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Approval In Canada Next Year?

BioMimetic's PDGF-Based Bone Therapy Wins In Trial

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BioMimetic Therapeutics Inc.'s positive top-line results in a 60-patient, pivotal Canadian study testing its GEM OSI Bone Graft in foot and ankle fusions helped the stock to an 11 percent hike, and could bode well for the ongoing U.S. trial, expected to complete enrollment in mid-2008.

Lead investigator Timothy Daniels said the trial results show more than success in bone fusion, the main goal with GEM OSI, which combines platelet derived growth factor with the bone matrix beta tricalcium phosphate.

"One of the unexpected benefits that I noticed from this study was a very low, almost negligible incidence of delayed wound-healing difficulties, which is commonly seen in the patient population we're talking about – particularly the smokers and diabetics," Daniels told investors during a conference call. That outcome "often made me wonder if the platelet derived growth factor is actually having a positive effect on the entire soft-tissue envelope at the surgical site," he said.

Shares of BioMimetic (NASDAQ:BMTI) closed Thursday at \$15.49, up \$1.59.

Ninety percent of the patients – including a large percentage of those classified as high risk for poor healing (such as smokers, diabetics, and obese people) – gained benefit, defined as a return to full weight-bearing and the lack of need for revision surgery, with a radiographic fusion rate of 87 percent at nine months after their operations.

Franklin, Tenn.-based BioMimetic's president and CEO Samuel Lynch called the results "at least comparable to what would be expected, based on the literature, for patients treated with autogenous bone grafts," the current gold standard.

Although he could not extrapolate directly from the Canadian results when discussing the data to emerge from the U.S. trial, Lynch called the available numbers "encouraging" in that regard, and BioMimetic plans to meet with

Health Canada to discuss a biologics license application filing. The firm hopes for approval there by the end of next year.

Meanwhile, some analysts seemed particularly intrigued by the apparent tissue-healing aspect of GEM OSI, which is similar to BioMimetics' marketed product, GEM 21S for periodontal disease, approved in November 2005.

Daniels didn't "want to sound over-enthusiastic" but noted that "the whole issue with wounds and delayed wound healing is huge. For example, today I did two ankle replacements, and my major concern is to make sure the soft tissues heal because if they don't, then I'm looking at a high possibility of an infected ankle and a very difficult salvage problem."

Sometimes, he said, the outcome can be catastrophic. In North America, he said, an ulcer precedes 85 percent of amputations.

Lynch said enrollment in the U.S. trial with GEM OSI has increased significantly since the firm's most recently quarterly report, but "we don't want to start down the slippery slope of giving updates every few weeks."

BioMimetic had about \$25.9 million in cash and cash equivalents at the end of the third quarter.

Revenue from product sales of GEM 21S totaled \$1.3 million for the quarter, compared to \$0.4 million for the same period last year, due to terms of the agreement with BioMimetic's worldwide marketing and distribution partner, Osteohealth Co., a division of Tokyo-based Sankyo Co. Ltd.'s U.S. subsidiary, Luitpold Pharmaceuticals Inc.

The deal obligates Luitpold to purchase all of its requirements for GEM 21S from BioMimetic, with minimum purchases for each of the seven years after the product was launched, and the partner tends to make the most of its buys of the product in the third and fourth quarters of BioMimetic's fiscal year. ■

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