BellaSeno Establishes GMP-Compliant High-Throughput Additive Manufacturing Facility for Resorbable Medical Implants

- Seamless transition from R&D to commercial-scale additive manufacturing
- Leading-edge cleanroom, no-touch manufacturing
- GMP capabilities for internal and contract manufacturing

Leipzig, Germany, November 17, 2020 - BellaSeno GmbH, an ISO 13485-certified medtech company developing absorbable scaffolds using additive manufacturing technologies, today announced the establishment of a novel, leading-edge additive manufacturing facility for medical implants supported by the Fraunhofer Institute for Cell Therapy and Immunology IZI, Leipzig, Germany.

It is the one of the first GMP-compliant manufacturing facilities worldwide to include innovative features such as high-througput additive manufacturing based on the so-called no-touch approach to significantly improve the safety and sterility of medical implants. Moreover, the facility allows for a seamless transition from R&D to commercial-scale manufacturing and provides capabilities for both internal and contract manufacturing.

While BellaSeno contributed its additive manufacturing expertise, Fraunhofer IZI was responsible for developing GMP-compliant processes, quality assurance and quality control. The resulting infrastructure, incl. SOPs and documentation, was then certified and transferred to BellaSeno.

“We are delighted to have established a truly unique additive manufacturing facility together with Fraunhofer IZI,” said Mohit Chhaya, PhD, Chief Executive Officer of BellaSeno. "This will not only ensure leading-edge manufacturing of our own products, but also enables us to provide contract manufacturing of resorbable medical implants for a wide range of applications."

He added that BellaSeno is the one of the first European companies with an ISO13485 certification covering the entire additive design and manufacturing process. Moreover, the Company is able to reproducibly and routinely manufacture scaffolds with feature sizes down to 150-µm - an important differentiation factor in the additive manufacturing sector.

“We are very glad to have developed a strong foundation of GMP-level production processes over the last three years in close collaboration with the Fraunhofer IZI team," said Arpita Desai, M.E., Head of Quality Management at BellaSeno. “The exchange of knowledge throughout the project will allow us to produce implants in our new ISO

14644 Class 7 cleanroom facility at a much higher quality compared to current standards – leading to safer patient outcomes."

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About BellaSeno

BellaSeno GmbH was founded in 2015 and is located on the BioCity campus in Leipzig, Germany. The Company is developing novel absorbable soft tissue reconstruction implants made by additive manufacturing (3D-printing) under ISO 13485 certification. The Company has received substantial financial support from private investors as well as from the Saxony Development Bank (SAB) and the European Fund for Regional Development (EFRE). The Company is thereby co-funded from tax resources based on the budget adopted by the members of Saxon State Parliament.

Europäische Union

Europa fördert Sachsen. ESF Europäischer Sozialfonds

Diese Maßnahme wird mitfinanziert durch Steuermittel auf Grundlage des von den Abgeordneten des Sächsischen Landtags beschlossenen Haushaltes.

About Senella®

Senella® is a patented porous scaffold made of absorbable Polycaprolactone (PCL) containing highly-specialized topological and design features, which act as recipients for injected fat tissue isolated with a standard liposuction procedure. The implant is designed to get absorbed over a span of two years and to provide a stable platform for the injected fat tissue to mature, adapt to its environment and stabilize. The clinical end result is a natural soft tissue – without remnants of foreign material. Senella® therefore has the potential to alleviate the complications found in current breast reconstruction and augmentation approaches.

About the Fraunhofer Institute for Cell Therapy and Immunology IZI

The Fraunhofer Institute for Cell Therapy and Immunology IZI investigates and develops solutions to specific problems at the interfaces of medicine, life sciences and engineering. One of the institute‘s main tasks is to conduct contract research for companies, hospitals, diagnostic laboratories and research institutes operating in the field of biotechnology, pharmaceuticals and medical engineering.

The Fraunhofer IZI develops, optimizes and validates methods, materials and products for the business units Cell and Gene Therapy, Drugs and Diagnostics. Its areas of competence lie in cell biology, immunology, drug biochemistry, bioanalytics and bioproduction as well as process development and automation. In these areas, research specifically focusses on the indications oncology, immunological diseases as well as infectious diseases and neurodegenerative diseases.

The institute works in close cooperation with hospital institutions and performs quality tests besides carrying out the GMP-compliant manufacture of clinical test samples. Furthermore, it helps partners obtain manufacturing licenses and permits.

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