Title: Phase II Study of Weekly Paclitaxel and Capecitabine in Patients with Metastatic or Recurrent Esophageal Squamous Cell Carcinoma

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Author's response to reviews: see over
Dear Editor-in-Chief,

Please find enclosed our manuscript entitled “Phase II study of weekly paclitaxel and capcitabine in patients with metastatic or recurrent esophageal cancer (PACE)” which we are submitting for consideration for publication as an original article in ‘BMC Cancer’.

The manuscript has not been published and not under consideration for publication in any other journals. All authors have read and approved this manuscript. In consideration of reviewing our submission, the undersigned authors transfer, assign, or otherwise convey all copyright ownership to ‘BMC Cancer’ in the event the work is published.

We corrected the manuscript as requested by reviewer’s comments and the changes are shown in red color in the final manuscript.

This study is registered at http://clinicaltrials.gov as NCT00453323.

Thank you for considering this manuscript for publication in ‘BMC Cancer’.

Sincerely yours,

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Reviewer's report
Title: Phase II Study of Weekly Paclitaxel and Capecitabine in Patients with Metastatic or Recurrent Esophageal Squamous Cell Carcinoma

Version: 2 Date: 8 June 2011
Reviewer: Laurent Bedenne

Reviewer's report:

Major compulsory revision:

It should be added in the exclusion criteriae “patients unable to swallow the capecitabine tablets, even after placement of a stent”. This seems evident but underlines a drawback of this type of treatment in esophageal cancer. The degree of dysphagia, if known, should be added in table 1.

➔ In page 6, study population section, we added the following exclusion criteria

“Patients unable to swallow the capecitabine tablets were also excluded, even after placement of a stent” However, we did not examine the degree of dysphagia of enrolled patients by objective examination. Patients who can eat liquid or solid diet were enrolled.

It would be most interesting to precise in the discussion the number of patients
otherwise eligible who were excluded for dysphagia, and hence discuss the advantage of capecitabin over infusional 5FU-leucovorin.

➔ In page 11, first paragraph of discussion section, we added the following comments.

“Dysphagia is a common symptom in esophageal cancer, which may be cause of reduced number of eligible patients treated with capecitabine-based regimen. However, during study period, patients otherwise eligible who were excluded for dysphagia did not proceed the screening process and screening failure due to dysphagia was not observed. Oral administration of capecitabine is feasible and more convenient compared with infusional 5-FU in esophageal cancer”

Minor essential revisions:

1- Page 10 “Efficacy”: line 13 “two patients out of three”, and line 14 “one patient out of six”….achieved partial response…The efficacy of PACE seems to be more than “slightly lower” in patients previously treated by docetaxel, which is not quite surprising.

➔ We corrected the first paragraph of efficacy as requested in page 10

2- Page 11 Safety and tolerability: delete lines 2 and 3 (redundant); delete the commentaries which have their place in the discussion, i e line 5 “but easily manageable”, and the last sentence line 9-10.
We deleted the sentences as reviewer requested.

3- Page 11 Discussion: the sentence line 5-6 does not seem essential, as it repeats a sentence of the previous paragraph.

We deleted the following sentence in first paragraph of discussion, page 11.

“The most common non-hematologic grade 3 or 4 toxicity was stomatitis (9.4%)”

4- Still 2 figures after the dot in figures 1 and 2

We changed figures as requested.

5- In table 6 use SCC rather than SQC

We corrected abbreviation in table 6 as requested.