HYDRONOVO: REGENERATING THE SALIVARY GLAND USING AN INJECTABLE HYDROGEL

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CLINICAL NEED

Xerostomia, or dry mouth, affects over 8 million people in the US and occurs as a result of salivary dysfunction due to autoimmune disease, medication usage, smoking, aging, and radiation therapy for head and neck cancer. Absence of saliva severely compromises the oral health and quality of life of patients: saliva protects the oral mucosa, facilitates food digestion and articulation, and aids in the remineralization of dental hard tissues. There are no viable long-term treatments for salivary dysfunction, driving a need for new, translatable solutions.

SOLUTION

Hydronovo is a promising therapy for improving salivary function and saliva flow that is based on stem cell-mediated regeneration via local delivery of a neurogenic agonist encapsulated in a biodegradable hydrogel. Through the technology development phase, they have defined the chemistry of the hydrogel to enable injection and linear distribution throughout the gland, along with controlled release of the muscarinic receptor agonist cevimeline. Our preclinical data demonstrates increased proliferation of stem cells in normal and irradiated salivary glands through application of this technology.

COMPETITIVE ADVANTAGE

As yet, no regenerative strategies are available for restoring salivary gland function. Their technology will enable patients to regain some or all, of their salivary gland function. Current treatment options fall into two categories: preventative and palliative. Preventative methods are designed to protect the salivary gland during radiation therapy; however, their low efficacy and high cost ($10,000 - $40,000/treatment), along with stringent eligibility requirements, has reduced their application. Palliative options include water, sugar-free gum, oral gels, or saliva-stimulating drugs. In addition to their effects being short-lived and only addressing the symptoms but not the cause of xerostomia, some of these therapies cause unpleasant side effects, leading many patients to discontinue use. Thus, our product will be the first commercially available long-term solution for xerostomia.

TARGET MARKET

For the initial market introduction, we will focus on head and neck cancer (HNC) radiotherapy (RT) patients (100% suffer dry mouth) with a serviceable available market being currently 500,000. Our secondary target population is the 4 million people living with Sjogren's Syndrome, an autoimmune exocrinopathy that destroys salivary tissue. Our product also has potential in the veterinary medicine market for the treatment of dry eye and dry mouth in dog patients (RT for head and neck cancer and autoimmune disease; >10,000 dogs per year).

REGULATORY PATHWAY

Combination product (drug-device) with PMOA being the drug. IND pathway with CBER as lead agency. PMOA is well defined so no Request for Designation should be required.

INTELLECTUAL PROPERTY

Provisional patent application 62/777,459 filed on December 10, 2018.

RELATED PUBLICATIONS

(1) Knox SM, Lombaert IM, Haddox CL, et al. Parasympathetic stimulation improves epithelial organ regeneration. Nat Commun. 2013;4:1494. **(2)** Emmerson E, May AJ, Nathan S, et al. SOX2 regulates acinar cell development in the salivary gland. Elife. 2017;6:e26620. **(3)** Emmerson E, May AJ, Berthoin L, et al. Salivary glands regenerate after radiation injury through SOX2-mediated secretory cell replacement. EMBO Mol Med. 2018;10(3):e8051.