



For more information, contact  
the Neuro-Oncology  
Clinical Trial Team at:  
[neuro.oncology@jwci.org](mailto:neuro.oncology@jwci.org)  
310-829-8265

#### Clinical Trial Investigators

Achal S. Achrol, MD

Garni Barkhoudarian, MD

Jose Carrillo, MD

Daniel Kelly, MD

Santosh Kesari, MD, PhD,

Steven O'Day, MD

Marlon Garzo Saria, PhD, RN

#### Clinical Trial Team

Jaya Mini Gill, RN, BSN  
[jaya.gill@providence.org](mailto:jaya.gill@providence.org)  
310-582-7437

Annie Heng, RN, BSN  
[HengA@jwci.org](mailto:HengA@jwci.org)  
310-582-7457

Tiffany Juarez, PhD  
[Tiffany.Juarez@jwci.org](mailto:Tiffany.Juarez@jwci.org)  
310-449-5225

Anand Moses, CRA  
[MosesA@jwci.org](mailto:MosesA@jwci.org)  
310-582-7097

Hanh Nguyen, CRA  
[NguyenThuyH@jwci.org](mailto:NguyenThuyH@jwci.org)  
310-582-7434

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# CLINICAL TRIAL ANNOUNCEMENT

## Study to Evaluate RRx-001 in Patients with Squamous Cell Carcinomas of the Oral Cavity or Oropharynx (PREVLAR)

**Official Title:** A Phase 2a Randomized, Parallel Group, Open-Label, Multicenter Study to Assess the Safety and Efficacy of Different Schedules of RRx-001 in the Attenuation of Oral Mucositis in Patients Receiving Concomitant Chemoradiation for the Treatment of Locally Advanced Squamous Cell Carcinomas of the Oral Cavity or Oropharynx

The purpose of this research study is to assess the safety and radioprotective potential of RRx-001 in patients undergoing chemoradiation therapy for locally advanced head and neck cancer.

Worldwide, head and neck cancer is the sixth most common form of the disease. The vast majority of patients with locally invasive cancers of the mouth or oropharynx are treated with concomitant chemoradiation, a combination that is superior to radiation alone since chemotherapy increases the susceptibility of the tumor cell to radiation-induced lysis. Oral mucositis is among the most common and devastating acute toxicities associated with radiation therapy to the head and neck. Concomitant chemotherapy increases both the risk and severity of mucositis. It can present with unrelenting pain that profoundly impacts the quality of life.

**RRx-001** is novel anticancer agent of the dinitroazetididine class that has demonstrated selectivity of action in tumor cells versus normal tissues, and inhibition of tumor growth in vivo with minimal toxicity. RRx-001 protects tissues from radiation injury via Nrf2 nuclear translocation and up-regulation of multiple antioxidant pathways, which minimizes oxidative stress and maintains the redox status.

Patients will be randomized 1:1:1:1 into one of three treatment arms (1) RRx-001 Pre-Treatment + SOC Chemoradiation, (2) RRx-001 Pre-Treatment + 2 Concurrent doses + SOC Chemoradiation, (3) RRx-001 Pre-Treatment + 6 Concurrent doses + SOC Chemoradiation, or (4) control group consisting of SOC Chemoradiation only.

#### Key Inclusion Criteria:

- Treatment planned to include standard cisplatin monotherapy with concomitant radiation
- Planned radiation fields must include at least 2 oral sites