products on its Unyvero Molecular Diagnostics platform and beyond.

“We are thrilled to have won in the competitive bidding process for this unique and exciting asset,” said Dr. Achim Plum, Chief Commercial Officer of Curetis. “With this platform, we are planning to build a network of strong and collaborative relationships with academics, clinicians and companies in the fields of diagnostics and pharmaceuticals alike. We will develop this repository into a valuable resource of antibiotic resistance biomarkers available to the global research community, while leveraging the proprietary nature of GEAR into our own Unyvero products and platform in the future.”

Oliver Schacht, CEO of Curetis, added, “Since our IPO, we have diligently executed on our commercial and product development plans. At the same time, we have kept our eyes open for strategic opportunities such as the GEAR acquisition. GEAR allows us to significantly expand the scale and scope of the Unyvero platform and complement it with NGS-based knowledge. GEAR will become an engine for even more comprehensive and differentiated content of antibiotic resistance biomarkers in our Unyvero products and allow us to stay on top of the development of cutting-edge molecular diagnostic products for critical hospital infections.”
Prof. Keller, one of the initiators of the project, highlighted the broad and unique character of GEAR: “The more than 11,000 whole bacterial genomes collected over three decades and across many countries in combination with culture-based phenotypic resistance profiles against 21 drugs enabled us to investigate multivariate genetic resistance mechanisms in a very comprehensive manner”. Prof. Keller also underlined that Curetis is a perfect partner for commercialization of tests for antibiotic resistance derived from GEAR: “We are convinced of the success of genetic antibiotic resistance tests and committed to support Curetis in their endeavor to improve care for patients suffering from bacterial infections”

About the GEAR Database and Assets:
The GEAR database includes genomic data of mostly Gram negative bacteria causing pneumonia, bloodstream infections, urinary tract infections, and gastric and wound infections. Samples were carefully selected across multiple geographies (USA, EU, Asia) and have been collected over three decades to reflect resistance development and variability over time. Sample collection was done at over 200 sites on 5 continents, with over 150 US institutes contributing. In addition to many of the most troublesome Gram negative bacteria, GEAR also includes *S. aureus,* demonstrating feasibility also for Gram positive bacteria.

Sample collection was designed to achieve significant statistical power with over 10,000 Gram negative bacterial strains and ca. 1,000 *S. aureus* (both MSSA and MRSA) strains tested. Overall, 21 antibiotic drugs in 182 different concentrations with all modes of action for resistance were tested for. Most commonly used drugs have been chosen by the former Siemens Microbiology Department. Antibiotic susceptibility testing (AST) reference methods as per CLSI (Clinical and Laboratory Standards Institute) guidelines were used and results interpreted according to EUCAST (European Committee on Antimicrobial Susceptibility Testing) guidelines. Seven out of nine combinations of bacteria and antibiotics identified as being of international concern by the WHO were analyzed in detail. Individual patent filings have been made for each bacteria for all antibiotics as well as certain method and process patents.

Next generation sequencing (NGS) was performed at one of the leading German Sequencing Centers (IKMB Institute of Clinical Molecular Biology in Kiel) on HiSeq 2000 and HiSeq 2500 Sequencers with over 300 Mio bases sequenced per sample. Taken together, 4 billion reads with 0.4 trillion bases were sequenced. Advanced bioinformatics approaches developed by the group of Prof. Dr. Andreas Keller, Chair for Clinical Bioinformatics, Saarland University, were employed to combine NGS results with AST data to identify

potential novel and proprietary antibiotic resistance biomarkers and biomarker combinations.

GEAR enables a wide range of valuable clinical applications such as better genetic resistance testing for specific drug classes, broader syndromic resistance biomarker panels, and, in the future, potentially fully genetic antibiograms. It therefore can provide unique content for high-, medium-, and low-plexed MDx platforms.

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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. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical and Cempra Inc. as well as several international distribution agreements covering many countries across Europe, the Middle East and Asia.

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

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