BellaSeno's 3D-printed Resorbable Scaffold Successfully Used in Critical-Size Large Segmental Radius Bone Defect at Hannover Medical School

- *Trauma patient suffered from third degree open infected fracture of its radial shaft after injury by a bullet*
- *Graft vascularization was achieved by embedding vascular pedicle into the scaffold*
- *Recently published as a case report in the* Journal of Personalized Medicine

Leipzig, Germany, March 5, 2024 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, announced today that a team at the Hannover Medical School, Clinic for Trauma Surgery, led by Prof. Dr. med. Philipp Mommsen, successfully used a customized, resorbable bone replacement scaffold produced by BellaSeno to reconstruct a 14 cm segmental bone defect of the radial shaft after third degree open infected fracture due to traumatic gunshot injury.

Prior to his treatment at Hannover Medical School, the patient had undergone eleven surgeries with soft tissue and bony debridement to obtain secondary wound closure, while the radial fracture was only stabilized by a ring fixator. Following six further operations and systemic antibiotic treatment to achieve bacterial eradication of the surgical field, bone reconstructive surgery was performed at Hannover Medical School using BellaSeno's resorbable scaffold in conjunction with an autologous bone graft from the medullary cavity of the femoral bone. The scaffold is based on Resomer®, a biodegradable polymer platform developed by Evonik. The surgery succeeded and after three months, the patient showed timely bony integration and had adequate elbow function without any signs of wound healing disorder. Also, no more clinical signs of infection were apparent. The case study was published in this month's *Journal of Personalized Medicine*.

The scaffold was designed by BellaSeno as a customized cage to perfectly match the patient's anatomy and to ensure a secure hold of autologous bone graft (RIA material) in the large void. To enable proper internal vascularization by the positioning of an arterio-venous loop or a central vascular pedicle during reconstructive surgery certain design features were included to allow the placement of such a fragile structure inside the scaffold. The scaffold was manufactured by BellaSeno's proprietary AI-driven additive manufacturing facilities based on the so-called no-touch approach. The cage consisting of an inner and outer support frame with a basic and a locking part is made from completely bioresorbable, high-quality, GMP-grade Resomer® polycaprolactone (mPCL) and provides osteoconductive properties. During surgery, the team decided to use a vascular pedicle to ensure immediate internal vascularization, which was placed and fixed

through an aperture located on the outer cage frame. The procedure was carried out in October 2023.

“As the example of the 46-year-old patients demonstrates, sophisticated solutions to treat large bone defects are scarce. BellaSeno’s scaffold enabled us to conduct a new surgical technique for graft vascularization by embedding a vascular muscle arcade directly into a patient-specific, 3D-printed bioresorbable scaffold,” said Prof. Dr. med. Philipp Mommsen, Managing Senior Physician, Clinic for Trauma Surgery at Hannover Medical School and lead author of the paper. “This surgical procedure represents an innovative and promising approach for the restoration of extensive bone defects. As we see an increasing number of such catastrophic and very difficult to treat defects we are facing a rapidly growing medical need to reconstruct such injuries.”

“The sheer size of such defects and the lack of vascularization have limited the optimal treatment of large-volume bone defects,” said Priv. Doz. Dr. med. Tobias Grossner, CMO of BellaSeno. “Using one of our scaffolds, the outstanding team at Hannover Medical School was able to perform the reconstruction of such an extensive radial shaft bone while ensuring immediate vascularization. This demonstrates the power of our technology to improve the surgical treatment of large bone defects, individually customized to the specific anatomy of the patient and the design preferences of the surgeon.”

“This case study once again underlines the versatility of our technology,” said Dr. Mohit Chhaya, CEO of BellaSeno. “Almost any design request by a medical team can be fulfilled to optimize the patient’s treatment. The open structure of the scaffold enables vascularization which is crucial not only for proper bone healing but also to allow access of immune cells and anti-microbial drugs to prevent surgical site infections. We are currently working on next-generation bone scaffolds made of a composite of PCL and bio-active glass with anti-infective properties.”

BellaSeno´s MDR-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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Contact BellaSeno
BellaSeno GmbH
Dr. Mohit Chhaya
mohit.chhaya@bellaseno.com
Tel.: +49 176 2283 9583

Media Inquiries
akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68