significantly prolonged progression-free survival and that pazopanib was well-tolerated (ASCO 2009, #5021).
Methods: The EORTC QLQ-C30 and EQ-5D questionnaires were administered at baseline and weeks 6, 12, 18, 24, 48 in 233 treatment-naïve and 202 cytokine-pretreated pts (290 pazopanib; 145 placebo). The primary QOL endpoints were QLQ-C30 Global Health Status/QOL Score, EQ-5D Index and EQ-5D VAS. Mixed-model repeated measures analysis (MMRM) of change from baseline was conducted. Minimal clinically important differences (MCID) for summary scores are: QLQ-C30 (5−10), EQ-5D Index (.08), EQ-5D VAS (7).
Results: Completion rates for QOL were high across most time points (>90%). There was differential withdrawal of pts from the placebo arm due to progression. Longitudinal means for 3 pre-specified QOL endpoints showed a trend for maintenance of QOL across time between treatment and placebo, with differences that were also less than MCID. MMRM analyses showed no clinically important difference between pazopanib and placebo at each assessment timepoint for the 3 QOL endpoints (Table). Change from baseline for the 5 QLQ-functional scales across timepoints also showed trend for no clinically important differences.
Conclusions: Pts treated with pazopanib did not have a clinically important difference in QOL compared with placebo, even with the toxicities that may be expected with an active agent. Results are consistent with evidence that pazopanib is well-tolerated and are particularly important given that most RCC pts are often asymptomatic when therapy is initiated.

MMRM Analyses for Change from Baseline in QOL

	Week 6	Week 12	Week 18	Week 24	Week 48
EORTC-QLQ-C30					
N(pazo/pl)	243/110	219/81	191/61	164/49	96/24
Difference vs. placebo	−1.9	−2.8	−2.0	0.39	−0.67
95% CI	(−5.8, 2.0)	(−7.2, 1.5)	(−6.9, 2.9)	(−4.5, 5.2)	(−6.5, 5.1)
p-value	0.34	0.20	0.41	0.88	0.82
EQ-5D Index					
N(pazo/pl)	253/125	219/86	196/62	166/51	98/24
Difference vs. placebo	0.005	−0.044	−0.019	−0.026	0.034
95% CI	(−0.042, 0.051)	(−0.092, 0.005)	(−0.076, 0.037)	(−0.091, 0.040)	(−0.034, 0.102)
p-value	0.84	0.08	0.50	0.44	0.33
EQ-5D VAS					
N(pazo/pl)	239/111	212/80	189/60	161/49	95/23
Difference vs. placebo	1.9	0.1	−0.1	−0.2	−1.9
95% CI	(−2.4, 6.1)	(−4.8, 4.9)	(−5.0, 4.9)	(−4.8, 4.5)	(−9.0, 5.1)
p-value	0.39	0.98	0.98	0.95	0.58

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A retrospective review of treatment discontinuation and survival in patients with advanced renal cell carcinoma treated with sunitinib or sorafenib

