Titel des Beitrags:
Everolimus as treatment for breast cancer patients with bone metastases only: results of the phase II RADAR study.

Abstract:
Everolimus has shown to stop formation and activity of osteoclasts. Breast cancer patients with bone metastases only are candidates for effective but low toxic treatment. We evaluated everolimus in a double-blind, placebo-controlled, phase II, randomized discontinuation study in breast cancer patients with HER2 negative breast cancer patients with bone metastases only. After being stable on 8 weeks of everolimus 10 mg/day, patients were randomized to everolimus-continuation or placebo. Primary outcome was time (from randomization) to progression (TTP). Seventy-six patients would have had to be randomized to show a hazard ration (HR) of 0.5 for everolimus-continuation. Eighty-nine patients were enrolled in 4 years. Thirty-nine patients with SD after 8 weeks on everolimus were randomized to everolimus-continuation or placebo. TTP in patients with everolimus-continuation was 37.0 (95 % CI 16.7-40.3) versus 12.6 weeks (95 % CI 7.1-17.9) with placebo [HR 0.554 (95 % CI 0.282-1.09) p =
0.0818], adjusted for endocrine therapy [HR 0.464 (95 % CI 0.226-0.954) p = 0.037]. TTP in everolimus responders (n = 6) was 86 weeks. The RADAR study is mainly hypothesis generating. It suggests that everolimus has single-agent activity, and patients with bone metastases only may retrieve long-term benefit from everolimus if they do not progress within 8 weeks of treatment.