

# **Oral Mucositis - An Analysis of Drugs in Development, Market Opportunity, unmet need, Disease prevalence and occurrence in cancer in Various Geographies**

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## **Abstracts**

Oral Mucositis (OM) is a complication of aggressive chemotherapy and radiotherapy treatments in Head and neck cancer, Hematopoietic stem cell transplantation (HSCT) and multiple chemotherapies. Severe form of OM causes odynophagia and/or dysphagia leading to difficulty in eating/swallowing and can increase the cost of total cancer therapy. While the mechanism of OM is well established, there are very few targeted drugs or therapeutic options available to the patient. Untreated it can be life threatening (sepsis) and Palliative care offer temporary relief. Novel therapies could lead to a cut in this major cost burden along with improving the quality of life. There is a grave need for systematic management of oral mucositis triggered by anti-neoplastic protocols. Several products are marketed as palliative care for management of the OM that include anti-oxidant, anti-inflammatory agents, cryotherapy, oral rinse and ointments. However, there is high unmet medical need for systemic interventions. Currently, ~800,000 worldwide patients per year suffer from mucositis during cancer therapy and the incidence is increasing. ~80-100% of Head and Neck cancer patients develop Ulcerative OM. The incidence of oral cancer in Asia, especially in India and China, is very high due to the lifestyle and tobacco consumption. Only drug Amgen/SOBI's Kepivance (palifermin) is approved for oral mucositis in transplantation; but is contra-indicated for solid tumor patients. The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Considering all these factors we expect the market to grow manifold from the existing ~\$200mln (palliative and mouth wash) to \$5,000mln in the next ~ten years. Mid-size and small companies are targeting this opportunity through in-house pipeline offers a good opportunity for In-licensing or M&A.

In the report, we have highlighted novel mechanism / targets which have obtained Fast

Track designation from FDA and have advanced in the clinical trials. The report also indicates Drivers of M&A/Licensing Deals and Key Markets' potential.

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