

OPTIMIZATION OF A NOVEL ORGANIC-MINERAL BONE ADHESIVE FOR DENTAL BONE GRAFTING



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Clinical Need – Based on market research conducted by RevBio, almost half the patients that seek a dental implant supported crown suffer from chronic edentulism and require extensive bone grafting to rebuild their alveolar ridge. Over 30% of the time, these grafting procedures achieve suboptimal results and require some form of re-grafting adding to the overall cost, treatment time, and morbidity for these patients.

Solution – RevBio developed Tetranite® (TN) Adhesive Dental Bone Scaffold (TN-ADBS), a synthetic, porous, cohesive organic-mineral bone scaffold with adhesive properties that resorbs and is replaced by bone on a timescale commensurate with existing graft materials but does not require ancillary fixation or containment devices. The TN-ADBS comprises a kit consisting of the formulation powders sealed in a mixing bowl, a vial filled with highly porous granules, an aqueous medium pre-filled syringe, and spatula for mixing and application to the site.

Competitive Advantage – Currently available particulate bone grafting products require significant surgical skill to apply. In contrast, TN-ADBS is both cohesive and adhesive which enables the placement of the product without the need for ancillary containment or fixation aids. The product will reduce the overall time necessary to perform ridge augmentation procedures, better maintain graft volume over time, and minimize the need for re-grafting, which adds time, cost, and risk to successful patient care.

ITP Support – ITP support has enabled RevBio to accomplish key product development and marketing milestones, including market surveys to validate the clinical need and the lack of any known competitive products with a comparable clinical value proposition, refinement of the preclinical animal model and product formulation, GLP preclinical studies and supplier audits, provision of advice from user handling trials, and regulatory guidance in developing and refining a cohesive strategy for the commercial approval of the product.

FOUNDATIONAL PUBLICATION

Kirillova et al. Bioinspired Mineral-Organic Bioresorbable Bone Adhesive. Adv Healthc Mater 2018

INTELLECTUAL PROPERTY

US8,232,327 Tetra Calcium Phosphate Based Organophosphorus Compositions and Methods

ANTICIPATED REGULATORY PATHWAY

Device-led combination product

ANTICIPATED COMMERCIALIZATION STRATEGY

In development

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