

## Afinitor Disperz<sup>®</sup> (everolimus) – Expanded indication

- On April 10, 2018, the [FDA announced](#) the approval of [Novartis' Afinitor Disperz \(everolimus\)](#) tablets for oral suspension, for the adjunctive treatment of adult and pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures.
  - Afinitor Disperz is also approved for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma that requires therapeutic intervention but cannot be curatively resected.
- Everolimus is also available as Afinitor<sup>®</sup> and [Zortress](#)<sup>®</sup> tablets.
  - Afinitor is approved to treat advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women; advanced neuroendocrine tumors in adults, advanced renal cell carcinoma in adults, renal angiomyolipoma with TSC in adults; and subependymal giant cell astrocytoma with TSC in adults and pediatric patients.
  - Zortress is approved for the prophylaxis of organ rejection in kidney and liver transplantation in adults.
  - Consult Afinitor and Zortress drug labels for more detailed indication information.
- The efficacy of Afinitor Disperz for the expanded indication was demonstrated in the EXIST-3 study enrolling 366 patients with TSC-associated partial-onset seizures. Patients were randomized to receive Afinitor Disperz at a dose to achieve a low trough (LT) level (3 - 7 ng/mL) or a high trough (HT) level (9 - 15 ng/mL) or placebo. The major efficacy outcome was the percentage reduction in seizure frequency.
  - The median percentage reduction from baseline in seizure frequency was significantly greater among patients randomized to Afinitor Disperz LT (29.3%; 95% CI: 18.8, 41.9; p = 0.003) and HT (39.6%; 95% CI: 35.0, 48.7; p < 0.001) vs. placebo (14.9%; 95% CI: 0.1, 21.7).
- The most common adverse reaction (≥ 30%) with Afinitor Disperz use in TSC-associated partial-onset seizures was stomatitis.
- The recommended starting dose of Afinitor Disperz for TSC-associated partial-onset seizures is 5 mg/m<sup>2</sup> orally once daily until disease progression or unacceptable toxicity.
  - The dose should be titrated to attain trough concentrations of 5 ng/mL - 15 ng/mL.
  - Consult the Afinitor Disperz drug label for dosing recommendations for other indications.