Prevention of Everolimus/Exemestane Stomatitis in Postmenopausal Women With Hormone Receptor-Positive Metastatic Breast Cancer Using a Dexamethasone-Based Mouthwash: Results of the SWISH Trial

US-based, single-arm, phase 2 prevention trial with 23 investigational sites

ALCOHOL-FREE DEXAMETHASONE-BASED MOUTHWASH
- 10 mL of alcohol-free dexamethasone 0.5 mg/5 mL oral solution
- Commercially available: NDC 00054-3177-63 (500 mL) or NDC 00054-3177-57 (240 mL)

92 patients were enrolled, 86 patients received treatment
- Postmenopausal women with HR+ metastatic breast cancer
- Prescribed everolimus 10 mg plus exemestane 25 mg

Mouthwash started on day 1 of treatment with everolimus plus exemestane and was used for 8 weeks

UPON INITIATION OF EVEROLIMUS PLUS EXEMESTANE, SWISH 10 mL OF SOLUTION IN MOUTH FOR 2 MINUTES AND SPIT
- Avoid eating or drinking for at least 1 hour after rinse
- Patients could continue dexamethasone mouthwash regimen for an additional 8 weeks by clinician discretion

AFINITOR® (everolimus) Tablets is indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole.

Important Safety Information
- AFINITOR is contraindicated in patients with hypersensitivity to everolimus, other rapamycin derivatives, or any excipients
- There have been reports of noninfectious pneumonitis (including some with pulmonary hypertension as a secondary event), infections, and renal failure (including acute renal failure) in patients taking AFINITOR, some with fatal outcomes
- Patients taking concomitant angiotensin-converting enzyme (ACE) inhibitor therapy may be at increased risk for angioedema
- Mouth ulcers, stomatitis, and oral mucositis have occurred in patients treated with AFINITOR at an incidence ranging from 44% to 78% across the clinical trial experience. Grade 3/4 stomatitis was reported in 4% to 9% of patients. In such cases, topical treatments are recommended, but alcohol-, hydrogen peroxide-, iodine-, or thyme-containing mouthwashes should be avoided as they may exacerbate the condition. Antifungal agents should not be used unless fungal infection has been diagnosed
- Exercise caution with the use of AFINITOR in the perisurgical period, as everolimus delays wound healing and increases the occurrence of wound-related complications
- In the randomized advanced hormone receptor-positive, HER2-negative breast cancer study, the incidences of deaths due to any cause within 28 days of the last AFINITOR dose and adverse reactions leading to permanent treatment discontinuation were greater in patients ≥65 years of age compared with patients <65 years of age
- Elevations of serum creatinine, proteinuria, glucose, lipids, and triglycerides, and reductions of hemoglobin, lymphocytes, neutrophils, and platelets have also been reported; monitoring of laboratory tests is recommended
- The use of live vaccines and close contact with those who have received live vaccines should be avoided
- AFINITOR can cause fetal harm when administered to a pregnant woman
- The most common adverse reactions in BOLERO-2 (incidence ≥30%) were stomatitis (67%), infections (50%), rash (39%), fatigue (36%), diarrhea (33%), and decreased appetite (30%). The most common grade 3/4 adverse reactions (incidence ≥2%) were stomatitis (8%), infections (5%), hyperglycemia (5%), fatigue (4%), dyspnea (4%), pneumonitis (4%), and diarrhea (2%)
Primary outcome measure:
Incidence of grade ≥2 stomatitis at 8 weeks (56 days) compared to BOLERO-2 historical controls

- Grade ≥2 stomatitis by physical exam or telephone interview, based on evidence of changes to patient’s oral mucosa that were consistent with stomatitis, and ≥1 of the following criteria also being met:
  - Patient’s oral intake reported at ≤50 using the NDS and/or
  - Patient-reported oral pain using VAS was 7 on 2 consecutive days or a rating of 8, 9, or 10 on any 1 day

Following the study protocol, the incidence of stomatitis of any grade was 21.2%.1

Secondary outcome measures at 8 weeks (56 days) included:

- In the SWISH trial, stomatitis occurring from date of first study drug administration until day 56 is included in the full analysis set. The safety population captured AEs (CTCAE version 4.0) during the period beginning with signing of informed consent until 4 weeks after the patient had stopped study treatment. The overall incidence of stomatitis was 27.2% (all grades) upon study completion: grade 1, 18.5%; grade 2, 7.6%; and grade 3, 1.1%. No grade 4 events were reported.
- 13% of patients discontinued EVE/EXE due to treatment-related AEs1

AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; NDS, normalcy of diet scale; VAS, visual analog scale.


Click here for Important Safety Information.
Click here for full Prescribing Information.