**RegendoGEL: A Bioinspired Hydrogel System for Endodontic Therapy**

**CLINICAL NEED**
Dental caries is the most prevalent chronic infectious disease in humans. If not treated, virtually all caries lesions will progress to affect the dental pulp, eventually requiring some form of root canal therapy. The current standard of care using polymeric/ceramic-like materials can elicit tertiary dentin formation in vital young teeth, but fail to mimic the composition, physical properties, and regenerative/biological capacity of the native pulp.

**SOLUTION**
A team led by Luiz Bertassoni, DDS, PhD and Pamela Yelick, PhD has developed a novel material for regenerative pulp treatment, intended to be the first-of-its-kind clinical product to promote vital pulp regeneration. RegendoGEL contains key stimulatory molecules found in healthy teeth that naturally promote pulp repair and regeneration, and may be used for direct pulp capping and pulpotomy.

**COMPETITIVE ADVANTAGE**
As compared to the existing synthetic rigid silicate or calcium hydroxide-based products currently used for endodontic treatments, RegendoGEL is a soft hydrogel system that more closely resembles the natural pulp tissue. Unlike traditional non-degradable cements, RegendoGEL stimulates cells to migrate into the defect site and regenerate living dental pulp tissue and dentin, thus revitalizing the tooth and regenerating tooth tissues in the target location. In addition, RegendoGEL is designed as a ready-to-use system that can be integrated into routine dental procedures in the clinic.

**ITP SUPPORT**
With a focus on direct pulp capping and pulpotomy, the support from the ITP program will be used to complete *in vivo* validation and optimization of the RegendoGEL system to enable FDA submission.

---

**CLINICAL TRANSLATION PATHWAY**

**Publications:**

**Intellectual Property:**
- US 16/618,329 Dental pulp construct
- US 15/777,304 Pulp regeneration compositions and methods of forming and using the same

**Regulatory Pathway:**
- Anticipated: Device, IDE to enable 510(k)

**Commercialization Strategy:**
- In development with the MPWRM Commercialization/Market Needs Core

**Product Launch Strategy:**
- In development with the MPWRM Commercialization/Market Needs Core

---

Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center is supported in part by the National Institute of Dental & Craniofacial Research of the National Institutes of Health under Award Number U24DE028915. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Contact Information:
Mutsumi Yoshida, PhD | Managing Director, U-M site | yoshidam@umich.edu | www.doctr.com