

BellaSeno Demonstrates Superior Biomechanical Properties of its 3-D Printed, Resorbable Scaffolds for Bone Reconstruction

- *Data presented at the 24th EFFORT Congress in Vienna (Austria)*

Leipzig, Germany, June 20, 2023 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced comparative data on the biomechanical properties of different polycaprolactone/hydroxylapatite bone reconstruction scaffolds. The results, presented at the 24th EFORT Congress in Vienna, Austria, demonstrate that BellaSeno's established manufacturing process results in bone scaffolds that can withstand higher loads and longer stress cycles than those produced by competing technologies.

The current orthopedic gold standard for the treatment of large long-bone defects and non-unions typically is the diamond concept which involves the insertion of an osteoconductive structure (scaffold) to guide bone regeneration. To perfectly match the patient's anatomy, several companies have used additive manufacturing (3D printing) to develop new, customized scaffolds to fulfill this demand of the diamond concept. These scaffolds are printed from resorbable materials such as polycaprolactone (PCL), polylactic acid, or composites of PCL and hydroxyapatite (HA) and are intended to hold the autologous bone graft in place. Selective laser sintering (SLS) and fused deposition modeling (FDM) are the most common methods for printing these medical scaffolds. There is an ongoing debate as to which technology is best suited to produce the most durable scaffolds. Depending on the required properties of a scaffold, BellaSeno is working with either SLS or FDM and has customized and fine-tuned the manufacturing process for both methods.

For the study, BellaSeno compared how the most common additive manufacturing processes (SLS and FDM) affect the biomechanical properties of polycaprolactone/hydroxylapatite (PCL/HA) scaffolds produced for bone regeneration. Standard lattice

design triangular scaffolds (30 x 30 mm) were fabricated under optimized conditions from a PCL/HA composite of polycaprolactone with 4% hydroxyapatite by SLS and BellaSeno's proprietary FDM technology. The scaffolds were then placed in a mechanical testing machine for high-precision axial compression-deformation testing. An increasing axial load was applied to the specimens for 1,000 cycles each, starting with 500 N, then 700 N, 1,000 N, and 1,100 N. The strain was measured in % proportional to the applied force.

For the FDM scaffolds, almost similar hysteresis strain curves were observed for the 500 N, 700 N, and 1,000 N axial tests without any scaffold fatigue. Only the application of 1,100 N resulted in permanent deformation and scaffold failure. In contrast, the SLS fabricated scaffolds tolerated much less axial load: The application of 700 N resulted in immediate failure of the scaffold structure with complete and permanent deformation.

"The data clearly demonstrate that our proprietary FDM-based technology has a decisive impact on the axial mechanical stability of the final product," said Dr. med. Tobias Grossner, Chief Medical Officer of BellaSeno. "PCL/HA composite scaffolds produced by selective laser sintering have much lower mechanical integrity. Moreover, the overall waste of raw material is less for FDM compared to SLS."

"To our knowledge, this is the first time such a comparison has been published," said Mohit Chhaya, CEO of BellaSeno. "We are very pleased that our approach using FDM can be considered the more robust and more economical technology for the production of scaffolds for bone reconstruction. However, SLS still is an option for applications where we need higher design freedom, e.g., when overhanging structures are necessary. In these cases, it is superior to FDM."

BellaSeno has established fully automated, proprietary manufacturing processes and facilities designed to meet the requirements of medical scaffolds ranging from soft tissue to bone. The Company's manufacturing is ISO 13485 certified and allows for the highly scalable production of both custom-made and off-the-shelf sterile medical implants.

Initial findings from ongoing Phase I studies demonstrate that BellaSeno's resorbable implants are safe, well tolerated and support natural tissue growth.

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About BellaSeno

BellaSeno GmbH was founded in 2015 and is headquartered on the BioCity campus in Leipzig, Germany, with a subsidiary in Brisbane, Australia. The Company is developing novel resorbable soft tissue and bone 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), the European Fund for Regional Development (EFRE), Germany's Federal Ministry of Education and Research (BMBF) and the Australian government. The Company is thereby co-funded from tax resources based on the budget adopted by the members of Saxon State Parliament.



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