

What is mucositis?

Oral mucositis is often a complication of cancer chemotherapy or of radiation therapy to the head and neck region. Currently available therapy is usually inadequate, and more effective treatment to minimize the extent and duration of mucositis is clearly needed. Historically, treatment of mucositis has been palliative and aimed at minimizing mucosal trauma. Mucositis and infection of the mouth have remained major complications despite the usual oral care provided for patients with cancer such as frequent mouth cleansing and rinsing with buffered saline and fluoride solutions and administration of topical and systemic antimicrobial agents.

What is MuGard™?

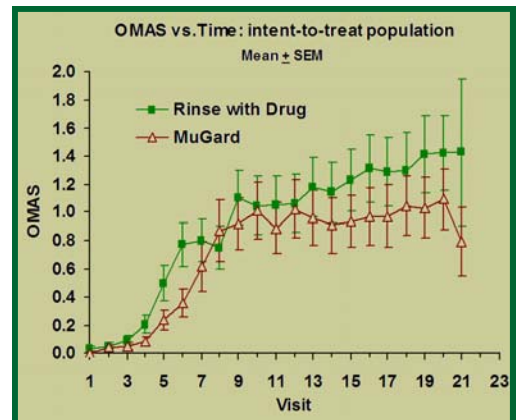
MuGard™ is a mucoadhesive rinse which provides a protective hydrogel coating to the oral mucosa. In a comparison of patients undergoing standard care with patients using MuGard™, the incidence and severity of mucositis was significantly lower for the MuGard™ group. The FDA has provided Access with clearance to proceed with the marketing of MuGard™ in the U.S. Access has recently announced that its European commercial partner, SpePharm Holdings BV, has launched MuGard in several countries in the EU.

For additional information contact:

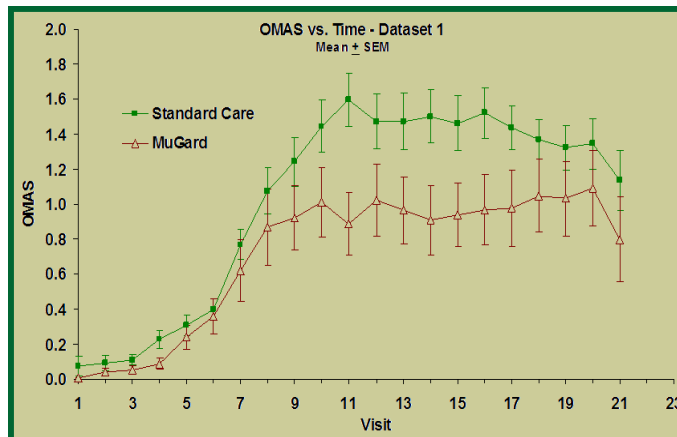
Phillip Wise
Vice President, Business
Development and Strategy
phillip.wise@accesspharma.com
<http://www.accesspharma.com>

History of MuGard™

MuGard™ was originally developed as a vehicle for an anti-allergic, anti-inflammatory compound that has been approved for marketing by the FDA for the acceleration of healing of aphthous ulcers. In a clinical study of the rinse with drug versus the rinse without the drug, in patients at high risk of developing mucositis, many investigators commented that the patients were receiving a beneficial effect from the study medication compared with patients that had been treated previously on standard care. However, when the study was unblinded, the vehicle rinse was found to have performed slightly better than then rinse with drug. The graph to the right shows the mean oral mucositis assessment scale (OMAS) scores for patients in each arm of the study.



Comparison with Historical Data



(Data are shown from one of the two comparisons)

From the clinical study it was apparent that the vehicle, MuGard™, might be providing a benefit. As a result, the OMAS scores of patients treated with the MuGard™ in this study were compared with historical data obtained from two different sources (Cancer; 1999, 85 (10): 2103-2113, and Cancer; 2000, 89 (11): 2258-2265). In both cases, it was shown that mean mucositis scores were lower for patients using MuGard™ than for similar patients on standard care.

Beneficial effect

One of the most striking features of the comparison is that 43% of patients on MuGard™ experienced no mucositis (OMAS score never exceeded 0.5) compared with only 7% in the historical control group

