BellaSeno Presents Novel Production Workflow for Customized, 3D-Printed Bone Scaffolds

- *Presentation at the German Congress of Orthopaedics and Traumatology (DKOU)*
- *Treatment of large segmental bone defects with resorbable scaffolds*
- *Leading-edge workflow for the design and manufacturing of customized bone scaffolds*

Leipzig, Germany, October 30, 2023 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced that the Company has presented novel data on the design and manufacturing of customized, 3D-printed bone scaffolds at the recent German Congress of Orthopaedics and Traumatology (DKOU).

BellaSeno is one of the first Company to present an MDR-compliant (Medical Device Regulation) and ISO 13485 audited workflow for the design and manufacturing of 3D-printed, resorbable, custom-made polycaprolactone scaffolds for the treatment of segmental bone defects in conjunction with an autologous bone graft (RIA Reamer Irrigator Aspirator or cancellous bone).

The presentation titled "Semi-automated workflow for the design and fabrication of 3D-printed patient-specific resorbable scaffolds for the treatment of large segmental bone defects while complying with MDR regulations" outlined the potential of BellaSeno´s novel resorbable scaffolds for curing large segmental bone defects (> 5cm size). In these large injuries, biological reconstruction using the diamond concept is preferred. It provides for the application of osteogenic cells in conjunction with a scaffold. The scaffold is needed to hold the autologous bone graft in position for optimal vascularization and bone healing. Scaffolds made by additive manufacturing from bioresorbable polymers represents a highly attractive opportunity to produce such patient-specific open-pore scaffolds.

Following specialist indication, digital segmentation of the CT is performed with 3D reconstruction. The exact defect is defined and, following the treating surgeon’s direction, BellaSeno creates an anatomically oriented design to fill the defect. This is followed by adjustment of various parameters to customize the fit and mechanical performance of the scaffold. Depending on whether the scaffold is to be used in conjunction with plate or nailless osteosynthesis, additional features are integrated. Fused deposition modeling (FDM) will be used as a 3D printing technique as it offers clear biomechanical and economic advantages over other techniques (e.g., Selective Laser Sintering SLS). A prototype is sent to the practitioner for design freeze and is then biomechanically tested before manufacturing the scaffold under cleanroom conditions with subsequent post-processing and sterilization.

"This specific workflow allows a very time- and cost-effective manufacturing process for patient-specific scaffolds while complying with highest regulatory standards," said Dr. med. Tobias Grossner, Chief Medical Officer of BellaSeno. "Depending on the desired properties of the scaffolds, the products can absorb static non-deformable axial forces of up to 4,000 N or shorten by up to 1cm under a load of up to 1,000N in a controlled manner without breaking. This results in a new generation of high-performance bone scaffolds which are well suited for the biological reconstruction of large bone defects."

BellaSeno´s ISO 13485 certified manufacturing platform is designed to meet the requirements of medical scaffolds ranging from soft tissue to bone and enables the production of both custom-made and off-the-shelf sterile medical implants.

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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 has been co-funded from tax resources based on the budget adopted by the members of Saxony State Parliament.

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

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Federal Ministry
of Education
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