

New investigator-initiated clinical trials of BellaSeno's resorbable tissue regeneration scaffolds to be conducted in Europe

- *New clinical trial site opened in Italy for pectus excavatum and planned in Germany for bone reconstruction*
- *Company aims to expand EU market authorization from custom-made to off-the-shelf products and to pursue market approval in the USA*

Leipzig, Germany, January 31, 2024 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced that additional, investigator-initiated clinical trials of its novel regenerative scaffolds for bone reconstruction and chest-wall defects (pectus excavatum) will be conducted in Germany and Italy, respectively. In 2023, BellaSeno had received market authorization for its custom-made, resorbable bone and pectus excavatum scaffolds in Europe.

The clinical pectus excavatum trial in Italy will enroll a total of 10 patients, with 4 individuals having undergone surgery already. While initial clinical use cases in Australia demonstrated promising outcomes last year, this is the first time that a fully resorbable sternal prosthesis is being used in Europe. For each patient, the prosthesis was individually designed and 3D printed using polycaprolactone - a proven medical material in use for decades, e.g., for resorbable suture material. There will be a 2-year patient follow-up to assess the outcome of the operation.

Following the publication of first clinical data by BellaSeno, a total of four European university hospitals have announced their plans to set up independent, investigator-initiated clinical trials to investigate further into this promising technology. Among the first sites, the Clinic for Trauma and Reconstructive Surgery at the University Hospital Heidelberg under the lead of Professor Dr. med. Gerhard Schmidmaier plans to initiate its IIT in Q1/2024, aiming to include up to 20 patients with a follow-up time of 2 years.

"We are excited that several leading European university hospitals have decided to evaluate our scaffolds in independent clinical trials. This will help us obtain further clinical evidence on our proprietary approach of treating both soft and hard tissue defects," said Dr. Mohit Chhaya, Chief Executive Officer of BellaSeno. "The addition of real-world data will be beneficial for our planned market approval for off-the-shelf breast and bone reconstruction products in the USA and EU."

"We look forward to learning more about the scientific background of BellaSeno's groundbreaking technology, especially how such a scaffold is being vascularized while it secures the position of the autologous bone graft in a large size defect," said Professor

Dr. med. Gerhard Schmidmaier, the primary investigator of the IIT in Heidelberg. “The initial results are promising, and as a team, we are committed to supporting these trials comprehensively. This technology has the potential to deliver a step change in the field of regenerative medicine, and we are eager to demonstrate the benefits it brings to patients with complex reconstructive needs.”

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