Reviewer's report

Title: Phase II Study of Weekly Paclitaxel and Capecitabine in Patients with Metastatic or Recurrent Esophageal Cancer (PACE)

Version: 1 Date: 11 November 2010

Reviewer: Laurent Bedenne

Reviewer's report:

Major compulsory revisions:

- The patients are insufficiently described: indicate the frequency of locoregional/metastatic recurrences, the location of the metastases, the number of metastatic sites, the degree of dysphagia. The last point is important with an oral treatment like capecitabin, which entails taking several large tablets twice a day. Did all the patients with dysphagia need a stent?

- The authors should define what is first line and second line. In the case of first line one can suppose that patients never had any treatment for their disease. But does “second line” mean second line CT after failure of a first line CT or second treatment after recurrence of a patient having had a previous treatment with curative intent? This question is raised by the fact that 6/20 “second line patients” had surgery or radiotherapy, and that 7/20 of those had a treatment free interval of more than 3 months.

- There has been a methodological change during the trial, with the inclusion of first line patients, which was not originally planned. It would have been more correct to start a new trial with first line patients, or keep the initially calculated number of second line patients. At least, the response rate for second line patients should indicate the confidence interval, to verify that it does not include 10% (page 10). If it does, the main endpoint will not be fulfilled and it should be taken into account in the discussion and the conclusion.

- The authors should take into account in the discussion the randomised phase II trial by Tebbutt et al (Br J Cancer 2010;102:475-81). The results with weekly docetaxel-capecitabin are less favourable than those reported here, particularly in terms of response rate (26%).

Minor essential revisions:

- Results: lines 3-8 of “Patient characteristics” should be deleted, as the inclusion of first line patients was already signalled in the Methods.

- In § “Efficacy”, it is difficult to conclude to a similar efficacy for patients having received docetaxel-platinum, with 1 PR out of 6, versus 4 PR out of 7 after irinotecan-platinum. Possible cross resistance between docetaxel and paclitaxel should be discussed.

- In § “Efficacy”, and elsewhere, for survival, one figure after the dot should be
enough (0.01 month is 7.2 hours!)

- In § “Safety”, give the exact number and not percentages on such a small effective. It is generally accepted to give percentages above 50 patients. This remark applies elsewhere (page 13, 6.3% of patients are 2 patients)

- Ref 25 is not complete and is the same as ref 29 (to be replaced in table 7 by ref 25)

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.