BellaSeno Reports Positive Interim Findings of Australian Clinical Trials in Breast Scaffold Patients

- *Favorable safety profile of resorbable breast scaffolds in one-year follow-up*
- *No major scaffold-related complications or scaffold removals*
- *BellaSeno will initiate multicenter pivotal clinical trial with more than 100 patients*

Leipzig, Germany/ Brisbane, Australia, June 12, 2024 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced that 10 breast scaffold patients and 5 pectus patients have successfully passed one-year follow-up in BellaSeno´s Australian clinical trials.

In the first-ever breast implant trial using PCL scaffolds and fat transfer, the interim analysis confirms a favorable safety profile of the Company´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.

Data review by the Independent Data Safety Monitoring Committee confirmed that all adverse events were within the expected range of complications for removal / replacement surgeries. In general, the Clinical Investigators observed a trend towards 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 and patients did not report awareness of the scaffold in situ after six to twelve months. Identical findings were made in the one-year follow up in pectus excavatum patients.

Based on the positive data, BellaSeno plans to initiate a pivotal clinical trial to obtain regulatory approval of the breast scaffolds.

“Following this favorable interim analysis, we are now well positioned to begin our pivotal clinical study to obtain full regulatory approval of our breast scaffolds in Europe and the U.S.,” said Mohit Chhaya, CEO of BellaSeno. “We are excited that our resorbable scaffolds do not only meet the desired safety criteria but have also shown an improvement of patients´ quality of life.”

“All patients have had consistently favorable outcomes in the follow-up ranging from six months to two years. We’re excited by the progress and at the end of this year will publish the detailed one-year interim analysis for the scientific community," said Professor Owen Ung, Primary Investigator in the clinical trial.

So far, 41 patients have been successfully operated and received BellaSeno´s hard or soft tissue scaffolds (5 bone scaffolds, 36 breast or pectus scaffolds).

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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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