

Subject: Axitinib Phase 3 RCC Data Published in The Lancet - November 4, 2011

The Phase 3 AXIS trial evaluating Pfizer's investigational agent axitinib compared with sorafenib for patients with previously treated advanced renal cell carcinoma (RCC) was published in *The Lancet* ([Axitinib Phase 3 RCC Data Published in The Lancet](#)). The Phase 3 AXIS trial was the first completed head-to-head pivotal trial in advanced RCC to evaluate the efficacy and safety of two active targeted therapies.

According to researchers in *The Lancet*, these data might establish axitinib as a therapeutic option for patients with advanced RCC. Axitinib is currently under review by regulatory agencies including those in the U.S. and E.U.

Despite the advances made in recent years in the treatment of advanced RCC, the need remains for additional therapies for this patient population, particularly in previously treated patients. Approximately 273,000 new cases of RCC are diagnosed worldwide each year,^[i] representing 2-3 percent of all cancers, and approximately 20 to 30 percent of patients have advanced disease upon diagnosis. Five-year survival rates for patients with advanced disease remain low, at approximately 10 to 20 percent,^{[ii], [iii]} and a large proportion of patients currently do not receive a second-line therapy after progressing on initial treatment.^[iv]

^[i] World Health Organization International Agency for Research on Cancer, GLOBOCAN 2008; Cancer Incidence and Mortality Worldwide in 2008. Available at <http://globocan.iarc.fr>. Accessed July 21, 2011.

^[ii] National Cancer Comprehensive Network. *Practice Guidelines in Oncology: Kidney Cancer*. 2011.

^[iii] Howlader N, Noone AM, Krapcho M, Neyman N, Aminou R, Waldron W, Altekruse SF, Kosary CL, Ruhl J, Tatalovich Z, Cho H, Mariotto A, Eisner MP, Lewis DR, Chen HS, Feuer EJ, Cronin KA, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2008/, based on November 2010 SEER data submission, posted to the SEER web site, 2011.

^[iv] Vickers M, et al. Clinical Outcome in Metastatic Renal Cell Carcinoma Patients After Failure of Initial Vascular Endothelial Growth Factor-Targeted Therapy. *Journal of Urology*. 2010 76 (2); 430-434.