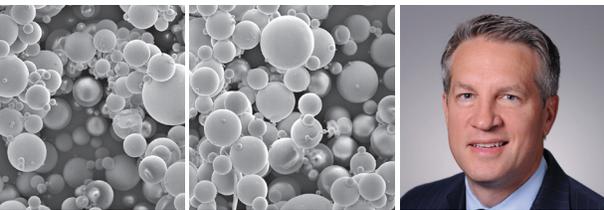


Romozosumab to Treat Alveolar Bone Loss for Dental Implant Reconstruction



WILLIAM GIANNOBILE,
DDS, DMEDSC
University of Michigan

“This novel technology offers systemic bone anabolic drug delivery to promote the regeneration of bone defects around teeth affected by periodontal disease or dental implants needing bone reconstruction.”

[media.dent.umich.edu/
labs/giannobile/](http://media.dent.umich.edu/labs/giannobile/)

CLINICAL NEED

Periodontitis is known to affect approximately 50% of the U.S. adult population, with approximately 10% of patients afflicted with severe form of the disease leading to tooth loss. Although various procedures have been explored for the regeneration of the periodontium and bone, predictable treatments to arrest and rebuild lost tissues around teeth and/or tooth-replacing dental implants are limited, and to date, there are no FDA-approved bone anabolic agents available to treat periodontal or peri-implant bone loss.

SOLUTION

A team of researchers led by Dr. William Giannobile at the University of Michigan, is developing a systemic delivery of sclerostin monoclonal antibody to restore lost periodontium or implant-supporting alveolar bone. The approach offers the potential for easy dosing of sclerostin antibody to regenerate lost periodontium or improve peri-implant bone density.

COMPETITIVE ADVANTAGE

By taking advantage of easy delivery of sclerostin monoclonal antibody, which is already clinically approved for improvement of bone density in other indications such as osteoporosis, this approach may represent an improved access to drug therapies for periodontal and dental implant-related diseases that might otherwise not be as available due to limited reimbursement through typical dental insurance.

ITP SUPPORT

The work supported by the ITP program is focused on the IND submission for the design of a phase I/II human clinical trial to use systemic sclerostin antibody delivery to treat periodontal disease.

CLINICAL TRANSLATION PATHWAY

Publications:

Sclerostin neutralizing antibody enhance bone regeneration around oral implants. *Tissue Eng Part A*. 2018.

Sclerostin antibody stimulates bone regeneration after experimental periodontitis. *J Bone Miner Res* 2013.

Intellectual Property:

US 9,657,090 Method of treating alveolar bone loss through the use of anti-sclerostin antibodies

Regulatory Pathway:

Anticipated: Biologic, IND to enable BLA or NDA

Commercialization Strategy:

In development with the MPWRM Commercialization/Market Needs Core

Product Launch Strategy:

In development with the MPWRM Commercialization/Market Needs Core

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