PRESS RELEASE 9 OCTOBER 2025

Tensive publishes positive long-term clinical follow-up data in *Breast Cancer* on REGENERA™ / SOFTAG™ breast implant

- **24-month Phase I follow-up data show positive outcomes are maintained**
- **High levels of investigator and patient satisfaction, excellent safety profile**
- **Ongoing registrational trial will yield top-line results before the end of 2025**
- **Product could be approved in U.S. and Europe by early 2027**

Milan, Italy – 9 October, 2025 – Tensive S.r.l, a clinical-stage advanced biomaterials medical device company developing REGENERA™ (EU) / SOFTAG™ (U.S.) bioresorbable scaffolds for breast reconstruction and tissue marking, today announces the publication of a positive interim analysis in a long-term study with its REGENERA™ / SOFTAG™ implants in the leading peer-reviewed journal *Breast Cancer*. The data show that positive outcomes were maintained after 24 months of follow-up following placement of the device in breast-conserving lumpectomy surgery. The data also continue to show high levels of investigator and patient satisfaction, an excellent safety profile, and no interference with imaging. The study also showed that resorption of the implant is taking place in all patients.

"The publication of these encouraging data in *Breast Cancer* strengthens our confidence in the transformative potential of Tensive's implants. The gradual maturation of soft tissue, replacing the scaffold with newly grown tissue, highlights a truly lasting regenerative process. We're expecting to submit the product for regulatory approvals as early as spring 2026, a crucial step to fulfill our mission of improving clinical outcomes and quality of life for breast cancer patients," **said Alberto Cantaluppi, Chief Medical Officer at Tensive.**

The ongoing long-term observational study was into 14 women who received the REGENERA™ / SOFTAG™ implant after lumpectomy for benign lesions in Tensive's first-in-human trial. Patients were evaluated for safety (incidence of adverse events), performance of the device (changes in breast appearance and interference with imaging), and investigator and patient satisfaction. Further interim results will be published at 36 and 48 months, and final results after 60 months of follow-up.

Separately, Tensive's ongoing multi-center pivotal trial completed enrollment of 94 patients with malignant lesions receiving adjuvant cancer therapy following lumpectomy in March. Final data on the primary endpoints are expected in late 2025, and patients will be followed

over a period of five years. Recent interim data from the ongoing pivotal trial confirmed the strong safety and positive performance of the REGENERA™ / SOFTAG™ device.

Of the 2.1 million lumpectomies performed worldwide each year, 1.6 million are not reconstructed, constituting a sizeable unmet clinical need [1]. Despite the psychological impact of breast disfigurement, common cosmetic surgery options are rarely used, as they entail invasive and complex procedures that often fail to achieve the desired outcome.

REGENERA™/SOFTAG™ advanced biomaterial is a bioresorbable implant designed to be inserted in place of the surgically removed tumor during a lumpectomy procedure. The biomaterial used in REGENERA™/SOFTAG™ resembles a sponge with a fine scaffold matrix; its placement is a one-step, minimally invasive, rapid and easy-to-adopt procedure. The device does not require surgical removal as it is gradually absorbed by the body and enables the patient's own healthy tissue to regrow in its place. The result is restoration composed of natural tissue that preserves the original shape and feel of the patient's breast. In addition, the implant is clearly differentiated from surrounding tissue on diagnostic imaging, demarcating the boundaries of the lumpectomy and thereby supporting more targeted delivery of radiotherapy and more accurate monitoring for potential recurrence than would be feasible without the implant.

[1] Analysis based on estimates from the International Society of Aesthetic Plastic Surgery (ISAPS), Breast Cancer Research Foundation (BCRF), the American College of Surgeons (ACS), the World Health Organization (WHO) and Global Market Insights.

Tensive S.r.l. (www.tensive.com) is a clinical-stage advanced biomaterials medical device company developing bioresorbable polymeric scaffolds for breast reconstruction and tissue marking. Its patented REGENERA™ biomimetic scaffold is designed to allow regeneration of a patient's own breast tissue to create natural, safe, and lasting reconstruction for patients recovering from lumpectomy or undergoing cosmetic procedures, while its SOFTAG™ precision tissue marking device enables more targeted delivery of radiotherapy and increases the accuracy of surveillance and follow-up. Tensive's mission is to improve clinical outcomes and the quality of life for breast cancer patients worldwide through accessible, innovative, and sustainable solutions.

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