Reviewer's report

Title: Randomized phase 3 open-label trial of first-line treatment with gemcitabine in association with docetaxel or paclitaxel in women with metastatic breast cancer: a comparison of different schedules and treatments

Version: 1 Date: 6 January 2013

Reviewer: Khalil Zaman

Reviewer's report:

It's an interesting and well written paper

METHODS

1) Minor Essential Revisions:
Paragraph “outcome measures”: please precise the version of RECIST 1.0 versus 1.1?

2) Minor Essential Revisions:
The definition of “stable disease” is not clear in your description: any patient without progression after 9 weeks?

RESULTS

3) Minor Essential Revisions:
Could you please describe the recruitment period of the study and the median follow up?

4) Minor Essential Revisions:
Patient disposition and treatment compliance, last paragraph: “Treatment-related discontinuations occurred in 6.7%, 6.2%, 10.3% and 13.6% of patients in Arms A, B, C and D…”, but in the figure 1 only one third of the patients completed the study: is one of the conclusions of the study that the feasibility of these regimen is limited?

DISCUSSION

5) Minor Essential Revisions:
In your study and in your abstract and paper conclusions, you mix paclitaxel weekly with docetaxel weekly. The superiority of weekly paclitaxel over 3-weekly paclitaxel was shown in neoadjuvant, adjuvant and metastatic setting. This was not the case for docetaxel. Therefore it could be useful to stress in your conclusions the existence of these trials and the fact that the good results of the weekly taxanes is probably driven by paclitexel.

6) Minor Essential Revisions:
The study arms were different in term of taxane (paclitaxel vs docetaxel) and
schedule (weekly vs 3-weekly) but also in term of dose intensity of gemcitabine: Arm A=1000 ArmB=1250 ArmC and D=800 used for different durations (A and B vs C and D). The potential impact of gemcitabine dose intensity is not discussed in the conclusions.

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

**Quality of written English:** Acceptable

**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