

**FAST FACTS**

**A221701 - Phase III placebo-controlled trial to evaluate dexamethasone use for everolimus-induced oral stomatitis: prevention versus early treatment approaches: MIST (My Individualized Stomatitis Treatment)**

**ELIGIBILITY CRITERIA**

1. Documentation of Disease
  - Current cancer diagnosis, about to receive oral everolimus 10 mg/day with or without an endocrine agent. Patients about to receive everolimus for off label use for any cancer are also eligible.
2. Prior Treatment
  - Not currently receiving chemotherapy or any other agent known to cause mucositis or stomatitis. Trastuzumab and ovarian function suppression are allowed.
  - Any prior chemotherapy or other stomatitis/mucositis-causing therapy must be completed at least 2 weeks prior to registration.
3. Not currently suffering from stomatitis/mucositis or mouth ulcers. Patients should not have had any stomatitis or mouth pain for at least 7 days prior to registration.
4. Patients should not receive any other agent which would be considered treatment for stomatitis or impact the primary endpoint.
5. No history of candida infection (thrush) within the last 3 months
6. Not currently being treated with corticosteroids
7. Comorbid conditions
  - No uncontrolled diabetes mellitus, defined by hemoglobin A1C greater than 8%, although A1C is not needed for all patients, HgbA1C <8 is required for everyone with diabetes or suspected diabetes.
8. Patients must be able to read and comprehend English. Local translation, including verbal translation of PROs is not permitted.
9. Not pregnant and not nursing, because this study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown. Therefore, for women of childbearing potential only, a negative pregnancy test done  $\leq 7$  days prior to registration is required
10. ECOG Performance Status 0, 1 or 2.
11. Age  $\geq 18$  years
12. Required Initial Laboratory Values: *None*

**Schema**

