Reviewer’s report

Title: Phase II clinical trial of sorafenib plus interferon-alpha treatment for patients with metastatic renal cell carcinoma in Japan

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Reviewer: Pablo P Maroto

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To your attention:

This paper Phase II clinical trial of sorafenib plus interferon-alpha treatment for patients with metastatic renal cell carcinoma in Japan exposes the results of a phase II clinical trial combining interferon plus sorafenib. Results are well explained, although it is only a phase II trial, so conclusions should be less confident and no recommendation could be stated from this trial that the combination should be a first line in metastatic renal cell carcinoma.

Some recommendations: I would not explain about the patients considered as wrong inclusions, simply I would exclude them and I would not speculate about results. In addition, it should be explained why the patients in Japan go better with immunotherapy than in other countries. Finally, terms like excellent, should be avoided.

Regarding the discussion, there are no much data about the combination of immunotherapy and TK inhibitors, and this is one of the strengths of this manuscript. I would suggest to review data about combinations in the discussion, may be through a table summarizing the data available.

Besides, review of phase I and II trials with Sorafenib plus immunotherapy should be contemplated.

More data about the statistical design should be added.

Finally, at least in Europe, Sorafenib is not anymore a first line therapy for patients with metastatic Renal Cell Cancer. It should be described why authors could or not still considered Sorafenib for first line.

To summarize, the paper might be published but like a phase II, not making recommendations about first line, redrawing the discussion with a review about combination of immunotherapy and TK inhibitors and I believe, clearly describing the role of Sorafenib in first line nowadays.

Best regards

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:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests