ABALOPARATIDE TO TREAT ALVEOLAR BONE LOSS FOR DENTAL IMPLANT RECONSTRUCTION



William Giannobile, DDS, DMedSc Harvard University

Clinical Need – Two million patients receive dental implants in the U.S. annually and up to 50% are post-menopausal women with osteoporosis. Dental implants are an effective treatment, but osteoporosis patients may be denied implant therapy due to compromised bone quantity and quality. Predictable treatments to regenerate lost tissues around teeth or implants are limited, and to date, there are no FDA-approved bone anabolic agents available for this indication.

Solution – A team of researchers led by Dean William Giannobile at the Harvard School of Dental Medicine is investigating the therapeutic potential of a systemic osteoanabolic drug, abaloparatide, to restore lost periodontium or enhance formation of implant-supporting alveolar bone. This approach offers easy dosing to regenerate lost periodontium or improve peri-implant bone density.

Competitive Advantage – By taking advantage of easy delivery of abaloparatide, 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 – With the support of the ITP program, a preclinical experiment has been performed to assess the potential of abaloparatide in dental applications. Our team is now focused on the progression to a phase I/II human clinical trial to use on-label systemic abaloparatide to adjunctively treat alveolar bone loss and enable implant treatment for patients with compromised bone quality.



FOUNDATIONAL PUBLICATION

Miller et al. Bone mineral density response rates are greater in patients treated with abaloparatide compared with those treated with placebo or teriparatide: Results from the ACTIVE phase 3 trial. Bone 2019



INTELLECTUAL PROPERTY

US10,568,937 Formulations of abaloparatide, transdermal patches thereof, and uses thereof



ANTICIPATED REGULATORY PATHWAY

FDA-approved since 2017



ANTICIPATED COMMERCIALIZATION STRATEGY

In development with the MPWRM Commercialization/ Market Assessment Cores and Radius Health.

Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center is supported in part by the National Institute of Dental & Craniofacial Research of the National Institutes of Health under Award Number U24DE029462. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

