BellaSeno Announces First-In-Human Trial of its Novel, Absorbable Soft Tissue Reconstruction Scaffold and Granting of Key U.S. Patent

- First patient with Pectus Excavatum congenital defect has undergone surgery in Australia
- Minimally invasive procedure and fully absorbable scaffold expected to provide for improved safety and recovery
- Key U.S. patent granted for the design and porosity of Senella® platform

Leipzig, Germany, July 21, 2020 - BellaSeno GmbH, an ISO 13485-certified medtech company developing absorbable scaffolds using additive manufacturing technologies, today announced the initiation of a first-in-human trial of its novel, absorbable soft tissue reconstruction scaffold (Senella®). A patient with Pectus Excavatum congenital defect has undergone surgery at Princess Alexandra Hospital in Brisbane, Australia, earlier this month. The procedure was performed by Dr. Michael Wagels, Principal Investigator of the trial and Plastic and Reconstructive Surgeon at Princess Alexandra Hospital.

Primary endpoint of the trial will be the assessment of post-operative adverse device effects (ADE) 12 and 24 months after pectus scaffold implantation. Secondary endpoints cover safety criteria such as adverse events, frequency of complication (short term and long term), number of revision surgeries due to ADEs and pain.

Pectus Excavatum (or funnel chest syndrome) is a rare malformation of the thorax characterized by a median or lateral depression of the sternum. Funnel chest occurs in 1 to 2% of the population. This is the most common congenital thoracic deformity. Pectus Excavatum is a challenging medical setting and usually requires a two-step surgical process. The condition can impair cardiac and respiratory function and cause pain in the chest and back.

The benefit of using an absorbable scaffold is the simplicity compared to other orthopaedic techniques which use silicone or metal implants. The surgery is designed as a minimally invasive procedure where no bones are touched and the recovery is expected to be less painful than other treatment approaches. Moreover, Senella® scaffolds are designed to be fully absorbed by the recipient´s body within two years after surgery, leaving no harmful or risky substances.

Moreover, BellaSeno announced that a key patent covering design and porosity features of its Senella® platform has been granted in the U.S. The Company has exclusively licensed the patent from Technical University Munich, Germany.

"Today marks a major milestone in the history of BellaSeno as we transition into a clinical-stage medtech company," said Mohit Chhaya, PhD, Chief Executive Officer of BellaSeno. "Our first-in-human study with Senella helps build the foundation for expanding clinical trials to European sites and additional breast reconstruction indications later this year. In addition, we are delighted to further strengthen our global patent portfolio."

"The versatility of our design and manufacturing platform allows us to efficiently produce patient-specific as well as standardized scaffolds," added Navid Khani, PhD, Head of R&D at BellaSeno. "We therefore hope that our approach will transform reconstructive surgery and make a meaningful difference in the lives of patients."

"Our first aim is always the safety and satisfaction of the patient. We are glad that the close collaboration between the surgeons, our supply chain partners and the entire BellaSeno team has made such a rare disease trial possible," said Sara Lucarotti, M.E., Head of Design at BellaSeno.

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About BellaSeno

BellaSeno GmbH was founded in 2015 and is located on the BioCity campus in Leipzig, Germany. The Company is developing novel absorbable soft tissue 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) and the European Fund for Regional Development (EFRE). The Company is thereby co-funded from tax resources based on the budget adopted by the members of Saxon State Parliament.

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

About Senella®
Senella® is a patented porous scaffold made of absorbable 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 two 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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