In the RECORD-1 trial, patients who had measurable disease but no rising tumor burden in 47% of patients treated with everolimus, showed improved PFS (median 13.1 months) vs placebo (median 3.4 months, HR = 0.44, P < .001).

**Patients and Methods**

**Background:** In the phase 3 RECORD-1 trial, evaluating everolimus vs placebo in patients with metastatic renal cell carcinoma (mRCC) who were intolerant of sunitinib or sorafenib, the primary endpoint was 1-year tumor burden progression. This study formed the basis for the US Food and Drug Administration (FDA) approval of everolimus for this indication.

**Methods:** The RECORD-1 trial was an open-label, randomised, placebo-controlled trial conducted from April 2008 to August 2009. Patients with mRCC intolerant to sunitinib or sorafenib were enrolled. Patients were stratified according to the number of prior vascular endothelial growth factor receptor–tyrosine kinase inhibitor (VEGFr-TKI) therapies received (0, 1, ≥2). Patients had a Karnofsky Performance Status (KPS) ≥60 and were treated with everolimus 10 mg/day (n = 277) or placebo (n = 81). The primary endpoint was 1-year tumor burden progression as assessed centrally.

**Results:** At study end, patients who received everolimus showed reduced tumor burden in 47% of patients treated with everolimus, showed improved PFS (median 13.1 months) vs placebo (median 3.4 months, HR = 0.44, P < .001).

**Conclusions:** Everolimus significantly prolonged PFS vs placebo in patients with no deterioration in KPS, including those with minimal or no reduction in tumor burden. Additional analyses of RECORD-1 demonstrated further improvements in PFS for patients with minimal or no reduction in tumor burden who received everolimus compared with placebo, and by 56% in patients with no deterioration in KPS treated with everolimus compared with placebo.

**Acknowledgments:** Editorial assistance was provided by ApotheCom, Yardley, PA, and funded by Novartis Pharmaceuticals Corporation.

**References:**
