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Tensive provides positive clinical updates highlighting potential of REGENERA™ / SOFTAG™ device to transform post-cancer breast reconstruction

- **Clinical data from two ongoing trials in patients undergoing lumpectomy confirm strong safety profile and growing performance benefits of device**
- **Primary safety and secondary performance objectives met in interim analysis of 25 patients in pivotal trial, with high levels of patient and surgeon satisfaction**
- **A separate cohort of 15 patients showed the device to be supportive in identifying the tumor bed, guiding radiotherapy treatment planning**
- **Three year-results from first-in-human study further demonstrate durable satisfaction following lumpectomy reconstruction**
- **Expects first regulatory approvals in the EU and U.S. as early as Q1 2027**

Milan, Italy – September 5, 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 provides top-line results from two ongoing trials in patients undergoing lumpectomy to treat benign and malignant lesions respectively. The new data underscore the device's potential to provide a natural, minimally invasive, permanent and safe solution for the 1.6 million patients per year who do not receive reconstruction after lumpectomy because of the lack of viable options.

"The successful interim analyses of our pivotal trial and additional positive follow-up data continue to demonstrate the transformational potential of REGENERA™ / SOFTAG™. These results add momentum to our progress in bringing the devices to market for patients with breast cancer in Europe and the U.S.," **said Sanjay Kakkar, Chief Executive Officer of Tensive.** "The data follow on from last month's appointment of Bill Hunter, a leading expert in the medical device field, as Chairman of our Board of Directors, and the publication of the first interim analysis of our pivotal trial in April [1]. With our team, we are working toward first regulatory approvals as early as Q1 2027, so that we can improve clinical outcomes and preserve the quality of life for the millions of women who currently have no solution for breast reconstruction after lumpectomy," he said.

REGENERA™ achieved the primary safety and secondary performance objectives in an interim analysis of Tensive's ongoing pivotal trial based on 6-month follow-up of 25 patients receiving adjuvant therapy (radiotherapy, chemotherapy, and/or targeted therapy).

Top-line results from a separate interim analysis of the trial, currently being prepared for publication, showed that in 25 patients who received only adjuvant radiotherapy, REGENERA™ was safe, biocompatible, and feasible for volume replacement in breast-conserving surgery. REGENERA™ provides high satisfaction, favorable aesthetics, and does not compromise radiotherapy delivery or follow-up imaging, investigators concluded.

Moreover, in a sub-study of 15 patients in the trial only receiving adjuvant radiotherapy, the accuracy for device detection and localization showed encouraging preliminary results for the use of the scaffold in identifying the tumor bed.

The pivotal trial completed enrollment of 94 patients with malignant lesions who are receiving adjuvant cancer therapy following lumpectomy in March. Final data on the primary endpoints are expected in late 2025. Secondary endpoints include surgeon satisfaction, pain, patient satisfaction and quality of life measured using the validated Breast-Q breast cancer patient questionnaire, and interference with imaging. Patients will continue to be followed for five years.

The interim analyses from the pivotal trial build upon previously published positive results from a first-in-human trial in 15 women who underwent lumpectomy of non-malignant breast lesions and received the REGENERA™ bioresorbable implant [2].

Follow-up data from the first in human study of the REGENERA™ device recently accepted for publication in a peer-reviewed journal show a continued excellent safety profile at two years, no interference with imaging, consistently favorable aesthetic outcomes, and high levels of patient and surgeon satisfaction.

Of the 2.1 million lumpectomies performed worldwide each year, 1.6 million are not reconstructed, constituting a sizeable unmet clinical need [3]. 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 during the lumpectomy surgery is a one-step, minimally invasive, rapid and easy-to-adopt procedure. The device is gradually absorbed by the body and enables the

patient's own healthy tissue to regrow in the area it fills. The result is breast restoration composed of natural tissue that preserves the patient's original breast shape and feel. In addition, the implant is clearly differentiated from surrounding tissue on diagnostic imaging, supporting more targeted delivery of radiotherapy and more accurate monitoring for potential recurrence.

1) A.V.E. Lisa et al. Updates in Surgery Apr 2025. https://doi.org/10.1007/s13304-025-02212-2
2) Mariniello et al. Breast Cancer 2023. https://doi.org/10.1007/s12282-023-01446-5
3) 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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