STEM-CELL BASED THERAPIES FOR BONE REGENERATION AROUND AILING DENTAL IMPLANTS

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CLINICAL NEED

Peri-implantitis is a devastating dental implant complication, where bone loss leads to functional and esthetic complications, often ending in implant loss with significant medical burden and health care costs. Unfortunately, no therapy exists to regenerate bone around implants, leaving a major unmet need, where treatment will have a large market and immediate clinical adoption.

SOLUTION

We have developed, optimized, and finalized a cell-based therapy where bone marrow aspirate with osteoconductive properties are delivered to inflamed peri-implant bone defects by a light curable, adhesive hydrogel that is easily applied in the moist oral environment. Our product will significantly improve current therapies, where implants with peri-implantitis are generally removed and cost thousands of dollars with high morbidity and esthetic concerns.

COMPETITIVE ADVANTAGE

We provide a regenerative approach for currently unpredictable treatment that focuses on only decreasing inflammation and arresting bone loss. Our team is led by clinician-scientists with expertise in implant dentistry, biomaterials, and stem cell biology who have developed an innovative approach to bone regeneration in an inflamed wound with the ability to adhere to surrounding tissues in the moist oral environment.

TARGET MARKET

In 2022, the global dental implant market was $4.6 billion, and will grow by 9.8% by 2030. According to the American Dental Association, 5 million implants are placed per year, and a conservative estimate of 10% peri-implantitis means 500,000 new cases annually. This is in addition to existing cases that develop bone loss over time, targeting specific patients at risk for disease progression and increased severity (smokers, history of periodontal disease, diabetics). Although this proposal focuses on implant inflammatory defects, the technology is well-positioned to address other dental and craniofacial defects such as cleft lip/palate, benign and malignant surgical defects, alveolar defects after tooth extraction, and periodontal disease. Beyond dentistry, infected or inflamed bone defects in orthopedics and spine surgery are areas where further investigation is warranted.

REGULATORY PATHWAY

IDE through CDRH for the hydrogel. The autologous stem cells used in this product are “minimally manipulated” and are, therefore, not regulated by the FDA.

INTELLECTUAL PROPERTY

As a result of the product’s innovation, in vitro and in vivo data, and recent publications, the United States permanent patent application (Serial No. 16/979,215) was filed and published on 9/9/20 by Pearl, Cohen, Zedek, Latzer, Baratz LLP in New York City, NY.

RELATED PUBLICATIONS

(1) Ansari S, Sarrion P, Hasani-Sadrabadi MM, Aghaloo T, Wu BM, Moshaverinia A. Regulation of the fate of dental-derived mesenchymal stem cells using engineered alginate-GelMA hydrogels. J Biomed Mater Res A. 2017;105(11):2957-2967. **(2)** Ansari S, Seagroves JT, Chen C, et al. Dental and orofacial mesenchymal stem cells in craniofacial regeneration: The prosthodontist’s point of view. J Prosthet Dent. 2017;118(4):455-461. **(3)** Hasani-Sadrabadi MM, Sarrion P, Pouraghaei S, et al. An engineered cell-laden adhesive hydrogel promotes craniofacial bone tissue regeneration in rats. Sci Transl Med. 2020;12(534):eaay6853.

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