First Patient Treated in U.S. Clinical Study of Cohera Medical’s TissuGlu Surgical Adhesive

Cohera Medical, Inc.®, a leading innovator and developer of absorbable surgical adhesives and sealants, today announced the treatment of the first patient in a prospective, multicenter, randomized clinical trial for its lead product, TissuGlu® Surgical Adhesive in the United States. Initiation of the study marks a significant milestone in the Company’s progression of the lead product toward commercialization in the United States.
The study will investigate the effectiveness of TissuGlu on the reduction of wound drainage and post-surgical complications in abdominoplasty surgeries in 150 patients at six sites in the U.S. TissuGlu is a resorbable, high-strength surgical adhesive for large flap surgeries, such as abdominoplasty (tummy tuck), that helps eliminate or reduce fluid accumulation and the need for post surgical drains. Enrollment in the study is expected to proceed quickly and upon favorable conclusion will allow the company to complete a PMA application for TissuGlu with the FDA.

"We are excited to have treated the first patient in the TissuGlu study," said Joseph P. Hunstad MD, FACS, of the The Hunstad-Kortesis Center, Charlotte, N.C. “We look forward to enrolling more patients and believe that these procedures represent a key step forward in helping patients recover faster and more comfortably following large flap procedures.”

“Initiation of the US clinical trial is a major milestone for Cohera,” said Patrick Daly, President and Chief Executive Officer of Cohera Medical. “We are honored to be working with such a distinguished group of surgeons who share our vision for excellent clinical outcomes. We look forward to working with FDA to bring this breakthrough technology to patients and clinicians here in the United States.”

Cohera Medical recently received CE Marking approval for TissuGlu and began selling product to hospitals and surgeons in Germany in September 2011. The company plans to expand the commercial availability of TissuGlu to additional European markets in 2012. TissuGlu has been used successfully in over 350 surgical procedures in Germany by leading plastic and reconstructive surgeons.

Currently, most patients who undergo abdominoplasty procedures and other 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.

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