Press Release 04/2011

Curetis AG and its Partners obtain Additional € 0.5 Million Funding under German Federal Innovation Grant Program

Federal funding for joint R&D project of Curetis AG (Holzgerlingen, Germany), Polytechnic Schmalkalden (Germany) and Contexo GmbH (Winterbach, Germany) towards mass production optimization of consumables for innovative infectious disease diagnostics.

(Holzgerlingen, Germany, 19 April 2011). Curetis AG announced today that a consortium including Curetis, the Polytechnic Schmalkalden (Germany) and Contexo GmbH (Winterbach, Germany) has been awarded about € 0.5 million for 2011 under the Federal German Central Innovation Program (ZIM). The Federal Ministry of Economics and Technology thereby supports the optimization of certain plastics joining processes for mass production of consumables for innovative diagnostics.

Acute severe infections require rapid and comprehensive diagnostics to support physicians in therapeutic decision making. Thus it is key that clinically relevant pathogens and antibiotic resistances get detected within a few short hours. Curetis AG has developed a product solution that uses molecular methods to detect 17 different bacteria and more than 20 antibiotic resistances within a couple of hours. The system uses a disposable cartridge that integrates the isolation, amplification and specific detection of bacterial DNA.

For economic and efficient molecular diagnostic application disposables, plastics is the material of choice. Plastic materials that are employed must allow for complex three-dimensional structures, enabling the actuation and transportation of sample liquids and reagents, and at the same time allow for bio-compatible surfaces. Although it is possible to provide complex structures with them, currently available joining processes do not always allow for bio-compatible surfaces that can be produced economically. Therefore the ZIM grant supports the optimization of bio-compatible joining processes for fluidic systems in an enclosed disposable cartridge that can be reliably and cost effectively mass manufactured.

Each of the project partners contributes complementary skills towards this challenging manufacturing issue: Curetis has broad competencies in developing and in the industrial scale up of instruments and disposables for the medical device and diagnostics industry. Polytechnic Schmalkalden contributes with its research facilities for applied plastics technologies in terms of know how on materials selection, processing, analytics and construction. Contexo GmbH has decades of experience in designing and building high-throughput production lines for molecular diagnostics products including the integration of varied separation, joining, filling and sealing processes.

Dr. Gerd Lüdke, co-founder and Director Bio-Assay Development at Curetis AG explains the project's goals: „Together with our partners we are optimizing a process for routine production of our disposable cartridge that allows for joining plastic parts without compromising the bio-compatibility of surfaces. This is the

second ZIM grant in only a few years and underscores the successful development work to date. We are looking forward to working with our renowned partners and experts in this field.“

The Central Innovation Program for medium-sized companies (ZIM) has been offering such companies a reliable perspective by funding individual projects as well as collaborative networks. This makes the ZIM grants the cornerstone of the Federal Ministry's market oriented technology support for innovative SMEs in Germany. It helps reduce the risks of R&D projects and translation into market-ready innovations. Curetis has already been a successful recipient of such funding in 2009 and 2010.

The Polytechnic Schmalkalden with its lab for Applied Polymer Engineering has access to all relevant means to address specific materials issues. Their research emphasis is on product development under DIN EN ISO13485, as well as Design Control Guidance for Medical Device Manufacturers (FDA). They are also experts in determining metrics for bio-compatible and medical polymers and tools construction especially in the medical device field. The lab has state of the art equipment for analytics and processing of plastics. Professor Dr. -Ing. Thomas Seul, faculty of machine tool manufacturing at Polytechnic Schmalkalden: „In today's molecular in vitro diagnostics world disposable plastics cartridges play a major role. Hence the safe and cost effective manufacturing and application of such cartridges is a prerequisite which imposes highest demands on plastics molding and joining processes.“

Contexo GmbH is a medium sized company specialized on developing tailor-made automation solutions for assembly, testing and production equipment. They have successfully completed hundreds of custom-designed automated manufacturing facilities. The offering includes solutions of semi-automated manufacturing servo-cells, efficient rotary indexing systems as well as continuous motion systems with an output of thousands of parts per minute. Their core competence lies in the assembly, packaging and medical device industries. The grant project enables Contexo to apply results from this project directly for the Curetis manufacturing line. „Joining of components of the Curetis disposable cartridge in a fully automated high-throughput process was an interesting challenge for us at Contexo. This project allows us to optimize the current prototype pilot manufacturing line with regards to throughput and costs; thus support the commercialization of Curetis' innovative diagnostics.“ says Karl Müller, Head of Sales at Contexo GmbH.

Oliver Schacht, CEO of Curetis AG, adds: „By allowing for a deeper collaboration with the Polytechnic Schmalkalden and Contexo this grant is a major contribution towards further efficiency gains in our product development and their routine production. This project helps us to optimize an integral part of our Unyvero platform and our first IVD application – the pneumonia panel cartridge – that we expect to launch in Europe in 2012.“

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About Curetis (Germany)

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

About the Polytechnic (FH) Schmalkalden (Germany)

The laboratory of Applied Polymer Engineering at the University of Applied Sciences in Schmalkalden was founded in 2008 and contains modern equipment focused on polymer analysis and polymer processing. The laboratory concentrates on doing product development for polymer parts and tool construction. Furthermore the research group is handling different research projects including following scientific focus points:

- identification of biobased polymers and polymers for medical applications
- manufacturing of injection moldings, especially lubricant free tools
- product development for medical engineering
- surface technologies (metallic coating of polymer parts).

About Contexo GmbH (Germany)

Contexo GmbH is a machine tool manufacturing company focused on automation solutions. Based on platform systems Contexo develops and builds high-performance assembly lines for the medical device, pharmaceutical and packaging industries. Based on individual customer requirements Contexo implements round indexed, linear-indexed or continuous motion machines. Integration of common processes such as laser welding, visual inspection and leak testing can be implemented in various combinations. Implementation of systems follows and is qualified under GMP guidelines.

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