

Cytori breast reconstruction cell therapy trial results published

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Cytori Therapeutics announced today the publication of RESTORE-2 trial results in the peer-reviewed *European Journal of Surgical Oncology*.

RESTORE-2 is a 71 patient multi-center, prospective clinical trial using autologous adipose-derived regenerative cell (ADRC)-enriched fat grafting for reconstruction of the breast after [cancer surgery](#). The majority of patients underwent radiation prior to the procedure, creating an unfavorable ischemic environment for which breast reconstruction with ADRC-enriched fat grafting appears to be ideally suited.

Key findings of the trial were:

- High rates of investigator (85%) and patient (75%) satisfaction with the overall treatment results at 12 months;
- High rates of investigator (87%) and patient (67%) satisfaction with overall breast deformity (based on functional and [cosmetic outcomes](#)) at 12 months;
- Improved breast contour at both six and 12 months, demonstrated by blinded MRI assessment; and
- No local cancer recurrences or [serious adverse events](#) related to the ADRC-enriched fat grafting procedure.

"Following [cancer treatment](#), the patient's [breast tissue](#) can suffer from radiation injury, scarring and tight skin," said Consultant Plastic and Reconstructive Surgeon Mrs. Eva Weiler-Mithoff, co-principal

investigator for RESTORE-2 at the NHS Glasgow Royal Infirmary Hospital. "This new technique is exciting because it may offer the opportunity to resolve some of the most difficult to treat conditions where other approaches, including fat alone, do not achieve satisfactory results."

ADRC-enriched partial mastectomy [breast reconstruction](#) is marketed in the EU as the RESTORE Procedure and represents an innovative treatment option with significant cost savings potential. The procedure can be performed on an outpatient basis. Satisfactory results can be achieved in a single procedure for the majority of patients. In contrast, competitive approaches are more costly with lengthy hospital stays, require repeat procedures and increase the overall burden on the healthcare system. Furthermore, because of these limitations, physicians are often reluctant to recommend reconstruction for patients with partial mastectomy defects and radiation-induced damage in the breast.

Each year, approximately 450,000 European women are diagnosed with breast cancer. Of the newly diagnosed breast cancer cases, 70-80% are eligible for breast conserving surgery, where only a portion of the breast is removed rather than the full [breast](#). In the European G5, there are an estimated 1.25 million women who have undergone partial mastectomy. The majority of these patients are left with a sizeable volume defect, scarring and often radiation damage.

"Given that there is no widely accepted reconstructive option available today for [partial mastectomy](#) patients, this procedure could well address this substantial unmet need and help complete the overall cancer treatment," said Marc H. Hedrick, president of Cytori.

More information: The *European Journal of Surgical Oncology* is the official journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology.

Provided by Cytori Therapeutics

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