PRESS RELEASE

Independent study presented at ECR highlights REGENERA™ bioresorbable scaffold potential for breast restoration after lumpectomy

- **Independent investigators from the University of Pisa presented new data at the 2026 European Congress of Radiology (ECR)**
- **Ultrasound follow-up documented predictable scaffold bioresorption and progressive soft-tissue regrowth**
- **REGENERA™ did not interfere with imaging, preserving full assessability of surrounding breast tissue throughout follow-up period**
- **Findings confirm Tensive's top-line clinical data supporting REGENERA™'s ability to allow the body to regenerate its own breast tissue**

Milan, Italy – March 04, 2026 – Tensive S.r.l, a clinical-stage advanced biomaterials medical device company developing REGENERA™ bioresorbable scaffolds for breast reconstruction and tissue marking, today announced that independent investigators from the University of Pisa and the AOUP Breast Center (Pisa University Hospital) presented new data at the European Congress of Radiology (ECR 2026) in Vienna, Austria.

Poster details: ECR 2026 | Poster C-23223 (EPOS Radiologist – Scientific Presentation))

The new data underscore REGENERA™'s potential as an off-the-shelf, natural, permanent, and safe solution. Each year 2.1 million lumpectomies are performed worldwide; 1.6 million are not reconstructed due to a lack of satisfactory solutions, a large unmet clinical need [1]. Despite the physical and 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.

Investigators observed progressive scaffold shrinkage consistent with the expected bioabsorption process, with early postoperative imaging findings showing predictable regression over time. Color Doppler assessment documented dynamic vascularization within and around the scaffold during follow-up, consistent with progressive tissue integration.

Importantly, investigators reported that scaffold-specific structured reporting did not compromise diagnostic evaluation of the surrounding breast tissues, which remained fully assessable throughout follow-up.

"We are encouraged to see independent investigators present data reinforcing our clinical findings and specifically documenting both REGENERA™'s predictable performance over time and compatibility with imaging," said **Sanjay Kakkar, MD, Chief Executive Officer of Tensive**. "As we work toward first regulatory approvals in the EU in early 2027, our focus is to bring an off-the-shelf, one-step solution for natural breast reconstruction to patients."

This prospective, single-center study evaluated 15 female patients (age range 20–51) with benign breast pathology undergoing lumpectomy with immediate implantation of REGENERA™. Serial high-frequency ultrasound examinations began one week after surgery and were performed at predefined follow-up intervals.

These findings are consistent with Tensive's recently announced top-line results from its ongoing multicenter pivotal trial (NCT05941299), in which REGENERA™ was shown to be safe, biocompatible, and feasible for volume replacement in breast-conserving surgery in all eligible patients. To date, data show REGENERA™ is providing high satisfaction, favorable aesthetics, and no compromise to radiotherapy delivery or follow-up imaging during the post-surgical or adjuvant treatment in the registrational European trial.

REGENERA™ is an off-the-shelf advanced bioresorbable biomaterial implant designed to be inserted in place of the surgically removed tumor during a lumpectomy procedure. REGENERA™ resembles a sponge with a fine scaffold matrix that is 97% porous (i.e. 97% empty space); 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 does not include any growth factors, enables the patient's own healthy tissue to regrow in the area it fills, and 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 and feel. In addition, the implant is clearly differentiated from surrounding tissue on diagnostic imaging, supporting more targeted delivery of radiotherapy and accurate surveillance and follow-up.

[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 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.

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