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
RegendoGEL – a bioinspired hydrogel for endodontic therapy

Luiz Eduardo Bertassoni¹, Pamela Yelick²
¹ Oregon Health & Science University, ² Tufts University

UNMET CLINICAL NEED
Dental caries is the most prevalent chronic infectious disease in humans. It has an estimated prevalence of over 90% of adults and 20% of children in western countries. If not treated, virtually all caries lesions will progress to affect the dental pulp, eventually requiring some form of endodontic treatment. The current gold standard of care for teeth with extensive caries or non-cavitated injury is direct pulp capping, or pulpotomy, which proposes a partial amputation of dental pulp and replacement with either a Silicate cement (i.e. MTA) or the fixation of remaining pulp tissue using formocresol (Fig 1). Silicate cements are non-resorbable, and result in complete loss of pulp tissue responses. Formocresol contains 20% formaldehyde, and is officially classified as a potent carcinogenic as defined by the Center for Disease Control.

For most endodontists, it was agreed that RegendoGEL would be a “high value” indication. Most respondents agreed that there is an unmet clinical need for root canal therapy because of pulp tissue responses. Formocresol contains 20% formaldehyde, and is officially classified as a potent carcinogenic as defined by the Center for Disease Control. There is an important need to develop improved materials for pulpotomy treatment that allow for regeneration (rather than amputation) of dental pulp and the lost dentin tissue.

MARKET ANALYSIS
Interviews with clinical experts in Endodontics

– OHSU/Tufts Tech Transfer office have been supporting our work since the submission of 3 IP patents/disclosures (pending or issued).

– Additionally, our group have the support from the Oregon Clinical and Translational Research Institute (OCTRI), via its biomedical innovation program (BIP) in developing and implementing commercialization strategies for RegendoGEL.

– We have partnered up with Research Bridge Partners, a business development firm, that is advising on all issues related to IP and commercial development in the PI’s laboratory and particularly on RegendoGEL commercial development.

– Consulted with Mayo Clinic GMP facility to begin manufacturing in 2021 if approved by advisory team and consortium leadership.

INTELLECTUAL PROPERTY
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REGULATORY PATHWAY
• MDRS LLC. determined RegendoGEL to be regulated by the FDA as a class 1 medical device

• It will require a pending premarket notification (PMN) or 510k submission for clearance by the FDA

• MDRS anticipates a substantial equivalence to known predicate devices via a stacked predicate approach

• RegendoGEL is currently completing milestones to freeze formulation:
  A. Determination of size variation of microgels (completed)
  B. Ensuring ability to scale up manufacturing per GMP requirements (completed)
  C. Determination of reproducibility of active compound isolation from tooth matrix (experiments ongoing)

• Next GMP plans will be discussed and reviewed with Regulatory & QA/QC Core to ensure that the CRO is pre-qualified to do the proposed work.

TIMELINE & FUTURE DIRECTIONS

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