Surgical Adhesive Receives Approval For First Module Of Its PMA

/PRNewswire/ -- Cohera Medical, Inc.®, a leading innovator and developer of absorbable surgical adhesives and sealants, has announced that it has received approval from the United States Food and Drug Administration ("FDA") for the first of four modules of the Company's PMA filing plan for its TissuGlu® Surgical Adhesive product. Earlier this year, the Company received approval of its modular approach to filing the PMA from the FDA, and submitted the first module pursuant to this plan.

The first module contained the pre-clinical testing profile for TissuGlu including extensive biocompatibility and toxicological testing information. The Company expects to file the second module containing information related to the characterization and specifications of TissuGlu before the end of the year, and the remaining two modules describing the manufacturing, quality system and clinical study information in 2013.

"We are pleased to receive FDA approval for the first module of the PMA in which the biocompatibility and pre-clinical testing profile of TissuGlu is acceptable," said Chad Coberly, JD Vice President of Clinical, Regulatory and Legal affairs of Cohera Medical. "We appreciate the professional and interactive review by the FDA for this module and look forward to working with the Agency on the review of the future modules."

"The first module approval of the TissuGlu PMA is another significant milestone for Cohera and its investors," said Patrick Daly, President and Chief Executive Officer of Cohera Medical. "The approval for this information confirms the basic safety profile of this important new product and allows the Company to proceed with its modular PMA filings on plan."

Cohera Medical recently received CE Marking approval [1] for TissuGlu and began selling [2] product to hospitals and surgeons in Germany in September 2011. The Company plans to expand the commercial availability of TissuGlu in 2012.

Source URL (retrieved on *04/21/2015 - 1:11am*):
http://www.surgicalproductsmag.com/news/2012/10/surgical-adhesive-receives-approval-first-module-its-pma?qt-recent_content=0&qt-recent_videos=0&qt-recent_blogs_articles=0

Links:

[1] http://www.coheramedical.com/press_room/entry/cohera_medical_receives_ce_mark_approval_for_tissuglureg_surgical_adhesive
[2] http://www.coheramedical.com/press_room/entry/cohera_medical_commercializes_tissuglusupreg_sup_surgical_adhesive_in_germa