BellaSeno Successfully Completes Two Clinical Trials with Novel, Resorbable Breast Implants

- *One-year follow-up data confirm favorable safety profile of BellaSeno´s scaffolds compared to silicone implants*
- *Company plans expansion to primary breast augmentation and lumpectomy*

Leipzig, Germany/ Brisbane, Australia, January 14, 2025 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced that all 19 breast scaffold patients enrolled in 2022 in an Australian breast augmentation revision trial have successfully completed a one-year follow-up without any major scaffold-related complications or scaffold removals. In addition, in a parallel Australian clinical trial, 7 pectus excavatum patients have successfully passed one-year follow-up. The trials are the first-ever implant trials using a novel approach combining polycaprolactone (PCL) scaffolds, ultimately resulting in a fully resorbed implant and natural tissue. The data show that it is possible to replace silicone implants in breast augmentation with alternatives offering improved safety and quality of life.

The trials are sponsored, single-arm, open, mono-centric, interventional, prospective clinical investigation studies in patients requiring breast augmentation revisions or surgical pectus excavatum correction. Primary endpoint is post-operative device safety, secondary endpoints is post-operative patient safety and post-operative device performance (QOL, volume replacement).

The one-year assessment confirms a very favorable safety profile of BellaSeno´s resorbable soft tissue implants. No major complications such as capsular contracture, calcifications, oil cysts, infections, tissue necrosis, or wound healing issues were observed. No scaffold removals or replacements were necessary, and no scaffold-related complications were observed in any patients six months post-surgery.

The one-year data review by the Independent Data Safety Monitoring Committee stated that all adverse events were within the expected range of complications for removal / replacement surgeries. The Clinical Investigators reported higher patient satisfaction with breasts and quality of life associated with BellaSeno´s scaffolds compared to baseline (i.e. silicone implants). There was high acceptability; patients were pain-free and did not report awareness of the scaffold in situ after twelve months. Identical findings were made in the one-year follow up in pectus excavatum patients.

“This is a very encouraging one-year clinical outcome,” said Mohit Chhaya, CEO of BellaSeno. “The data confirm that our resorbable scaffolds do not only meet the desired safety criteria but also show an improvement of patients´ quality of life. We now have a very strong clinical data set to initiate a pivotal study of our resorbable breast scaffolds in the U.S. and Europe. We will also expand the use of our scaffolds to primary breast augmentation and lumpectomy and also provide a final two-year follow-up next year.”

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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.

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

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