

HB-EGF to prevent radiation-induced oral mucositis



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Clinical Need

The clinical indication we are targeting is the prevention and treatment of radiation-induced oral mucositis (severe mouth ulcers). Oral mucositis is often a dose-limiting toxicity preventing optimal radiation therapy for patients. It causes pain and also septicemia in neutropenic patients. The incidence is approximately 80% in head and neck radiation and 40% in standard radiation. Annually, there are approximately 400,000 cases of treatment-induced damage to the oral cavity.

Solution

We deliver a topical growth factor as a mouth wash that enhances epithelial migration, proliferation and keratin thickness during the 2–3 week period following radiation therapy. This will increase patient compliance with radiation protocols and increase cancer survival.

Competitive Advantage

There remain limited treatment options for this indication. These include oral care, analgesia and anti-inflammatories (e.g. Benzydamine), and cryotherapy (e.g. swallowing ice chips immediately before treatment). Keratinocyte Growth Factor (KGF) (Palifermin / Kepivance. Amgen) ceased manufacturing in 2017. Kepivance (Amgen) was delivered systemically and was poorly adopted clinically as the cost was thought to outweigh the benefits achieved. There were also difficulties surrounding the systemic administration. There is an unmet need for a topical therapy that has high efficacy. HB-EGF as a treatment option can be provided topically, has a potentially high efficacy for oral squamous proliferation and low potential for toxicity and systemic side effects.

Target Market

Head and neck cancer patients are at greatest risk for developing oral mucositis. There were an estimated 65,000 newly diagnosed cases in the U.S. alone in 2017, and an estimated 700,000 worldwide. By 2030, the global incidence is expected to exceed 1M per year. For head and neck cancer patients only, the market has been estimated to range from between \$500 million and \$1.5 billion on an annual basis. The market extends to all forms of chemoradiation where the incidence of oral mucositis ranges between 20% and 40%. There was thought to be a mean per patient saving of \$3,595 when using Kepivance (Amgen) for chemoradiation-induced mucositis in hematological malignancy.

Regulatory Pathway

Biologic – IND with CBER as lead agency

Intellectual Property

A patent (US20170232065A1) covering the method is currently at the PCT stage. (2015) A second patent is at the non-provisional stage. Another patent covering the delivery is at the provisional stage. An independent analysis of patentability and freedom to operate identified no concerns.