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Regenerative Medicine Resource Center

Hylafix: A Technology that Accelerates Bone Healing

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Clinical Need

An exigent problem confronting head and neck cancer reconstruction is overcoming the impediments of damage imposed by radiation therapy (XRT) on surrounding tissue, resulting in the need for autologous free tissue transplantation. While these operations provide solutions for delivering sizable vascularized tissues to the irradiated area of reconstruction, they are complex and introduce significant donor site morbidity. In the case of dental concerns for patients with osteoradionecrosis and other post-radiation bony sequelae, there are currently no good clinical solutions, demonstrating a significant limitation in the current standard of care.

Solution

A team of University of Michigan researchers led by Steven Buchman, MD, has developed an implantable, sustained-release formulation of a known angiogenic small molecule, deferoxamine (DFO), conjugated to hyaluronic acid (HA) backbone for reconstruction of craniofacial bone. Through this approach, the team has shown accelerated bone regeneration in preclinical murine models of mandibular fracture repair. Moreover, in a patient with previously irradiated maxilla, enhanced bone formation following deferoxamine application was observed.

Competitive Advantage

Using a molecule previously approved for medical use in a new formulation, this HA-DFO product presents a non-cellular approach to bone defect repair. This approach may enable once-precluded reconstructive strategies, such as distraction osteogenesis and non-vascularized bone grafting to be viable reconstructive options for patients with XRT-induced bone degradation.

"We are on the cusp of translating the exciting results that we have seen at the bench to the bedside, with the ultimate potential to impact millions of patients who undergo fracture repair each year."

How the ITP Program Supports this Project

The work supported by the ITP program is focused on the completion of non-GLP pre-IND studies including pharmacokinetics and toxicology studies, as well as efficacy studies in irradiated bone fracture model.

Clinical Translation Pathway

Publications:

Momeni, A., Rapp, S., Donneys, A., Buchman, S. R., & Wan, D. C. (2016). Clinical Use of Deferoxamine in Distraction Osteogenesis of Irradiated Bone. The Journal of craniofacial surgery, 27(4), 880. *(https://www.ncbi.nlm.nih.gov/pubmed/27171947)*

Donneys, A., Weiss, D. M., Deshpande, S. S., Ahsan, S., Tchanque-Fossuo, C. N., Sarhaddi, D., Levi, B., Goldstein, S.A. & Buchman, S. R. (2013). Localized deferoxamine injection augments vascularity and improves bony union in pathologic fracture healing after radiotherapy. Bone, 52(1), 318-325. *(https://www.ncbi.nlm.nih.gov/pubmed/23085084)*

Intellectual Property:

PCT/US2016/067320 Devices, Compositions, and Related Methods for Accelerating and Enhancing Bone Repair. *(https://patents.google.com/patent/WO2017106744A1/)*

For more information about this technology, please visit: http://bit.ly/MPWRM_bonehealing

Commercialization Strategy:

In development with the MPWRM Commercialization/ Market Needs Core

Regulatory Pathway:

In development with the MPWRM Regulatory Core

Product Launch Strategy:

In development with the MPWRM Commercialization/ Market Needs Core

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