Protocol Title: A Phase 2, Multi-center, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of Topically-applied AG013 for the Attenuation of Oral Mucositis in Subjects With Cancers of the Head and Neck Receiving Concomitant Chemoradiation Therapy

Target Population: Male or Female patients 21 years or older undergoing chemoradiation for the treatment of Head and Neck Cancer

Summary: The purpose of the study is to evaluate, safety and tolerability administered AG013 compared to placebo for reducing Oral Mucositis in patients undergoing chemoradiation for the treatment of head and neck cancer, as measured by the duration, time and development, and overall incidence of Om during the active treatment phase, beginning from the start of radiation therapy until 2 weeks following its completion.

Key Inclusion Criteria:
- Pathologically-confirmed squamous cell carcinoma of the head and neck.
- Oral cavity, oropharynx (or HPV positive unknown primaries presumed to be of oropharyngeal origin) or hypopharynx primary site.
- Planned to receive either primary or postoperative CRT.
- Planned Intensity-Modulated Radiotherapy (IMRT).
- Planned administration of cisplatin administered weekly or tri-weekly during RT.
- Karnofsky Performance Score (KPS) ≥ 70%.
- Subjects of childbearing potential must agree to utilize effective contraceptive methods of birth control during study participation and for 30 days following the last treatment with IMP.
- Screening laboratory assessments:
  - Hemoglobin ≥ 10g/dl
  - White blood count ≥ 3500 cells/mm3
  - Absolute neutrophil counts ≥ 1500 cells/ mm3
  - Direct bilirubin ≤ 2x upper limit of normal (ULN)
  - Serum AST (aspartate aminotransferase) and ALT (alanine aminotransferase) ≤ 3 x ULN
  - Calculated Creatinine Clearance of 50 ml/min
  - Pregnancy test: negative for females of childbearing potential

Key Exclusion Criteria:
- Prior radiation to the head and neck.
- Presence of active infectious oral disease excluding oral candidiasis or presence of any oral lesions that may confound the ability to assess oral mucositis grade.
- Current use of antibiotic rinses or troches.
- Herbal, alternative remedies, and alcohol containing over-the-counter mouthwashes are excluded during the course of the study.
- Alcohol abuse syndrome; recovered alcoholics may be included.
- Chronic immunosuppression.
- Known seropositive for HIV.
- Use of investigational agent within 30 days of signing informed consent.
- Tooth extraction prior to radiation, as well as signs and symptoms of active dental disease.
- Female subjects who are pregnant or nursing.

Contacts:
Principal Investigator: Paul Page, MD
Research Nurses (RN): Sharon Jerdonek (sharon.jerdonek@ochsner.org, ext. 23929)
Amanda Woolery (amanda.woolery@ochsner.org, ext. 20275)

For additional information: https://www.clinicaltrials.gov/ct2/show/NCT03234465