TRANSDERMAL DEFEROXAMINE FOR TREATMENT OF IRRADIATED SOFT TISSUE

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CLINICAL NEED

Approximately one-third to one-half of all patients with cancer receive radiation therapy, and greater than 90% of patients experience radiation-induced collateral soft tissue injury including severe, debilitating chronic fibrosis. Current therapeutic approaches for patients with radiation-induced soft tissue fibrosis are limited. A mechanism to improve local perfusion and skin quality would help to address the pathophysiologic limitation preventing rehabilitation in these patients.

SOLUTION

We have developed a transdermal patch delivery system for an FDA-approved medication, deferoxamine, to treat chronic, fibrotic radiation-injured soft tissue. Preclinical studies demonstrated that serial direct injection of this medication into irradiated tissue results in improved blood flow and tissue quality. However, translation for this route of administration is limited by logistical challenges of repeat injections as well as potential for poor patient tolerance. A transdermal patch delivery system is far more attractive to both clinicians and patients. Given the frequency and severity of debilitating radiotherapy side effects and limited available treatment options, our novel approach meets a large clinical need with potential for rapid clinical adoption.

COMPETITIVE ADVANTAGE

There are no approved topical formulations or transdermal delivery patches for deferoxamine in the EU or US. This transdermal deferoxamine patch would be a new product that could bring significant improvement in the care of post-radiation patients without encountering any therapeutic competition for quite some time.

TARGET MARKET

The largest targeted market would likely be represented by breast cancer reconstruction, with current market size estimated to be $526.5M worldwide in 2017. Breast reconstruction typically involves silicone or saline implants, and radiation is associated with increased implant exposure/failure risk and scar formation. A second potential target market would be head and neck cancer reconstruction. There are over 60,000 new cases diagnosed each year in the US, and 27,898 reconstructive procedures were performed in 2017 alone.

REGULATORY PATHWAY

Combination product (Drug-Device) with the PMOA being the drug so the regulatory pathway will be an IND with CDER as the lead agency. Deferoxamine is already FDA approved and in clinical use for other indications. The team filed their IND application on November 30, 2023 and received their "Study May Proceed" letter from the FDA on January 3, 2024.

INTELLECTUAL PROPERTY

Deferoxamine is off-patent. Application for improvement of radiation-induced fibrotic tissue represents a new indication. We have filed a patent for transdermal delivery of deferoxamine for wound healing and a patent application on the use of transdermal deferoxamine patch delivery to improve irradiated tissue to facilitate subsequent reconstructive procedures. US12/577,006, US20100092546A1, PCT/US2018/050626, WO2019055490A1

RELATED PUBLICATIONS

(1) Duscher D, Neofytou E, Wong VW, et al. Transdermal deferoxamine prevents pressure-induced diabetic ulcers. Proc Natl Acad Sci U S A. 2015;112(1):94-99. **(2)** Flacco J, Chung N, Blackshear CP, et al. Deferoxamine Preconditioning of Irradiated Tissue Improves Perfusion and Fat Graft Retention. Plast Reconstr Surg. 2018;141(3):655-665.

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