Reviewer's report

Title: Efficacy of Sorafenib on Metastatic Renal Cell Carcinoma in Asian Patients: Results from a Multicenter Study

Version: 1 Date: 3 February 2009

Reviewer: Christopher W Ryan

Reviewer's report:

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

Per the eligibility criteria, all subjects were AJCC stage IV. However, table 1 indicates that only 36.7% of patients were Robson stage IV. Please clarify this discrepancy –perhaps this represents the stage at diagnosis, rather than the stage at study entry?

The response rate (24.5%) and PFS (>12 months) are significantly greater than previous reports with sorafenib (2% and 5.5 months, respectively). The long PFS is commented on in the discussion, but no comment is given by the authors as to why the response rate was so much higher than in previous studies. Some comment should be made as to why this might be. The high response rate may cause some readers to question the methods used in determining radiographic response. Were the responses investigator-assessed, or was there a central review of the scans?

It is understood that this does not represent a phase II study. However, please provide a definition of what is meant by an "Institution treatment protocol?" Was there a primary objective of this protocol?

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

Consider using the AJCC stage in Table 1 rather than Robson stage.

Provide 95% confidence intervals for PFS and OS

Page 11: "No significant difference was found in patients received sorafenib plus interferon treatment as compare to those received sorafenib alone..." No data is presented to this end. Also, consider referencing the published literature regarding the sorafenib + interferon combination, as there have been several prospective trials that have studied this combination.

Page 11: It is unclear why “further investigation for a proven medication in the form of a prospective phase II clinical trial would not be easily acceptable by patients with a terminal disease.” Perhaps the authors are referring to a randomized trial, rather than a phase II study--?
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

There are grammatical errors throughout document that will need to be corrected

Table 1: Correct spelling of “Robsen”

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this paper, either now or in the future?

YES. I have received honorarium for consultation and lectures as well as research support from Bayer/ONYX, the maker of the drug that is the subject of the manuscript. I have also received honorarium and research support from companies that make competing products, including Pfizer, Wyeth, and Novartis

Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper, either now or in the future?

NO

Do you hold or are you currently applying for any patents relating to the content of the manuscript?

NO

Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

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Do you have any other financial competing interests?

NO

Do you have any non-financial competing interests in relation to this paper?

NO