PRESS RELEASE

Tensive reports positive pivotal trial top-line results showing REGENERA™ bioresorbable device may transform breast reconstruction

- **Clinical data from pivotal trial in patients undergoing lumpectomy confirm strong safety profile and growing performance benefits**
- **Primary safety endpoint met and encouraging secondary performance objectives at 6 months (in 94 patients) and 12 months (in 25 patients)**
- **REGENERA™ achieved high levels of patient and surgeon satisfaction**
- **Patients to be followed for up to five years to assess long-term safety**
- **First regulatory approvals in the EU expected in early 2027**
- **Tensive in San Francisco during the JP Morgan Healthcare Conference**

Milan, Italy – January 8, 2026 – Tensive S.r.l, a clinical-stage advanced biomaterials medical device company developing REGENERA™/SOFTAG™ bioresorbable scaffolds for breast reconstruction and tissue marking, today announced top-line results from a pivotal trial evaluating the REGENERA™ implant in patients undergoing lumpectomy to treat malignant lesions.

The new data underscore the minimally invasive device's potential to allow the body to reconstruct its own breast tissue. REGENERA™ is being developed to offer a natural, permanent, and safe solution to the 1.6 million women per year who do not receive breast reconstruction after lumpectomy because of the lack of viable options.

"Six-month follow-up represents a critical milestone in this patient population in the context of adjuvant cancer therapy," said **Manuela Roncella, MD, breast surgeon at the Breast Surgery Unit, Ospedale Santa Chiara**, and lead investigator of the pivotal trial. "In routine clinical practice, surgeons have limited options for volume replacement following lumpectomy. What we are seeing at six months is particularly encouraging: the scaffold shows consistent and robust behavior in situ and does not interfere with imaging, alongside strong qualitative feedback from both surgeons and patients. Together with follow-up data extending to 12 months in a subset of patients, these observations support the potential of this approach in the post-cancer breast reconstruction setting."

"These positive top-line results from our pivotal trial continue to demonstrate the transformational potential of REGENERA™. This adds momentum to our progress in bringing the device to market for patients with breast cancer in Europe and the U.S.," **said Sanjay Kakkar, MD, Chief Executive Officer of Tensive.** "We are working toward first regulatory

approvals in early 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."

REGENERA™ achieved the primary safety endpoint, demonstrating a strong safety profile at the three and six-month follow-up. Secondary performance findings showed consistent scaffold behavior in situ in an interim analysis of Tensive's ongoing pivotal trial on 94 patients based on 6-month follow-up in 90 patients and on 12-month follow-up in 25 patients receiving adjuvant therapy (radiotherapy, chemotherapy, and/or targeted therapy).

In the study, REGENERA™ was safe, biocompatible, and feasible for volume replacement in breast-conserving surgery in all eligible patients. Furthermore, REGENERA™ provided high satisfaction, favorable aesthetics, and did not compromise radiotherapy delivery or follow-up imaging during the post-surgical or adjuvant treatment period, investigators concluded. The results are consistent with previously reported interim and longer-term clinical follow-up data from this and earlier studies.

Moreover, a sub-study in 15 patients showed use of the scaffold for imaging in identifying the tumor bed was supportive for accurate delivery of adjuvant radiotherapy.

Full results from the pivotal trial, based on the currently available follow-up data, will be submitted for presentation at upcoming scientific conferences and for publication in a peer-reviewed medical journal.

The ongoing multicenter pivotal trial (NCT05941299) completed enrollment of 94 patients with malignant lesions who are receiving adjuvant cancer therapy following lumpectomy in March. 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 top line results from the pivotal trial build upon previously published positive results from this trial and an earlier first-in-human trial in 15 women who underwent lumpectomy of non-malignant breast lesions and received the REGENERA™ bioresorbable implant [1].

Follow-up data from the first in human study of the REGENERA™ device recently published in a peer-reviewed journal [2] show continued excellent safety at two years, no interference with imaging, high levels of performance, with an aesthetic score of 'Excellent' in 85.7% of patients, and high levels of patients and investigator 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 due to the irregular sizes and shapes of lumpectomies.

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; it can be rapidly adjusted for size and shape and its placement during the lumpectomy surgery is a one-step, minimally invasive, fast and easy-to-adopt procedure for surgeons. The biomaterial enables the patient's own healthy tissue to regrow in the area it fills and it is gradually absorbed by the body. The result is breast restoration composed of the patient's own natural tissue in the patient's original breast shape. 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] Mariniello et al. Breast Cancer 2023. https://doi.org/10.1007/s12282-023-01446-5
[2] Mariniello et al. Breast Cancer 2025. https://doi.org/10.1007/s12282-025-01780-w
[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.

JP Morgan Healthcare Week

Tensive will be in San Francisco for meetings with investors, partners and journalists during the **JP Morgan Healthcare Conference** (week of January 12, 2026). On **Tuesday, 13 January 2026, from 4:00–5:00 pm (Pacific Time) Sanjay Kakkar, Chief Executive Officer of Tensive**, will serve as a panelist at Biotech Showcase 2026 on "**MedTech 2026 and Beyond: Devices Transforming Surgery, Care, and Patient Outcomes**."

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™/SOFTAG™ 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 also supporting precision tissue marking to enable targeted delivery of radiotherapy and accurate 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.

PRESS RELEASE

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