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Background: Treatment of advanced renal cell carcinoma (RCC) has improved with the introduction of vascular endothelial growth factor receptor-tyrosine kinase inhibitor (VEGFr-TKI) therapies (sunitinib [Sutent®], sorafenib [Nexavar®]). Until recently, approved treatment options for patients whose disease progressed after use of VEGFr-TKIs were lacking, and survival data after failure of these therapies have not been reported outside the clinical trial setting. The objectives of this study were to examine treatment patterns among advanced RCC patients treated with VEGFr-TKI therapies and to evaluate survival rates following discontinuation of these therapies.
Materials and Methods: Administrative claims data from a large US managed care plan linked to mortality data were used to identify commercially and Medicare-insured RCC patients diagnosed from 1/1/2003 to 12/31/2007 and receiving sunitinib, sorafenib, or both. Data until death or end of the observation period (3/31/2008) were used. Therapy discontinuation was defined as a gap in prescription filling after run out of the last prescription fill with no refill before death or the end of the observation period.
Results: A total of 451 RCC patients with sunitinib or sorafenib treatment were identified; 222 treated with sunitinib alone, 127 treated with sorafenib alone, and 102 treated with both sunitinib and sorafenib. Mean age was 60 years, with 71% male, and 12% Medicare enrollees. Median length of treatment was 4 months for all patients; for the sorafenib-alone group, it was 2.9 months, and for the sunitinib-alone group, it was 2.6 months. Nearly 60% of subjects (n = 264) discontinued (and did not re-start) sunitinib or sorafenib therapy. Median survival following therapy discontinuation was 5.5 months (6.1, 5.3, and 4.8 months for sorafenib-alone, sunitinib-alone, and both treatments, respectively).
Conclusions: In this retrospective observational study, length of sunitinib and sorafenib treatment was nearly half of that reported in their respective clinical trials. The high rate of VEGFr-TKI therapy discontinuation and poor survival outlook following discontinuation of these therapies in advanced RCC patients suggest a need for additional treatment options in this setting.

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Bevacizumab (BEV) and interferon (IFN) therapy does not increase risk of cardiac events in metastatic renal cell carcinoma (mRCC)

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Background: Cardiac safety has recently become an important consideration when evaluating therapies for mRCC. Rates of cardiac toxicity with tyrosine kinase inhibitor therapy in mRCC have been reported to be as high as 34.8% [Schmidinger et al. JCO 2008]. We analysed the cardiac safety of BEV + IFN and IFN + placebo in the phase III AVOREN (BO17705E) trial in patients (pts) with previously untreated mRCC.
Methods: Eligible pts had predominantly clear-cell mRCC, prior nephrectomy, no prior systemic therapy for metastatic disease, KPS ⩾70%, no CNS metastases and adequate organ function. Pts were randomised to IFN (9MIU tiw) + BEV (10 mg/kg q2w) or placebo until disease progression. Listings of cardiac events were retrieved from the trial database and serious adverse event (SAE) reports from the safety database. The nature of events was compared between the two treatment arms and events were also evaluated based on type (non-serious adverse event [n-s AE] vs SAE), age, gender and recovery.
Results: Median BEV/placebo treatment duration was 42 and 22 weeks in the BEV + IFN and IFN plus placebo arms; median IFN duration was 34 and 20 weeks, respectively. 15 cardiac events, including four SAEs, were reported in 13 of 337 (4%) pts who received BEV + IFN; nine cardiac events (one SAE) were reported in eight of 304 (3%) pts who received IFN + placebo. Four of the total of five SAEs were reported as 'atrial fibrillation (AF)' and occurred in pts aged ⩾62 years. AF was shown to have a prevalence of 5.1% in pts aged ⩾60 years in general practice [Langenberg et al. BMJ 1996]. Although not directly comparable, the incidence of AF in AVOREN was not increased when grossly compared to a normal population. The other SAE was a myocardial infarction in a 78-year-old woman in the BEV + IFN arm, which resolved without sequelae; the event was judged by the investigator to be related to underlying hypertension rather than trial therapy. The most common n-s AEs were tachycardia/sinus tachycardia (n = 4) and arrhythmia (n = 4). All n-s AEs were reported to have resolved; 15 of the total 24 events were resolved between
Conclusions: The incidence of cardiac events in this trial was <5%. The majority of events were not serious, not suspected to trial medication, transient and did not require treatment interruption or discontinuation. We conclude that BEV + IFN has a favourable cardiac safety profile in pts with mRCC in the AVOREN trial.
Trial sponsored by F. Hoffmann-La Roche, Ltd.

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Phase II trial of continuous once-daily dosing of sunitinib as first-line treatment in patients with metastatic renal cell carcinoma (mRCC): preliminary results

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Background: Sunitinib, given at 50 mg/day on schedule 4/2 (4 wk on treatment, 2 wk off), has shown statistically superior progression-free