First Patient Treated In U.S. No-Drain Clinical Study Of TissuGlu

PR Newswire
PITTSBURGH /PRNewswire/ -- Cohera Medical, Inc., a leading innovator and developer of absorbable surgical adhesives and sealants, today announced that the first patient of its U.S. no-drain clinical study has been successfully treated. The full study will include a total of 130 patients and will investigate the safety and effectiveness of TissuGlu@ Surgical Adhesive in the reduction of wound drainage, post operative seroma and related complications in abdominoplasty patients without the use of drains.

The randomized, controlled, multicenter non-inferiority study will take place at five prominent surgery centers in Washington, DC; Baltimore, MD; Charlotte, NC; Los Angeles, CA; and Dallas, TX. "Participating in this breakthrough study to eliminate postoperative drains is exciting, because TissuGlu is so easy to use and extremely valuable to the abdominoplasty procedure healing process," said Joseph P. Hunstad MD, FACS, of the The Hunstad-Kortesis Center, Charlotte,
N.C.

Currently, most patients who undergo abdominoplasty procedures and other large flap procedures require the insertion of drains to remove fluids that accumulate under the skin at the surgical site. In some cases, drainage is inadequate and the excess fluid accumulation (seroma) requires additional procedures for removal. The drains are often painful for the patient and can lead to infection and impact the recovery process.

TissuGluadheres the tissue flap created during the procedure to the underlying tissue, helping to reduce the fluid that can accumulate in the space during healing and ultimately reducing the need for postoperative drains to remove the fluid. The ability to perform the procedure without drains would lead to a more comfortable recovery and a quicker return to normal activity for patients.

"We're thrilled to kick off the first no-drain trial in the U.S., bringing us one step closer to facilitating a more natural healing process in large flap procedures," said Patrick Daly, President and Chief Executive Officer of Cohera Medical. "By eliminating post-surgical drains, our product has the ability to significantly impact how millions of patients recover from surgeries throughout the world."

Cohera Medical received CE Marking approval for TissuGlu and began selling product to hospitals and surgeons in Germany in September 2011. An earlier no-drain study of 30 patients was successfully completed in Germany in July 2012. In the U.S., Cohera recently completed enrollment of a clinical trial for TissuGlu. TissuGlu has been used successfully in over 600 various surgical procedures by leading surgeons.

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