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Event – US approval for TissuGlu could make Cohera a takeover target

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A few years ago small medtech companies stood a chance of being taken out by one of the big players while still at the clinical stage. Now, though, the environment is far more risk-averse, and obtaining FDA approval for at least one product is almost a prerequisite for a buyout.

Cohera Medical is approaching this point. Its TissuGlu surgical adhesive is CE marked and has been on the European market for three years, but only now is US premarket approval approaching. The company has a date with the FDA's general and plastic surgery devices advisory panel on August 1, and the outcome of the meeting will give an idea of what the company's future might look like.

TissuGlu is a urethane-based adhesive designed to cure in the presence of moisture. It is intended principally for the aesthetic surgery market, particularly in abdominoplasty procedures in which excess skin and fat are removed from the middle and lower abdomen, but also has utility in other procedures that require the creation of large planar flaps of tissue. Mastectomy or inguinal lymph node dissection fall into this category, for example.

Cohera says it forms a bond between tissue layers that is five times stronger than any other product currently available for this indication. Despite the strength of this bond, TissuGlu is broken down and resorbed into the body over time.

Lucky seven

The US surgical adhesive market is currently split between six companies, according to data from *EvaluateMedTech*. But only three have been awarded PMAs (see table below): Johnson & Johnson was first to market with Dermabond, but the fact that Covidien and TissueSeal also obtained PMAs suggests that their products are too different to Dermabond to be able to use the earlier product as a predicate for 510(k) clearance, the quicker, easier path to market.

The other three firms with surgical adhesive products on the US market are B. Braun Melsungen, Advanced Medical Solutions and Adhezion Biomedical, with three separate 510(k) clearances each.

Adhesive wound closure devices approved in the US

Type of approval	Decision Date	Device Name	Company
PMA - First Approval	26/08/1998	Dermabond topical skin adhesive	Johnson & Johnson
PMA - First Approval	22/05/2002	Indermil tissue adhesive	Covidien
PMA - First Approval	16/02/2007	Histoacryl and histoacryl blue topical skin adhesive	TissueSeal

However, these adhesives are used in a slightly different way to Cohera's product. The marketed products are used to seal incisions in the skin as an alternative to stitches or staples. TissuGlu is intended for use under the surface, sealing tissue layers with the aim of reducing seroma – fluid accumulation during healing.

This in turn ought to abrogate the use of surgical drains – tubes that allow the removal of fluid from wounds – which are infection risks and are also uncomfortable for the patient.

The surgery devices panel will base its decision on data from two phase II/III trials, both in 130 patients.

The first study, named No Drain, proved that TissuGlu was superior to closed-suction drains for fluid

management in procedures such as abdominoplasty, Cohera says. TissuGlu-treated patients required less postoperative intervention and resumed activities such as going to work, showering and using the stairs more quickly than those with drains.

Naturally postoperative therapy for patients with seromas carries costs. Cohera says that medically indicated abdominoplasty, reimbursed at an average of €4,306 ($5,856) in Europe, has a reported rate of postoperative seroma formation of 41.7% and patients require an average of 2.7 subsequent interventions owing to fluid accumulation.

Thus there is a demand for a product that can sidestep these complications and their associated expense. This will no doubt weigh with the panel. Cohera has not released the full trial data, so it is hard to predict the outcome of the adcom. The company will be hopeful: a vote in favour would increase the chances of gaining that crucial PMA and open a range of possibilities for the company's future.

Trial	**Trial ID**
Phase II/III trial of TissuGlu in 130 patients with disorder of skin and/or subcutaneous tissue of trunk	NCT01791504
Phase II/III trial of TissuGlu in 130 patients undergoing abdominoplasty	NCT01526954

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