BellaSeno Presents Case Study on Regulatory Approval of Novel 3D-Printed Medical Devices

- *Presentation by BellaSeno's CTO Mohit P. Chhaya at 3DMedLive Conference in London*
- *Identifying an approval pathway for novel scaffolds in absence of regulatory standards*

Leipzig, Germany, October 04, 2019 - BellaSeno GmbH, a company developing absorbable scaffolds using additive manufacturing technologies, today announced that its CTO Dr. Mohit Chhaya presented BellaSeno's approach to obtain regulatory approval for its pioneering 3D-printed scaffold as a medical device in an uncertain regulatory environment. The presentation was held during the 3DMedLive Conference in London on October 3, 2019.

BellaSeno's first product, Senella®, is a patented, porous, absorbable breast implant which is expected to provide a significant improvement in the quality of life of breast reconstruction and augmentation patients around the world. The concept was developed in an academic environment and tested in two small animal and two large animal studies with a one-year follow-up. By conducting these trials, the group was among the first to demonstrate a sustained regeneration of large volumes of tissue.

While advancing the approach towards commercialization, BellaSeno's founders started risk management early on, developing a *House of Quality* matrix and obtaining ISO certification of all development steps. For the preclinical testing, the Company tried to comply to internationally recognized or already harmonized standards as much as possible and focused on testing towards clinical translation.

"However, there were aspects where there were no harmonized standards available," Chhaya said. "Therefore, we sought guidance from the U.S. FDA via their PreSubmission Program, from the German Federal Institute for Drugs and Medical Devices (BfArM), and from notified bodies assessing the conformity of medical products before being launched on the market. We found it was crucial to get classification confirmation early in development as this had a profound impact on all our planned future non-clinical and clinical testing."

For breast implants, the specific challenge was that all relevant standards and guidance documents only covered silicone-based implants. "There was no specific guidance for non-silicone-based breast scaffolds," Chhaya said. "We therefore devised a tailored mechanical testing plan, which we presented to the notified bodies and the FDA to get

feedback and buy-in. To this end, we disclosed our full non-clinical trial dataset in informational meetings."

For the clinical phase, BellaSeno obtained ISO 13485 certification prior to clinical studies and again started discussions on its first-in-human studies and the clinical development plan with the regulatory authorities for medical devices.

An important part in convincing the regulators has been BellaSeno's approach to ensure the high and consistent quality of its scaffolds. "To achieve this goal, we have not only developed our own 3D-printer to meet the FDA guidance for additive manufactured medical devices," Chhaya added, "but we developed an AI-based optimization and quality control process for the entire manufacturing chain."

BellaSeno's proprietary manufacturing platform, *Factory of the Future*, is based on an artificial intelligence system using the manufacturing data collected over a two-year period. The platform allows the Company to reduce optimization time and failure rates and to perform automated quality checks on the product during the printing process. This approach can greatly reduce the demand of printers when scaling up manufacturing.

"The key message is, get in touch with the regulators very early on in the process," Chhaya said, "and stay in touch on a regular basis."

BellaSeno's Senella® scaffold is scheduled to start clinical trials in Q4/2019 in Germany.

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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 breast implants made by additive manufacturing (3D-printing). 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.

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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 breast without remnants of foreign material and thus has the potential to alleviate the complications found in current breast reconstruction and augmentation approaches.

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