Positive Interim Data of BellaSeno's Clinical Trial with Resorbable Breast and Chest Implants Reported at RACS 2023

- *Data presented at RACS 91st Annual Scientific Congress 2023*
- *Initial findings demonstrate that BellaSeno's resorbable implants are safe, well tolerated and lead to natural tissue growth*

Leipzig, Germany, May 9, 2023 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced positive interim results from two clinical trials of its products sponsored by its Australian subsidiary, BellaSeno Pty. The results were presented at the 91st Annual Scientific Congress 2023 of the Royal Australasian College of Surgeons (RACS).

Michael Wagels, Principal Investigator of the first clinical trial evaluating BellaSeno's implant with autologous fat grafting for pectus excavatum camouflage, reported 3-year data from the first in-human case. Not only was the implant safe and well tolerated, but histologic studies demonstrated tissue growth and vascularization within the implant scaffold. Wagels also presented animal data from large 450 ccm scaffolds showing that tissue was fully regenerated in this large volume without the development of necrosis.

Prof. Owen Ung, M.D., Principal Investigator of the ongoing clinical trial evaluating BellaSeno's breast scaffold implantation with autogenous fat grafting for breast implant revision and congenital defect surgery, presented promising initial data from the trial, which is enrolling up to 20 patients undergoing either breast implant revision or congenital breast defect surgery.

Data from the first patients to receive large (up to 200 ccm) implant scaffolds showed good tissue retention, with tissue growth observed as early as two months. In addition, significantly improved quality of life scores demonstrate patient satisfaction with the scaffolds 2 months after surgery.

"We are very pleased with these positive data," said Mohit Chhaya, CEO of BellaSeno. "It is great to see that the implants are safe and result in tissue development within the scaffolds, including vascularization. Moreover, it is fantastic that the patients are happy and report an improved quality of life."

"These are breakthrough results," said Dr. med. Tobias Grossner, CMO of BellaSeno. "Both animal studies and patient data show that the approach of implanting resorbable scaffolds is not only safe and well tolerated, but also leads to results that resemble natural tissue. We look forward to additional results from our ongoing studies."

"The data demonstrate for the first time that it is possible to successfully regenerate such clinically relevant volumes of tissue without the development of necrosis," said Dr. Michael Wagels, Director of the Herston Biofabrication Institute (HBI), Consultant Plastic and Reconstructive Surgeon at Princess Alexandra Hospital, Director of the Australian Centre

for Complex Integrated Surgical Solutions (ACCISS) and Senior Lecturer at the University of Queensland. "This is very impressive and underlines the huge potential of BellaSeno's technology for reconstruction of large defects."

"Current solutions for breast reconstruction are associated with many risks," added Prof. Owen Ung, Director of the Centre for Breast Health, Head of Breast and Endocrine Surgery at the Royal Brisbane and Women's Hospital and Professor of Surgery at the University of Queensland Medical School. "The procedures are complex, costly, only suitable for small volumes, can lead to infection and some have even been linked to cancer. In contrast, BellaSeno's implants can replace large volumes of tissue and support cell attachment, migration and proliferation. In addition, implantation can be performed in one to two hours and patients can be discharged from the hospital the day after surgery."

BellaSeno's implants are porous polycaprolactone scaffolds produced in the Company's AI-driven additive manufacturing facilities using an AI-guided no-touch approach. Polycaprolactone has been used in the healthcare industry for decades as an absorbable suture material. After implantation, the scaffolds are grafted with the patient's own fat tissue obtained through liposuction. After surgery, the polycaprolactone scaffold is slowly but completely resorbed and replaced by the patient´s own vascularized tissue, leaving no permanent foreign material in the body and resulting in natural tissue.

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

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About Senella®

Senella® is a patented porous scaffold made of resorbable 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 up to 5 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.

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