

BIO WORLD[®] TODAY

TUESDAY
NOVEMBER 22, 2005

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 16, No. 224
SPECIAL REPRINT

BioMimetic's PDGF Product Approved In Dental Indication

By Aaron Lorenzo
Washington Editor

WASHINGTON – The FDA approved a new dental therapy, comprising a tissue growth factor and a synthetic bone matrix, paving the first portion of a bone regenerative pathway, of sorts, for developer BioMimetic Therapeutics Inc.

“To go from company inception to a combination drug-device product in four and a half years,” said BioMimetic President and CEO Samuel Lynch, “is a testimony to the expertise of the team at BioMimetic.”

Called GEM 21S, the synthetic regeneration system was cleared through the FDA’s pre-market approval process to treat periodontal bone defects and associated gingival recession. Composed of recombinant human platelet-derived growth factor (rhPDGF-BB) and beta-tricalcium phosphate, GEM 21S represents the first totally synthetic product combining a purified recombinant growth factor with a synthetic bone matrix to receive FDA approval for human use.

Lynch said GEM 21S’s clearance provides proof-of-principle “that this technology will be effective in regenerating bone in other parts of the skeleton, as well.” The rhPDGF-BB provides the biological stimulus for tissue repair by stimulating the proliferation and in-growth of osteoblasts, while the beta-tricalcium phosphate provides the scaffold for new bone growth. “This approval really provides a foundation for us moving forward in the orthopedic space,” he added.

Studies have demonstrated that GEM 21S, the Franklin, Tenn.-based company’s lead product, stimulates bone and periodontal regeneration and leads to earlier resolution of periodontal lesions. Its approval was based on results from a single pivotal study, per the pre-market approval process. The double-blinded, randomized, multicenter trial involved 180 patients who required surgical intervention to treat periodontal bone defects, and they were studied for six months following the product’s implantation to assess both soft-tissue attachment levels and bone regeneration.

Results demonstrated that GEM 21S treatment led to “a very robust effect” in stimulating bone regeneration, Lynch said, and accelerated tissue attachment level gain, compared to the control arm of beta-tricalcium phosphate without growth factor. Also, there was no evidence of either local or systemic adverse effects resulting directly from placement of GEM 21S.

Previously, the product received unanimous backing from an FDA advisory panel. BioMimetic has rights to intellectual property on the growth factor per terms of a couple of licensing deals with ZymoGenetics Inc., of Seattle, and Harvard University in Cambridge, Mass. (See *BioWorld Today*, May 30, 2002, and Feb. 7, 2003.)

The product will reach physicians within the coming two weeks, with launch efforts being handled by Osteohealth Co. Per terms of a 4 and a half year-old agreement, the company is responsible for the worldwide marketing, sales and distribution of GEM 21S, as well as further studies to expand its label for additional indications such as repairing or reconstructing cranio-maxillofacial osseous defect indications. Osteohealth is a division of Luitpold Pharmaceuticals Inc., which is part of Tokyo-based Sankyo Co. Ltd.

“There is a potential large-market opportunity here,” Lynch said of this initial approval, noting that it mostly includes private payers. “That’s good and bad. It’s good because you don’t have to be as concerned about reimbursement, but on the other hand, by not having a lot of third-party coverage and instead people having to pay out of pocket, it probably limits somewhat the amount that you can charge.”

The product will cost about \$300 per unit, with one to two units used per procedure. There are more than 2 million periodontal surgeries performed in the U.S. annually, using allografts and xenografts at present, which Lynch labeled “one of the most frequently performed types of surgeries on the human body.” Physicians will not require any additional training to employ GEM 21S.

BioMimetic, which received a milestone payment of an undisclosed amount upon approval, also will receive license fees, royalties and marketing assistance. The company will be the sole source manufacturer of GEM 21S and also is due additional milestone payments. Approval in Europe is expected next summer, and BioMimetic is seeking approval in Canada. Osteohealth is handling regulatory affairs elsewhere in the world, such as Asia.

Armed with the FDA approval to confirm the bone regenerative properties of its rhPDGF-BB technology, the company plans to focus on developing other product candidates for treating orthopedic and sports injury conditions in bone, cartilage, ligaments and tendons. A fraction repair study is under way in Europe, and plans have been made to begin orthopedic trials in the U.S. and Canada in the first half of next year.

Privately held BioMimetic has all rights to the technology in those areas, and with manufacturing ramping up for its early commercialization, production for future studies and other markets shouldn't be an issue.

The company received funding a year ago – a \$25.7 million Series C round – and added another \$12.8 million in a follow-on tranche this spring. It has raised more than \$50 million since its March 2001 inception. (See *BioWorld Today*, Nov. 5, 2004.) ■