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Research April 24, 2013

Overall Survival Did Not Differ Between Axitinib Versus Sorafenib Groups

Lancet Oncol. 2013 Apr 19;[EPub Ahead of Print], RJ Motzer, B Escudier, P Tomczak, et al

TAKE-HOME MESSAGE

Follow-up of a phase III trial compared axitinib versus sorafenib as second-line treatment for metastatic renal cell cancer. In this analysis, overall survival did not differ between the groups; however, PFS was longer in the axitinib group.

ABSTRACT

Background: In a phase 3 trial comparing the efficacy and safety of axitinib versus sorafenib as second-line treatment for metastatic renal cell carcinoma, patients given axitinib had a longer progression-free survival (PFS). Here, we report overall survival and updated efficacy, quality of life, and safety results.

Methods: Eligible patients had clear cell metastatic renal cell carcinoma, progressive disease after one approved systemic treatment, and an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0–1. 723 patients were stratified by ECOG PS and previous treatment and randomly allocated (1:1) to receive axitinib (5 mg twice daily; n=361) or sorafenib (400 mg twice daily; n=362). The primary endpoint was PFS assessed by a masked, independent radiology review committee. We assessed patient-

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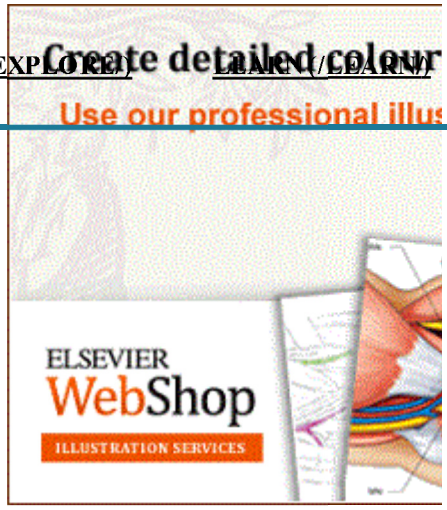
reported outcomes using validated questionnaires. Baseline characteristics and development of hypertension on treatment were studied as prognostic factors. Efficacy was assessed in the intention-to-treat population, and safety was assessed in patients who received at least one dose of the study drug.

Findings: Median overall survival was 20·1 months (95% CI 16·7–23·4) with axitinib and 19·2 months (17·5–22·3) with sorafenib (hazard ratio [HR] 0·969, 95% CI 0·800–1·174; one-sided p=0·3744). Median investigator-assessed PFS was 8·3 months (95% CI 6·7–9·2) with axitinib and 5·7 months (4·7–6·5) with sorafenib (HR 0·656, 95% CI 0·552–0·779; one-sided p<0·0001). Patient-reported outcomes scores were similar in the treatment groups at baseline, were maintained during treatment, but decreased at end-of-treatment. Common grade 3 or higher treatment-related adverse events were hypertension (60 [17%]), diarrhoea (40 [11%]), and fatigue (37 [10%]) in 359 axitinib-treated patients and hand–foot syndrome (61 [17%]), hypertension (43 [12%]), and diarrhoea (27 [8%]) in 355 sorafenib-treated patients. In a post-hoc 12-week landmark analysis, median overall survival was longer in patients with a diastolic blood pressure of 90 mm Hg or greater than in those with a diastolic blood pressure of less than 90 mm Hg: 20·7 months (95% CI 18·4–24·6) versus 12·9 months (10·1–20·4) in the axitinib group (p=0·0116), and 20·2 months (17·1–32·0) versus 14·8 months (12·0–17·7) in the sorafenib group (one-sided p=0·0020).

Interpretation: Although overall survival, a secondary endpoint for the study, did not differ between the two groups, investigator-assessed PFS remained longer in the axitinib group compared with the sorafenib group. These results establish axitinib as a second-line treatment option for patients with metastatic renal cell carcinoma.



The Lancet Oncology

Axitinib Versus Sorafenib as Second-Line Treatment for Advanced Renal Cell Carcinoma: Overall Survival Analysis and Updated Results From a Randomised Phase 3 Trial

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