# Abaloparatide to Treat Alveolar Bone Loss for Dental Implant Reconstruction

### **Clinical Need**

Two million patients receive dental implants in the U.S. annually and up to 50% are post-menopausal women with osteoporosis. 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 no FDA-approved bone anabolic agents are available for this indication.

#### Solution

A team of researchers led by Will 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 and/or improve peri-implant bone density.

# **Competitive Advantage**

By taking advantage of easy delivery of abaloparatide, which is already clinicallyapproved 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.

# **Foundational Publications & Patents**

- 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. <u>Bone 2019</u>
- <u>US10,568,937</u> Formulations of abaloparatide, transdermal patches thereof, and uses thereof



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#### **ITP Support**

Upon entry into the ITP program in 2021, extensive preclinical characterization of the study drug had been performed for the osteoporosis indication. In 2022, initial demonstration of efficacy of the study drug for dental applications was achieved. Key safety studies have already been conducted and data generated from the ITP program may support auxiliary benefits of abaloparatide for alveolar bone in osteoporotic patients.

# Key Inflection Points/ Regulatory Pathway

- Abaloparatide has been FDA-approved since 2017
- Completion of preclinical data generation projected in Q2 2023
- First-in-human study anticipated to start at end of Q4 2023

#### **Opportunities for Partnerships**

• Development with the MPWRM Commercialization/ Market Assessment Cores will explore commercialization and clinical adoption of technology

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.

