DRUG-INDUCED PERIODONTAL REGENERATION

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CLINICAL NEED

An estimated 42% of all US adults 30 years or older have some form of periodontitis (PD), a disease that affects all structures of the periodontium, including periodontal ligament, cementum and bone. In cases where strict oral hygiene is unsuccessful at ameliorating PD, standard-of-care therapies for progressive PD consist of aggressive cleaning, antibiotic therapy and ultimately surgery. Often, tissue losses are largely irreversible even if the active process is halted. We believe there is an unmet clinical need for regeneration of soft and hard tissues in cases of moderate to severe PD. Even after tooth loss and placement of implants to restore dentition, the implants themselves can be subject to periimplantitis (PI) due to ongoing bacterial infections, causing great distress for patients and compromising restorative treatment. Hence, drug treatment that restores alveolar bone has utility in this case too.

SOLUTION

Our product is a polymer delivery system of a pro-regenerative drug that can activate regeneration of soft and hard tissues of the periodontium. Inspired by the mechanism underlying tissue regeneration in primitive organisms and “super-healing” mice, our technology aims to transiently upregulate a key transcriptional factor that enhances both hard and soft tissue regeneration.

COMPETITIVE ADVANTAGE

Our technology is novel in the marketplace, as it does not rely on scaffolds, progenitor cells or growth factors. Ultimately, we aim to develop a product that will allow patients with severe periodontitis to save their natural teeth, in a more cost-effective manner compared to implants.

TARGET MARKET

Given the prevalence of moderate-severe PD and recent consumer data estimating the average cost of moderate-severe periodontal care at about $400 per treatment, the total addressable market (TAM) is roughly $10 billion USD. We estimate the serviceable available market (SAM) to be those patients that seek periodontal care, which is currently only about 27% of patients. This marks out SAM to be roughly $2.7 billion USD. We also envision our technology as being a candidate non-surgical adjunctive treatment for PI, to be used in combination with standard therapy in moderate to severe cases of PI to improve clinical outcomes by enhancing soft and hard tissue regeneration.

REGULATORY PATHWAY

We are currently working with the C-DOCTOR regulatory core to plan a regulatory strategy for the technology.

INTELLECTUAL PROPERTY

The technology is protected by a US patent family entitled “Epimorphic Regeneration and Related Hydrogel Delivery Systems”: US 9,675,607; US 10,307,415; US 11,033,541. Additional patent applications have been filed.

RELATED PUBLICATIONS

(1) Zhang Y, Strehin I, Bedelbaeva K, et al. Drug-induced regeneration in adult mice. Sci Transl Med. 2015;7(290):290ra92. **(2)** Zebrowitz E, Aslanukov A, Kajikawa T, et al. Prolyl-hydroxylase inhibitor-induced regeneration of alveolar bone and soft tissue in a mouse model of periodontitis through metabolic reprogramming. Front Dent Med. 2022;3.

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