Enrollment of U.S. Clinical Trial of TissuGlu Surgical Adhesive Completed

/PRNewswire/ -- Cohera Medical, Inc., a leading innovator and developer of absorbable surgical adhesives and sealants, today announced the completion of enrollment of its prospective, multicenter, randomized clinical trial for its lead product, TissuGlu@Surgical [1] Adhesive in the United States.

The study is evaluating the effectiveness of TissuGlu on the reduction of wound drainage and post-surgical complications in abdominoplasty surgeries. The study included 150 patients enrolled at five sites throughout the U.S., including Atlanta, Baltimore, Charlotte, St. Louis, and Washington DC.

"We are delighted to complete enrollment in this critical trial for TissuGlu, which has the potential to eliminate wound drainage issues from large flap procedures," said Dr. Joseph Hunstad of the Hunstad-Kortesis Center for Plastic Surgery, Charlotte, NC. "The trial results so far are very promising for both the surgeons and the patients."

Completion of enrollment of the study marks a significant milestone in Cohera Medical's progression of its lead product toward commercialization in the United States. The Company will use the results from the study to submit a PMA application for TissuGlu with the FDA. There are currently no medical devices approved by the FDA, or in pivotal clinical trials, for a synthetic adhesive indicated for approximation of tissues in large flap surgeries.

"We are extremely pleased to have reached this very significant milestone in our clinical study," said Patrick Daly, President and Chief Executive Officer of Cohera Medical. "It is a testament to the surgeons and the Cohera team to enroll 150 patients in 90 days. We are encouraged by the positive feedback from the TissuGlu investigators and look forward to our work with the FDA to make TissuGlu available to surgeons and patients throughout the U.S."

Cohera Medical received CE Marking approval for TissuGlu and began selling product to hospitals and surgeons in Germany in September 2011. To date, TissuGlu has been used successfully in over 500 surgical procedures in Germany by leading plastic and reconstructive surgeons.

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. TissuGlu adheres the tissue flap created during the procedure to the underlying tissue, helping to reduce the fluid that can accumulate in the space and ultimately

reducing the time to drain removal. The use of TissuGlu may shorten the length of time that drains need to be in place, leading to a more comfortable recovery and a quicker return to normal activity for patients.

Source URL (retrieved on *05/24/2013 - 2:05am*):
http://www.surgicalproductsmag.com/news/2012/08/enrollment-us-clinical-trial-tissuglu-surgical-adhesive-completed?qt-recent_videos=0&qt-digital_editions=0

Links:
[1] mailto:TissuGlu@Surgical